ORIGINAL ARTICLE

Outcomes of PCI at Hospitals with or without On-Site Cardiac Surgery

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ABSTRACT

BACKGROUND

Performance of percutaneous coronary intervention (PCI) is usually restricted to hospitals with cardiac surgery on site. We conducted a noninferiority trial to compare the outcomes of PCI performed at hospitals without and those with on-site cardiac surgery.

METHODS

We randomly assigned participants to undergo PCI at a hospital with or without on-site cardiac surgery. Patients requiring primary PCI were excluded. The trial had two primary end points: 6-week mortality and 9-month incidence of major adverse cardiac events (the composite of death, Q-wave myocardial infarction, or target-vessel revascularization). Noninferiority margins for the risk difference were 0.4 percentage points for mortality at 6 weeks and 1.8 percentage points for major adverse cardiac events at 9 months.

RESULTS

A total of 18,867 patients were randomly assigned in a 3:1 ratio to undergo PCI at a hospital without on-site cardiac surgery (14,149 patients) or with on-site cardiac surgery (4718 patients). The 6-week mortality rate was 0.9% at hospitals without on-site surgery versus 1.0% at those with on-site surgery (difference, −0.04 percentage points; 95% confidence interval [CI], −0.31 to 0.23; P=0.004 for noninferiority). The 9-month rates of major adverse cardiac events were 12.1% and 11.2% at hospitals without and those with on-site surgery, respectively (difference, 0.92 percentage points; 95% CI, 0.04 to 1.80; P=0.05 for noninferiority). The rate of target-vessel revascularization was higher in hospitals without on-site surgery (6.5% vs. 5.4%, P=0.01).

CONCLUSIONS

We found that PCI performed at hospitals without on-site cardiac surgery was noninferior to PCI performed at hospitals with on-site cardiac surgery with respect to mortality at 6 weeks and major adverse cardiac events at 9 months. (Funded by the Cardiovascular Patient Outcomes Research Team [C-PORT] participating sites; ClinicalTrials.gov number, NCT00549796.)

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The potential need for emergency cardiac surgery to treat complications related to percutaneous coronary intervention (PCI) suggests that performance of PCI may be best limited to hospitals with on-site cardiac surgery. Among Grüntzig's first 50 PCI procedures, 10% of patients required emergency coronary-artery bypass grafting (CABG).[1] Although the need for emergency surgery subsequently diminished dramatically (by 2002, the incidence was 0.15%[2]), concern about the safety and quality of PCI performed without the availability of on-site cardiac surgery has persisted. Hospitals in which PCI is performed but that do not have cardiac surgery programs could have more adverse events and poorer outcomes for a number of reasons (including low institutional volume of PCI procedures and inexperienced staff), in addition to the need for emergency CABG.

Despite these concerns, many hospitals without on-site cardiac surgery developed stand-alone programs for the performance of primary PCI after studies showed that primary PCI was associated with better outcomes than medical therapy in the treatment of myocardial infarction with ST-segment elevation[3] and could be performed safely and effectively at such hospitals.[4] Door-to-balloon times may be shorter, and outcomes consequently better, if primary PCI is widely available. It has further been suggested that, given the relatively low volume of primary PCI procedures at some hospitals, the addition of other PCI procedures (including elective PCI and PCI for acute coronary syndromes without ST-segment elevation) could help sustain and improve these programs.

In addition, previous studies have shown that, for patients with acute coronary syndromes presenting to centers without any revascularization capability, appropriate use of PCI and CABG is limited and outcomes are suboptimal.[5-7] Extension of PCI capability to such hospitals could improve access to appropriate care, particularly in areas where recruitment and retention of cardiologists may be difficult[8] and treatment options for patients are limited.

The Cardiovascular Patient Outcomes Research Team (CPORT) Non-Primary PCI (CPORT-E) trial was designed to help address these issues. CPORT-E was a randomized noninferiority trial that compared outcomes of PCI procedures (excluding primary PCI) at hospitals with and those without on-site cardiac surgery.

