

## Randomized Trial Comparing Same-Day Discharge With Overnight Hospital Stay After Percutaneous Coronary Intervention

### Results of the Elective PCI in Outpatient Study (EPOS)

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**Background**—Percutaneous coronary intervention (PCI) in a day-case setting might reduce logistic constraints on hospital resources, but data on safety are limited. We evaluated the safety and feasibility of same-day discharge after PCI.

**Methods and Results**—Eight hundred consecutive patients scheduled for elective PCI by femoral approach were randomized to same-day discharge or overnight hospital stay. Four hours after PCI, patients were triaged as suitable for early discharge or not. Suitable patients were discharged immediately or kept overnight, according to randomization. Patients with an indication for extended hospital stay were not discharged regardless of randomization. Primary end points were death, myocardial infarction, coronary artery bypass graft surgery, repeat PCI, or puncture-related complications occurring within 24 hours after PCI. A total of 403 patients were assigned to same-day discharge, of whom 77 (19%) were identified for extended observation; 397 patients were assigned to overnight stay, of whom 85 (21%) were identified for extended observation. Among all patients, the composite primary end point occurred in 9 (2.2%) same-day discharge patients and in 17 (4.2%) overnight stay patients (risk difference,  $-0.020$ ; 95% CI,  $-0.045$  to  $-0.004$ ;  $P$  for noninferiority  $<0.0001$ ). Among patients deemed suitable for early discharge, the composite end point occurred in 1 of 326 (0.3%) same-day discharge patients and 2 of 312 (0.6%) overnight-stay patients (risk difference,  $-0.003$ ; 95% CI,  $-0.014$  to  $0.007$ ;  $P$  for noninferiority  $<0.0001$ ). The last 3 events were related to puncture site.

**Conclusions**—Same-day discharge after elective PCI is feasible and safe in the majority (80%) of patients selected for day-case PCI. Same-day discharge does not lead to additional complications compared with overnight stay. (*Circulation*. 2007;115:2299-2306.)

**Key Words:** aftercare ■ angioplasty ■ cost-benefit analysis ■ day care ■ randomized controlled trials

The increasing number of percutaneous coronary intervention (PCI) procedures has led to accumulating logistic constraints. A reduction in hospital stay and the application of day-case facilities were advocated to reduce procedure-related costs. New developments in interventional cardiology such as stents and adjunctive antithrombotic therapy have made PCI safer.<sup>1-3</sup> Previous studies from our center demonstrated that short-term observation after PCI is safe. Patients could be adequately selected for additional observation to anticipate postprocedural complications.<sup>4,5</sup> Furthermore, it was shown that early ambulation after femoral-approach PCI was safe and did not add to the complication rate.<sup>6</sup>

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Nonrandomized studies that investigated same-day discharge were limited by a small number of study patients or patient selection.<sup>7-10</sup> Moreover, most of these studies concerned the use of the transradial approach.<sup>9-11</sup> Same-day discharge with the femoral approach has not been investigated in a sufficiently powered randomized study.

The Elective PCI in Outpatient Study (EPOS) was designed to evaluate the safety and feasibility of discharge the same day as PCI by testing the hypothesis that patients requiring extended observation can be selected effectively and that same-day

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discharge does not increase the complication rate compared with overnight hospital stay.

## Methods

### Patients

Eight hundred consecutive patients were entered into the study a week before the PCI. Patients scheduled to undergo elective PCI at the Academic Medical Center in Amsterdam were eligible for enrollment if they remained at home before the procedure and did not have an acute coronary syndrome. Patients who were scheduled to undergo a diagnostic coronary artery catheterization with possible ad hoc PCI were excluded. Other exclusion criteria were the scheduled use of guiding catheters >6 F in diameter, elective use of glycoprotein IIb/IIIa receptor blockers, and long-term systemic anticoagulation. Patients who lived >60 minutes away from the intervention center were excluded for safety reasons at the explicit request of the Institutional Review Board. Patients were excluded if follow-up was difficult. There were no angiographic exclusion criteria. Eligible patients were asked for written informed consent provided that their home circumstances allowed same-day discharge.