Methods

Study Design and Oversight

The CPORT-E trial was designed by the study chairman and the protocol-development committee and was funded through financial support provided by participating sites to the Johns Hopkins University and through in-kind support that included the provision of local study coordinators at each site. There was no support from the makers of equipment used in catheterization laboratories or of that used for PCI. The protocol was approved by each participating hospital's institutional review board and the Johns Hopkins institutional review board. Data were gathered by local research coordinators, reviewed for accuracy by central study coordinators at Johns Hopkins, and analyzed by the authors. The authors vouch for the accuracy and completeness of the data and the analysis and for the fidelity of this report to the trial protocol, which is available with the full text of this article at NEJM.org.

Trial Participants

Patients were eligible for participation in the trial if they presented for diagnostic cardiac catheterization at 1 of 60 participating hospitals without on-site cardiac surgery located in 10 U.S. states (Maryland, New Jersey, Pennsylvania, Ohio, Georgia, Texas, North Carolina, Illinois, Oregon, and Alabama). During the trial period, patients who did not undergo randomization, whether or not they met the inclusion criteria for the trial, were included in a registry that recorded a limited set of data that excluded identifying private information.

Patients 18 years of age or older with stable coronary artery disease or an acute coronary syndrome were included in the trial. Patients with an acute myocardial infarction with ST-segment elevation were excluded, as were those with an ejection fraction of less than 20% and those who required PCI of an unprotected lesion in the left main coronary artery. In addition, interventionalists could exclude any patient whom they deemed to be at too high a risk for PCI. For each trial participant, all lesions requiring PCI had to be considered treatable at the hospital without on-site cardiac surgery before randomization. Patients who had previously participated in the trial were excluded. Full inclusion and exclusion criteria are available in Table S1 in the Supplementary Appendix, available at NEJM.org.

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PARTICIPATING HOSPITALS AND INTERVENTIONALISTS

Interventionalists were required to meet criteria for competency developed by the American College of Cardiology (ACC), the American Heart Association (AHA), and the Society for Cardiac Angiography and Interventions (SCAI).[9] Participating centers were required to have primary PCI programs available 24 hours per day, 7 days per week, and to be capable of performing 200 PCI procedures annually. Most sites required a waiver from the state department of health to participate. All such waivers allowed for a first-year PCI volume of 100 procedures, increasing to 200 in the second year.

Each site had a formal agreement with a tertiary-care hospital partner specifying that the tertiary-care institution would accept emergency transfers from the enrolling site. However, participants in the trial who were randomly assigned to undergo PCI at a hospital with on-site surgery could have the PCI procedure at any tertiary-care hospital. A formal agreement with an advanced cardiac life-support service capable of transporting patients requiring intraaortic balloon counterpulsation was also required, with an anticipated response time of 30 minutes or less.

Before commencing recruitment, all participating sites were required to complete a formal PCI development program. This program included the development of detailed care plans and pathways, order sets, and logistics and the training of staff in the care of patients undergoing PCI. Details of this program are available in the Supplementary Appendix.

TRIAL PROCEDURES

Before undergoing diagnostic catheterization, study participants provided written informed consent. After catheterization, if PCI was required and all lesions were considered to be treatable at the hospital without on-site cardiac surgery, the participant was randomly assigned in a 3:1 ratio to undergo PCI at either the enrolling site (without on-site cardiac surgery) or another facility with on-site cardiac surgery. Randomization was performed with the use of an automated telephone-response system on a per-site basis in random permuted blocks (of 4, 8, or 12). Patients who were considered to be at too high a risk according to the study-exclusion criteria or in the judgment of the treating physician did not undergo randomization but instead underwent PCI, CABG, or other therapy as clinically indicated.

After randomization, all trial participants were to undergo PCI according to their randomized assignment. The timing of the index PCI procedure depended on individual case acuity, the need to perform PCI on a different day than the visit to the catheterization laboratory to minimize procedural risk (i.e., staged procedure), and scheduling and transportation constraints, but the procedure was to be performed as soon as possible for each participant. All treatments, devices, and drugs were administered and laboratory studies carried out according to routine practice; no specific PCI protocol was prescribed. However, the use of cutting balloons was limited to in-stent restenosis and atherectomy devices were not permitted at hospitals without on-site cardiac surgery.

Participants were contacted by telephone (or mail, if necessary) at 6 weeks and 3, 6, and 9 months after study entry to identify adverse events. Medical records required to document identified events were obtained as needed.

TRIAL OUTCOMES

Two coprimary outcomes were identified: all-cause mortality 6 weeks after the index PCI and the composite rate of major adverse cardiac events, including death from all causes, Q-wave myocardial infarction, and target-vessel revascularization, 9 months after the index PCI. Additional outcomes included the PCI success rate and the incidence of cardiac surgery, bleeding, stroke, renal failure, and any subsequent revascularization.

Except as noted, definitions of data elements followed those in the American College of Cardiology National Cardiovascular Data Registry module on cardiac catheterization, version 3.02.[10] Q-wave myocardial infarction was defined as the development of new Q waves in any two contiguous leads. Target-vessel revascularization was defined as any revascularization intervention (PCI or CABG) occurring in a treated vessel at any time after the index intervention. In randomly assigned participants who did not undergo an index PCI, any revascularization was considered a target-vessel revascularization. Bleeding was defined as any bleeding that required blood transfusion, except for transfusions associated with cardiac surgery. Vascular repair included thrombin injection, ultrasound-guided compression, and surgical repair. Further details of study definitions are available in the Supplementary Appendix.

All events were reported by the enrolling site to the central coordinating center and were con-

firmed by coordinating-center staff with the source medical records submitted. Occasionally, a review of source documents resulted in the identification of unreported events or the withdrawal of submitted events. A central review committee reviewed electrocardiographic findings without knowledge of the participant's randomized assignment.

STATISTICAL ANALYSIS

The CPORT-E trial was designed as a noninferiority trial. On the basis of previous studies, the 6-week all-cause mortality rate was estimated at 0.8%[11,12] and the rate of major adverse cardiac events at 9 months was estimated at 12.0%.[13-16] Noninferiority margins for the difference in event rates were set at 0.4 percentage points for the 6-week end point and 1.8 percentage points for the 9-month end point. With dual primary end points, the required number of participants for a one-sided test for noninferiority with an alpha level of 0.05 and a beta level of 0.80 was determined to be 18,360.

The primary outcome analysis was performed on data from the intention-to-treat population. Asymptotic normal approximations to the sample proportions were used to generate confidence intervals and P values for noninferiority. Categorical variables were compared with the use of Fisher's exact test or a chi-square test. A per-protocol analysis was also performed, which included only participants who underwent PCI at the site to which they were assigned. All statistical analyses were performed with the use of SAS software, version 9.2.

States that required a waiver from the department of health for trial participation typically specified that the participating hospitals should stop performing PCI when trial enrollment was completed. To allow the creation of a follow-up registry in these states, enrollment continued after the recruitment goal of 18,360 participants was reached. Ultimately, 18,867 participants underwent randomization.

RESULTS

STUDY POPULATION

Enrollment began on April 7, 2006, and ended on March 31, 2011. During that period, there were 99,479 patient visits for diagnostic catheterization at the participating hospitals. Among the 76.1% of patients who provided consent to participate, 21,165 were judged to require PCI after catheterization, and 18,867 underwent randomization (Fig. 1). Excluded were 2298 patients (10.9%) who required PCI but were judged to be at too high a risk for study participation. Reasons for the judgment that the risk was too high are shown in Figure S1 in the Supplementary Appendix. Overall, patients in the registry had fewer risk factors and less severe coronary disease than randomly assigned trial participants (Table S2 in the Supplementary Appendix).

Of the patients who underwent randomization, 319 did not undergo an index PCI. The proportion of patients who did not undergo an index PCI was higher among participants assigned to hospitals with on-site cardiac surgery than among those assigned to hospitals without on-site surgery. Reasons included referral for surgical or medical therapy and lesion resolution (Table S3 in the Supplementary Appendix). Crossovers between study groups were infrequent but were more frequent among participants randomly assigned to hospitals with on-site cardiac surgery (Fig. 1).

The baseline characteristics of the participants are shown in Table 1. There was a higher incidence of prior PCI in participants randomly assigned to hospitals without cardiac surgery on site. In addition, the rate of emergency catheterization was higher, and the rate of urgent catheterizations lower, among participants assigned to hospitals with on-site cardiac surgery.

The median annual volume of catheterizations per hospital was 150 procedures (interquartile range, 99 to 216). The median annual volume of primary PCIs was 51 procedures (interquartile range, 35 to 74). The participation of 12 hospitals was terminated during the trial because of low volume. Data from these sites were included in the data analysis.