### Design and Procedure

After the decision to perform a PCI but before the start of the PCI, patients were randomly assigned to discharge the same day as PCI or to overnight hospital stay after PCI by means of a randomization computer program that used an algorithm for simple, unblocked randomization at the Department of Biostatistics and Epidemiology. The outcome of the randomization was initially not disclosed to the operator. PCI was performed by the femoral approach using 5F to 6F guiding catheters. Patients were pretreated with aspirin 100 mg. According to a previously described protocol, a single dose of 5000 IU heparin was given after insertion of the arterial sheath, and an additional dose of 2500 IU heparin was given if the procedure lasted >90 minutes.<sup>6,12</sup> The sheath was removed immediately after the PCI. Hemostasis was obtained by manual compression and maintained with an inguinal pressure bandage. A 12-lead ECG was obtained before and after the PCI. Postinterventional therapy included 100 mg/d aspirin, and if a stent was implanted, a bolus of 300 mg clopidogrel was given, followed by 75 mg/d clopidogrel for 1 month. Successful angioplasty was defined as <50% residual stenosis and Thrombolysis in Myocardial Infarction grade 3 flow.

Directly after the PCI, patients requiring extended clinical observation, cardiac monitoring, or additional treatment were identified from the following predefined clinical and angiographic criteria derived from an earlier reported study<sup>4</sup>: occluded coronary artery, suboptimal angiographic result, dissection type C to E, residual dissection after stent implantation, occlusion of (major) side branch, angiographic thrombus, no-reflow/slow-flow phenomenon, perforation with guidewire, persistent or recurrent chest pain, ECG changes, congestive heart failure, and complicated hemostasis after PCI. The remaining patients were observed for 4 hours without cardiac monitoring in a dedicated unit of the cardiac catheterization laboratory. These patients were ambulated after 4 hours of bed rest; then, a formal triage was done to determine whether the patient was deemed suitable for early discharge. Suitability included freedom from symptoms and the absence of ECG changes and puncture site abnormalities. After the triage had been documented, the outcome of the randomization was divulged to the operator. Patients randomized to same-day discharge were discharged immediately. Patients randomized to overnight stay were transferred to the overnight stay facilities and were discharged the next day or later in the event of subsequent complications. Routine sampling of cardiac enzymes was not performed during the overnight stay.

Patients were interviewed by telephone at 24 hours, 3 days, and 30 days after PCI, and those who reported symptoms were referred to their own cardiologist. Data on complications were verified by medical records. Baseline data of the total PCI population not included during the study period were documented.

To measure patient satisfaction with same-day discharge, a standardized questionnaire was given to patients 3 days after PCI that contained the following topics: information received about the treatment, results of the PCI, attendance of the medical and nursing staff, and the discharge procedure. One-year follow-up data were collected for all patients with no loss to follow-up. The study protocol was approved by the Institutional Review Board.

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.

### End Points

The primary end point of the study was the composite of major adverse cardiac and cerebral events and severe complications of the arterial puncture with the need of blood transfusion or repeat compression from randomization until 24 hours after PCI. Major adverse cardiac and cerebral events were defined as cardiac death, myocardial infarction, stroke, coronary artery bypass grafting, and repeat PCI. The diagnosis of myocardial infarction was based on symptoms and typical ECG changes combined with creatine kinase-MB isoenzyme elevations >1 time the upper limit of normal. Secondary end points were the indication for extended observation, the occurrence of major adverse cardiac events, and puncture site complications from randomization until 30 days after PCI.

### Cost Analysis

We evaluated the effect of same-day discharge on health service costs by means of a cost minimization analysis. Prices per unit were based on actual costs or derived from the Dutch guidelines for economic healthcare evaluations. Actual costs were calculated for directly involved personnel, the observational unit, the cardiology ward, and the emergency room. Dutch guidelines for economic healthcare evaluations were used for overhead, equipment, accommodation, and cleaning costs. Standard charges, provided by the health insurance funds, were used for infrequently performed diagnostic or treatment modalities. Because of skewed distributions, group contrasts were assessed by evaluating the 95% CI of the mean differences after bias-corrected and accelerated nonparametric bootstrapping, drawing 5000 samples of the same size as the original separately for each group and with replacements.<sup>13</sup>

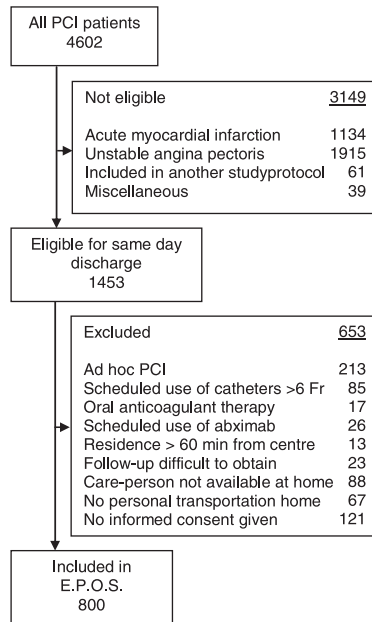
### Statistical Analysis

The absolute difference between the rates of the primary composite end point was used to test our primary (noninferiority) hypothesis that elective PCI in a same-day discharge setting would not lead to more cardiac or puncture-related complications than elective PCI in an overnight-stay setting. A secondary analysis was performed among patients deemed suitable for same-day discharge. In both analyses, events were counted according to the patient's randomized treatment allocation, regardless of the actual mode of discharge (intention to treat). The study was designed as a noninferiority trial with an assumed event rate of 10% and a noninferiority margin of 6%. To provide 80% power for a 2-sided test with  $\alpha$  at 5%, 393 patients were required in each group. Comparison of clinical end points was done with the absolute risk difference with 95% CI; other categorical data were analyzed with  $\chi^2$  or Fisher exact test. Continuous variables were described as mean  $\pm$  SD. A value of  $P < 0.05$  was considered statistically significant, and 95% CIs were used. Probability values for testing noninferiority were calculated by 1-sided normal approximation.<sup>14</sup> Statistical tests were done with the SPSS 11.5.2 software package for Windows (SPSS Inc, Arlington, Va).

## Results

### Patients

During enrollment from July 1, 2000, until March 21, 2003, a total of 4602 PCIs were performed in our center, 1453 of which were elective in patients with stable complaints. Figure 1 shows the selection of 800 patients according to the



**Figure 1.** Selection of patients for the Elective PCI in Outpatients Study (EPOS).

eligibility and exclusion criteria. In total, 403 patients were randomized to same-day discharge and 397 to overnight hospital stay. The clinical and angiographic characteristics of the patients, shown in Table 1, were well balanced between the randomization groups. The mean age of the total study population was 62 years; 648 patients (81%) were male, 121 (15%) had diabetes mellitus, and 320 (40%) had hypertension. The studied population included multilesion procedures (329 of 800, 41%), multivessel interventions (141 of 800, 18%), complex lesion anatomy such as type B2 and C lesions (927 of 1240, 75%), bifurcated lesions (174 of 1240; 14%), and total occlusions (191 of 1240, 15%).

### PCI Results

PCI was successful in 383 of 403 patients (95%) randomized to same-day discharge versus 369 of 397 patients (93%) randomized to overnight stay ( $P=0.21$ ). Coronary stents were placed in 72% of patients (573 of 800). This percentage was related to a provisional stenting strategy in the early phase of the study and to cases in which recanalization of chronic total occlusions failed. During or immediately after PCI, 67 of 403 patients (17%) in the same-day discharge group developed an indication for extended hospital stay, as did 80 of 397 patients (20%) of the overnight-stay group ( $P=0.42$ ) (Table 2). Thirty-three percent (22 of 67) of the same-day discharge group and 40% (32 of 80) of the overnight-stay group received additional low-molecular-weight heparin treatment during 24 to 48 hours ( $P=0.37$ ). Glycoprotein IIb/IIIa receptor antagonists were started ad hoc during the procedure in 20 and 31 patients, respectively ( $P=0.26$ ).

### Observation and Discharge

During the 4-hour observation period, another 10 patients randomized to same-day discharge developed an indication for extended hospital stay, as did 5 patients randomized to

overnight hospital stay (Table 2). Thus, 19% of patients (77 of 403) randomized to same-day discharge were identified for extended hospital stay versus 21% of patients (85 of 397) randomized to overnight stay.