PROCEDURE CHARACTERISTICS

A higher percentage of PCIs were staged among participants assigned to hospitals with on-site cardiac surgery than among those assigned to hospitals without on-site surgery, probably because of the need for transfer (Table 2). As a result, the number of visits to the catheterization laboratory that were needed to complete PCI was higher among participants assigned to hospitals with on-

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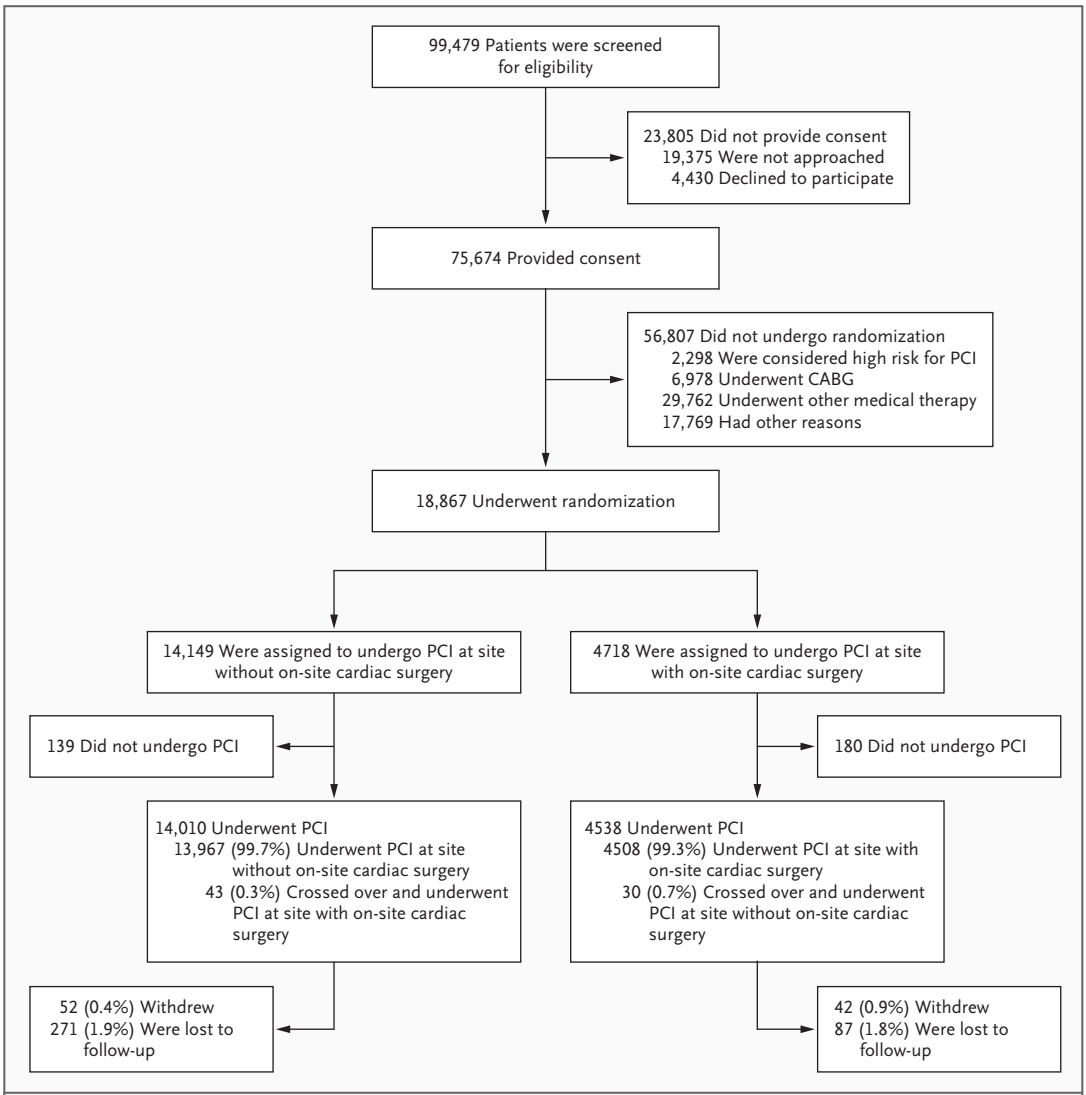

Figure 1. Enrollment and Randomization of the Study Patients.