On the basis of the formal triage after 4 hours of observation, 82% of patients (326 of 403) randomized to same-day discharge were considered suitable for immediate discharge versus 79% of patients (312 of 397) randomized to overnight stay (Figure 2). Actual discharge the same day occurred in 77% of patients (311 of 403) randomized to same-day discharge.

In both randomization groups, 15 patients without complications refused to comply with the randomization assignment and chose the opposite discharge policy.

### Follow-Up and Events

Table 3 shows the occurrence of clinical events specified by time of occurrence. Follow-up was complete in all patients at each time point. Two overnight-stay patients died. One patient died shortly after PCI as a result of a refractory cardiogenic shock caused by dissection of the left coronary artery. This patient could not be stabilized for coronary artery bypass grafting. The other patient died 3 days after emergency coronary artery bypass grafting following PCI complicated by an acute closure of the left main coronary artery. Most myocardial infarctions were diagnosed between 4 and 24 hours after PCI with a statistically nonsignificant preponderance in overnight-stay patients. Five patients underwent elective coronary artery bypass grafting for unsuccessful PCI. One patient developed late cardiac tamponade after coronary artery perforation that was treated surgically. In each randomization group, 3 patients developed a false aneurysm or an arteriovenous fistula within 24 hours after PCI. One overnight-stay patient developed a false aneurysm 2 days after PCI while still hospitalized. The frequency of readmission was similar between the 2 groups. Hematomas >5 cm occurred to the same extent in both randomization groups.

Of the 403 patients randomized to same-day discharge, 326 patients were suitable for early discharge, as were 312 of the 397 patients randomized to overnight stay. Table 4 shows the event rates in patients suitable for same-day discharge. In these patients, no cardiac events occurred within 24 hours after PCI. One same-day discharge patient was readmitted to hospital within 24 hours for a false aneurysm needing surgical treatment. In the overnight stay group, 2 patients were readmitted after discharge for a false aneurysm and treated with echo-guided compression therapy.

Table 5 shows the occurrence of the primary end point and the risk differences in all patients (top) and in patients deemed suitable for early discharge (bottom). Among all patients, the composite primary end point occurred in 9 same-day discharge patients (2.2%) and in 17 overnight-stay patients (4.2%) (risk difference,  $-0.020$ ; 95% CI,  $-0.045$  to  $-0.004$ ;  $P$  for noninferiority  $<0.0001$ ). Among patients deemed suitable for early discharge, the composite end point occurred in 1 of 326 same-day discharge patients (0.3%) and 2 of 312 overnight-stay patients (0.6%) (risk difference,  $-0.003$ ; 95% CI,  $-0.014$  to  $0.007$ ;  $P$  for noninferiority  $<0.0001$ ).

TABLE 1. Patient and Lesion Characteristics

	Same-Day Discharge (n=403)	Overnight Stay (n=397)
Mean age, y	62.1 (10.3)	61.1 (10.2)
Range, y	39–88	30–83
Male, n (%)	327 (81)	321 (81)
Hypercholesterolemia,* n (%)	262 (65)	254 (64)
Smoking current/previous, n (%)	102/112 (25/28)	106/127 (27/32)
Diabetes mellitus, n (%)	65 (16)	56 (14)
Hypertension, n (%)	165 (41)	155 (39)
Previous myocardial infarction, n (%)	130 (32)	155 (39)
Previous PCI, n (%)	84 (21)	84 (21)
Previous coronary artery bypass grafting, n (%)	13 (3)	15 (4)
NYHA angina classification, n (%)		
I	19 (5)	7 (2)
II	68 (17)	63 (16)
III	277 (69)	291 (73)
IV	39 (10)	36 (9)
Multivessel disease, n (%)	198 (49)	175 (44)
Procedural characteristics, n (%)		
Multilesion intervention	171 (42)	158 (40)
Multivessel intervention	71 (18)	70 (18)
Stent procedure	281 (70)	292 (74)
Balloon angioplasty	90 (22)	88 (22)
Procedural success	373 (93)	364 (92)
Stents per stenting procedure, n	1.22 (0.52)	1.22 (0.48)
6F/5F guiding catheters, n	289/114	290/107
Lesions, n	628	612
Location of lesion, n (%)		
Left main	4 (0.6)	3 (0.5)
Left anterior descending	249 (40)	239 (39)
Circumflex coronary artery	166 (26)	163 (26)
Right coronary artery	204 (32)	207 (34)
Saphenous vein graft	5 (0.8)	2 (0.3)
ACC/AHA lesion morphology, n (%)		
A	15 (2)	16 (3)
B1	160 (25)	122 (20)
B2	267 (43)	296 (48)
C	186 (30)	178 (29)
Restenotic lesion, n (%)	16 (3)	18 (3)
Bifurcated lesion, n (%)	83 (13)	91 (15)
Side-branch involvement, n (%)	264 (42)	249 (41)
Calcification, n (%)	177 (28)	165 (27)
Total coronary occlusion, n (%)	97 (15)	94 (15)

NYHA indicates New York Heart Association; ACC/AHA, American College of Cardiology/American Heart Association. Values presented are mean (SD) when appropriate. Clinical history and baseline characteristics were recorded from the patients' clinical records.

\*Defined as cholesterol >5.5 mmol/L or use of lipid-lowering agents.

One-year follow-up was complete in all patients. Table 6 shows typical event rates that were comparable for the 2 treatment groups, with values for noninferiority of  $P=0.02$  in all patients and  $P=0.09$  in patients suitable for early discharge.

### Patient Satisfaction

Eighty-eight percent of the patients completed the patient-satisfaction questionnaires. On a scale of 0 to 100, same-day discharge patients gave a 5.0 higher mean score for the discharge procedure (78.6) compared with overnight-stay



**TABLE 2. Indications for Extended Hospital Stay After PCI**

	Same-Day Discharge (n=403), n (%)	Overnight Stay (n=397), n (%)	P
During or after PCI	67	80	
Hospital admission for unstable angina	5 (1)	5 (1)	1.0
Temporary occluded coronary artery	3 (1)	2 (0.5)	1.0
Suboptimal angiographic result	7 (2)	5 (1)	0.77
Dissection type C–E	5 (1)	4 (1)	0.75
Residual dissection after stent	6 (1)	17 (4)	0.02
Occlusion of (major) side branch	7 (2)	14 (4)	0.13
Angiographic thrombus	1 (0.2)	1 (0.3)	1.0
No-reflow/slow-flow phenomenon	2 (0.5)	9 (2)	0.088
Suspected perforation	2 (0.5)	0 (0)	0.50
Persistent angina and/or ECG changes	5 (1)	3 (1)	0.73
Emergency CABG	0 (0)	1 (0)	0.49
Change to catheters >6F	9 (2)	3 (1)	0.14
Complicated hemostasis	4 (1)	2 (0.5)	0.69
Unspecified (discretion cardiologist)	11 (3)	14 (4)	0.55
After 4 h of observation after PCI	10	5	
Recurrent pain	1 (0.2)	0 (0)	0.50
ECG changes	1 (0.2)	2 (0.5)	1.0
Puncture-related complication	2 (0.5)	1 (0.3)	1.0
Unspecified (discretion cardiologist)	6 (1)	2 (0.5)	0.34
Total	77 (18)	85 (20)	0.28

CABG indicates coronary artery bypass graft surgery.

patients (73.6;  $P=0.001$ ). No significant difference existed in score on patient information, treatment by personnel, and the patient's subjective opinion on the effect of the PCI. Asked for their preference in the event of repeat PCI, patients randomized to same-day discharge preferred discharge the same day in 73% of the cases versus 32% of overnight-stay patients. Sixteen percent of same-day discharge patients would prefer overnight stay, as would 55% of overnight-stay patients.