The percentages for the patients who withdrew or were lost to follow-up are based on the patients assigned to undergo percutaneous coronary intervention (PCI). CABG denotes coronary-artery bypass grafting.

site cardiac surgery. In addition, drug-eluting stents were used more frequently in hospitals with on-site cardiac surgery.

The rate of PCI failure was lower among participants treated at hospitals with on-site cardiac surgery (Table 2). Emergency CABG was associated with high mortality but was rarely performed; it was performed more frequently among participants assigned to hospitals with on-site cardiac surgery. The incidence of unplanned re-catheterization and PCI before discharge was greater at hospitals without on-site cardiac surgery.

OUTCOMES

At 6 weeks after the index PCI, 132 participants assigned to hospitals without on-site cardiac surgery had died and 46 participants assigned to hospitals with on-site cardiac surgery had died. The event rates in the two groups were 0.9% and 1.0%, respectively (difference in event rates, −0.04 percentage points; 95% confidence interval [CI], −0.31 to 0.23; P=0.004 for noninferiority) (Table 3).

At 9 months, there were 1716 major adverse cardiac events in participants at hospitals without on-site cardiac surgery and 529 such events in

Table 1. Baseline Characteristics of the Study Patients.*

Characteristic	No On-Site Cardiac Surgery (N=14,149)	On-Site Cardiac Surgery (N=4718)
Age — yr	63.9±11.9	64.0±12.0
Male sex — no. (%)	9046 (63.9)	2970 (63.0)
White race — no. (%)†	11,185 (79.1)	3778 (80.1)
Medical history — no. (%)		
Hypertension	11,950 (84.5)	4024 (85.3)
Hypercholesterolemia	11,567 (81.8)	3865 (81.9)
Smoking (current or former)	8,719 (61.6)	2964 (62.8)
Diabetes	5,485 (38.8)	1868 (39.6)
Family history of CAD	7,730 (54.6)	2623 (55.6)
Heart failure	1,531 (10.8)	518 (11.0)
Prior myocardial infarction	6,011 (42.5)	2030 (43.0)
Prior PCI‡	4,506 (31.8)	1430 (30.3)
Prior CABG	1,852 (13.1)	632 (13.4)
Prior stroke or PVD	2,447 (17.3)	868 (18.4)
Angiographic findings at baseline		
One-vessel CAD — no. (%)	5,097 (36.0)	1645 (34.9)
Two-vessel CAD — no. (%)	5,087 (36.0)	1741 (36.9)
Three-vessel CAD — no. (%)	3,959 (28.0)	1326 (28.1)
Left main CAD — no. (%)	465 (3.3)	178 (3.8)
Graft disease — no. (%)	1,323 (9.4)	456 (9.7)
Left ventricular ejection fraction — %	54.2±10.6	54.3±10.7
Procedure status at time of catheterization — no. (%)§		
Elective	10,350 (73.2)	3414 (72.4)
Urgent¶	3,291 (23.3)	1127 (23.9)
Emergency‡	493 (3.5)	175 (3.7)
Clinical status at time of catheterization — no. (%)‖		
STEMI	390 (2.8)	147 (3.1)
NSTEMI	3,471 (24.5)	1210 (25.7)
Unstable angina	5,196 (36.7)	1665 (35.3)
Stable angina	2,011 (14.2)	636 (13.5)
Atypical chest pain	723 (5.1)	268 (5.7)
Other	2,356 (16.7)	790 (16.8)

* Plus–minus values are means ±SD. CABG denotes coronary-artery bypass grafting, CAD coronary artery disease, NSTEMI non–ST-segment elevation myocardial infarction, PCI percutaneous coronary intervention, PVD peripheral vascular disease, and STEMI ST-segment elevation myocardial infarction.

† Race was self-reported.

‡ P<0.05 for the comparison between groups.

§ For procedure status at time of catheterization, data were missing for 15 patients treated at hospitals without on-site cardiac surgery and 2 patients treated at hospitals with on-site cardiac surgery. The definitions for "urgent" and "emergency" were those used in the American College of Cardiology National Cardiovascular Data Registry module on cardiac catheterization, version 3.02.[10]

¶ P<0.01 for the comparison between groups.