### Cost

The medical costs per patient were €4675 in the same-day discharge group compared with €4933 in the overnight-stay

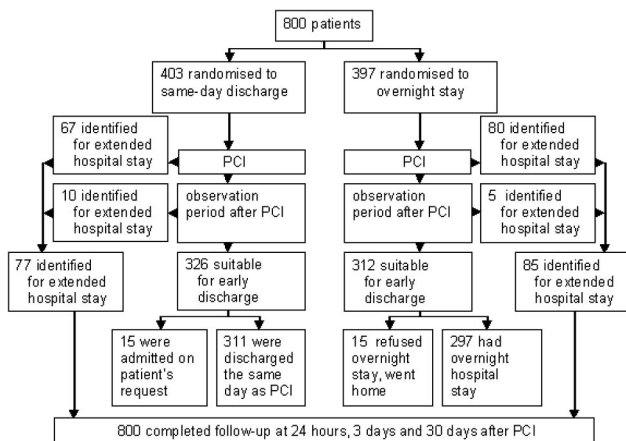
group. The mean difference of €258 (95% CI, –93 to 598) was due mainly to the extra night for overnight stay. The other costs were virtually the same for both treatment groups.

### Discussion

The present study demonstrates that same-day discharge after elective PCI can be performed safely in most patients. Same-day discharge after PCI did not lead to unattended cardiac events or to more complications at the femoral access site. Furthermore, it was found that the procedural result followed by a 4-hour observation period allowed adequate triage of patients to same-day discharge or to extended clinical observation.

Thus far, nonrandomized studies have reported same-day discharge after PCI in highly selected patients with either the femoral or the radial approach.<sup>7–11</sup> To the best of our knowledge, this is the first randomized study of same-day discharge after elective PCI in a wide range of patients. The protocol had only a few exclusion criteria, and none were angiographic. The patients included in our study represent a general elective PCI population, with a sufficient proportion of patients with complex coronary lesions such as type B2 to C lesions, bifurcated lesions, and total occlusions.

Our study shows that patients at risk for postprocedural complications can be identified effectively in a day-case setting on the basis of predefined clinical and angiographic criteria. All cardiac complications within 24 hours after PCI occurred in patients identified for extended hospital observation, whereas patients suitable for early discharge remained


**Figure 2. Trial profile.**

**TABLE 3. Occurrence of Cardiac Events and Puncture-Related Complications Among all Randomized Patients**

	Same-Day Discharge (n=403), n (%)				Overnight Stay (n=397), n (%)			
	<24 h	<4 h	4–24 h	1–30 d	<24 h	<4 h	4–24 h	1–30 d
Composite primary end point	9 (2.2)	3	6	6	17 (4.2)	2	15	4
Any MACCE	6 (1.5)	1	5	6	16 (4.0)	2	14	3
Death	0	0	0	0	1 (0.25)	1	0	1
Myocardial infarction	6 (1.5)	0	6	1	14 (3.5)	0	14	2
Cardiac surgery	1 (0.3)	1	0	3	2 (0.50)	1	1	2
Repeat PCI	1 (0.3)	1	0	4	1 (0.25)	0	1	6
Stroke	0	0	0	0	0	0	0	0
False aneurysm	3 (0.8)	2	1	0	2 (0.5)	0	2	1
Arteriovenous fistula	0	0	0	0	1 (0.25)	0	1	0
Readmission	1 (0.3)	0	1	16	2 (0.5)	0	2	18
Hematoma >5 cm	20 (5.0)	0	20	23	18 (4.5)	0	18	23

MACCE indicates major adverse cardiac or cerebral event.

free of events. Readmission for puncture-related complications was rare. Our study shows that the physical activity of a patient selected for early discharge does not lead to more puncture-related complications.

The present study shows that triage 4 hours after PCI is pivotal for the safety of a same-day discharge protocol. After PCI, 7 patients developed an indication for extended hospital stay during the 4-hour observation period. Therefore, a definitive decision for same-day discharge can be made only after an uncomplicated clinical course of at least 4 hours, which is in line with previous reports.<sup>5,15</sup>

It was found that same-day discharge leads to a cost reduction of €258 per patient. Next to minor cost reduction, same-day discharge renders substantial logistic benefits for the hospital; ≈80% of patients selected for same-day discharge do not require a hospital bed after PCI.

**TABLE 4. Occurrence of Cardiac Events and Puncture-Related Complications in Patients Deemed Suitable for Same-Day Discharge**

	Same-Day Discharge (n=326), n (%)		Overnight Stay (n=312), n (%)	
	4–24 h	1–30 h	4–24 h	1–30 d
Composite primary end point	1	0	2	3
Any MACCE	0	0	0	3
Death	0	0	0	0
Myocardial infarction	0	0	0	2
Cardiac surgery	0	0	0	1
Repeat PCI	0	0	0	1
Stroke	0	0	0	0
False aneurysm	1	0	2	0
Arteriovenous fistula	0	0	0	0
Readmission	1	8	2	13
Hematoma >5 cm	17	15	11	18

MACCE indicates major adverse cardiac or cerebral event.

Previous investigators have shown that the radial approach is a suitable technique for same-day discharge PCI because it enables immediate ambulation.<sup>9,11,16</sup> Although the radial approach is increasingly being adopted, the femoral approach has remained the most widely applied technique. Therefore, the results of our study evaluating the femoral approach are applicable to most PCI settings. Our study shows that only a few patients (1.1%) developed an indication for extended observation secondary to complications at the femoral puncture site.

The use of femoral artery closure devices enables early ambulation within 2.2 hours even with 7F to 8F catheters.<sup>17–19</sup> However, the effect of closure devices on puncture-related complications compared with manual compression is still controversial.<sup>20,21</sup> Therefore, closure devices were not used in our study to avoid a confounding effect by these devices on the incidence of puncture-related complications. Reports on closure devices and actual same-day discharge are limited.<sup>22,23</sup> Patients scheduled for PCI with 7F and 8F catheters could have been included in the study if such devices had been used. However, this would have marginally increased patient eligibility (1.8%).

### Study Limitations

The trial failed to reach the anticipated event rate. The low event rate is explained by the improvement in angioplasty and stent techniques and by the improved care for the arterial puncture site. As a consequence, the relative risk of the 2 strategies cannot be adequately estimated. On the other hand, our study has sufficient power to conclude that the absolute difference in event rates is small. The CI for the difference in the composite primary outcome was −0.4% to 4.5%, indicating that one may be reasonably confident that the 2 strategies do not lead to substantially different outcomes.

Patients scheduled for a diagnostic coronary angiogram and ad hoc PCI were excluded for trial logistical reasons. Nevertheless, the results of the present study can be generalized to patients undergoing ad hoc PCI, provided that they

**TABLE 5. Crude Rates and Absolute Risk Difference for Combined Primary End Points and Major Adverse Cardiac or Cerebral Event**

	Same-Day Discharge	Overnight Stay	Absolute Risk Difference, % (95% CI)
All patients, n (%)	403	397	
Composite primary end point <24 h	9 (2.2)	17 (4.2)	2.0 (−0.4–4.5)
Composite primary end point <30 d	15 (3.7)	21 (5.3)	1.6 (−1.3–4.4)
Any MACCE <24 h	6 (1.5)	16 (4.0)	2.5 (−0.3–4.8)
Any MACCE <30 d	12 (2.9)	19 (4.8)	1.8 (−0.9–4.5)
Patients deemed suitable for early discharge, n (%)	326	312	
Composite primary end point <24 h	1 (0.3)	2 (0.6)	0.3 (−0.7–1.4)
Composite primary end point <30 d	1 (0.3)	5 (1.6)	1.3 (−0.2–2.8)
Any MACCE <24 h	0 (0)	0 (0)	
Any MACCE <30 d	0 (0)	3 (1.0)	1.0 (−1.0–2.0)

MACCE indicates major adverse cardiac or cerebral event. All values for noninferiority were  $P < 0.0001$ .

otherwise fulfill the study inclusion criteria and the 4-hour triage criteria for discharge.

Our anticoagulation regimen may differ from the weight-based, activated clotting time-monitored practice in many centers. The safety of the chosen approach in elective patients was reported earlier, including resulting activated clotting time levels.<sup>12</sup> In the present study, no indication exists of an excess of ischemic complications attributable to the anticoagulation regimen. Activated clotting time-guided sheath removal might have reduced femoral access complications.

By virtue of the design of the study, asymptomatic postprocedural creatine kinase-MB increases could not be observed in patients discharged to home after the triage at 4 hours. Therefore, the protocol expressly stipulated that routine creatine kinase-MB measurements not be performed in patients deemed suitable for same-day discharge at 4 hours who had been randomized to overnight stay. Consequently, some periprocedural enzyme releases might have been missed, but this did not lead to a bias between the 2 treatment groups.

Drug-eluting stents were not available at the time the study was conducted. It is difficult to predict how these stents might have resulted in different early outcomes; the 1-year results are compatible with those expected in the pre-drug-eluting stent era.

The results of our study may be not applicable to centers using glycoprotein IIb/IIIa inhibitors routinely during elective procedures. Appropriate use of these agents requires a 12-hour infusion after PCI and is therefore a priori incompatible with a same-day discharge strategy. It has been demonstrated that direct thrombin inhibitors such as bivalirudin may be an alternative to glycoprotein IIb/IIIa inhibitors and unfractionated heparin,<sup>7,24</sup> thus enabling same-day discharge PCI according to the presented protocol.

It is conceivable that the findings of our study are determined in part by the experience of the operator or PCI volume. Therefore, the present results cannot be extrapolated to settings with less-experienced operators and/or to low-volume centers.

**TABLE 6. Outcomes at 1-Year Follow-Up of Patients Undergoing Elective PCI and Randomized to Same-Day Discharge or Overnight Stay**

Outcome	All Patients, n (%)		Suitable for Same-Day Discharge at 4 h, n (%)		Triaged to Overnight Stay at 4 h, n (%)	
	Same-Day Discharge (n=403)*	Overnight Stay (n=397)*	Same-Day Discharge (n=326)*	Overnight Stay (n=312)*	Same-Day Discharge (n=77)*	Overnight Stay (n=85)*
MACCE†	67 (16.6)	65 (16.4)	49 (15.0)	37 (11.9)	18 (23.4)	28 (32.9)
Cardiac death	2 (0.5)	2 (0.5)	1 (0.3)	1 (0.3)	1 (1.3)	1 (1.2)
Myocardial infarction	17 (4.2)	26 (6.5)	9 (2.8)	10 (3.2)	8 (10.4)	16 (18.8)
Periprocedural	6 (1.5)	14 (3.5)	0 (0.0)	0 (0.0)	6 (7.8)	14 (16.5)
Spontaneous	11 (2.7)	12 (3.0)	9 (2.8)	10 (3.2)	2 (2.6)	2 (2.4)
Surgical TVR	16 (4.0)	12 (3.0)	6 (1.8)	8 (2.6)	10 (13.0)	4 (4.7)
Percutaneous TVR	50 (12.4)	44 (11.1)	40 (12.3)	31 (9.9)	10 (13.0)	13 (15.3)
Stroke	4 (1.0)	3 (0.8)	3 (0.9)	1 (0.3)	1 (1.3)	2 (2.4)
Noncardiac death	3 (0.7)	5 (1.3)	2 (0.6)	2 (0.6)	1 (1.3)	3 (3.5)
NTVR	16 (4.0)	21 (5.3)	12 (3.7)	11 (3.5)	4 (5.2)	10 (11.8)

NTVR indicates percutaneous non-target vessel revascularization.

\*Patients were randomized before the procedure and triaged at 4 hours after the procedure.

†Major adverse cardiac or cerebral events (MACCE) include cardiac death, myocardial infarction, surgical or percutaneous target vessel revascularization (TVR), or stroke.

We conclude that same-day discharge after elective PCI via the femoral approach is feasible and safe in the majority of patients (80%) selected for day-case PCI. Same-day discharge does not lead to additional complications compared with overnight stay. Triage of patients for an extended observation period can be performed adequately on the basis of clinical and procedural criteria.

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### Disclosures

None.

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### CLINICAL PERSPECTIVE

The Elective PCI in Outpatients Study (EPOS) is a prospective, randomized, single-center study of 800 patients to evaluate the safety and feasibility of same-day discharge after percutaneous coronary intervention with overnight hospital stay in patients scheduled for elective percutaneous coronary intervention performed from the femoral approach. After 24 hours, 3 days, and 30 days, the safety end points were similar between the randomization groups, and same-day discharge did not lead to additional complications compared with overnight stay. Furthermore, it was found that triage of patients for an extended observation period can be performed adequately on the basis of clinical and procedural criteria. Timely discharge of eligible patients after PCI not only may add to the patient's comfort but also may be of interest to optimize the use of restricted hospital facilities in the setting of increasing costs and resource use.