‖ For clinical status at time of catheterization, data were missing for 2 patients in each study group. "Other" includes patients presenting with heart failure, arrhythmia, positive stress tests, syncope, and other non–chest-pain syndromes and patients undergoing cardiovascular risk assessment before a noncardiac surgical procedure.

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Table 2. Characteristics of the Index Procedure.*

Characteristic	No On-Site Cardiac Surgery	On-Site Cardiac Surgery	P Value
PCI staged — no./total no. (%)†	3652/14,010 (26.1)	3084/4538 (68.0)	<0.001
Single-vessel PCI — no./total no. (%)	11,212/14,010 (80.0)	3716/4538 (81.9)	
Multivessel PCI — no./total no. (%)	2937/14,010 (21.0)	1002/4538 (22.1)	
No. of catheterization laboratory visits needed to complete index PCI	1.28	1.73	<0.001
No. of days from randomization to index PCI — median (IQR)	0 (0–3)	1 (0–3)	<0.001
Stent use — no./total no. (%)			0.03
DES only	10,074/14,010 (71.9)	3343/4538 (73.7)	
BMS only	2790/14,010 (19.9)	877/4538 (19.3)	
Both DES and BMS	596/14,010 (4.3)	156/4538 (3.4)	
Balloon only	550/14,010 (3.9)	162/4538 (3.6)	
PCI success — no./total no. (%)			
By patient‡			0.007
Complete success	12,714/14,010 (90.7)	4148/4538 (91.4)	
Partial success	808/14,010 (5.8)	253/4538 (5.6)	
Failure	482/14,010 (3.4)	113/4538 (2.5)	
By lesion§			0.04
Success	19,886/21,292 (93.4)	6499/6907 (94.1)	
Failure	1406/21,292 (6.6)	408/6907 (5.9)	
Emergency procedures			
Emergency PCI — no./total no. (%)	23/14,010 (0.2)	6/4538 (0.1)	
Death associated with emergency PCI — no. of deaths/total no. of emergency PCI procedures (%)	1/23 (4.3)	0	
Emergency CABG — no./total no. (%)	13/14,010 (0.1)	10/4538 (0.2)	0.11
Death associated with emergency CABG — no. of deaths/total no. of emergency CABG procedures (%)	2/13 (15.4)	2/10 (20.0)	

* Data are for all randomly assigned patients who underwent PCI. BMS denotes bare-metal stent, DES drug-eluting stent, and IQR interquartile range.

† Staged PCI indicates that PCI was performed on a different day than the visit to the catheterization laboratory to minimize procedural risk.

‡ Thirty patients (6 in hospitals without on-site cardiac surgery and 24 in hospitals with on-site cardiac surgery) did not have valid postprocedure data available on coronary-artery flow (according to the Thrombolysis in Myocardial Infarction [TIMI] scale, which ranges from 0 to 3, with 0 indicating no flow and 3 normal flow) or percentage of residual stenosis. These 30 patients were excluded from the analysis of PCI success by patient. Complete success was defined as a postprocedure TIMI flow grade of 3 and residual stenosis not exceeding 20% in all treated lesions. Partial success was defined as a postprocedure TIMI flow grade of 3 and residual stenosis not exceeding 20% in at least one (but not all) treated lesions. Failure was defined as no treated lesions with a postprocedure TIMI flow grade of 3 and residual stenosis of more than 20%.

§ Success by lesion was defined as a postprocedure TIMI flow grade of 3 and residual stenosis not exceeding 20%. Failure was defined as a postprocedure TIMI flow grade of less than 3 or residual stenosis of more than 20%.

patients at hospitals with on-site cardiac surgery (12.1% vs. 11.2%; difference in event rates, 0.92 percentage points; 95% CI, 0.04 to 1.80; P=0.05 for noninferiority) (Table 3). There were no significant differences in all-cause mortality or Q-wave myocardial infarction between the two groups, but there was a significant difference in the rate of target-vessel revascularization — 6.5% among participants at hospitals without on-site cardiac surgery versus 5.4% among those at hospitals with on-site cardiac surgery (P=0.01).

Several exploratory analyses were conducted (Table 3). If CABG was not considered to qualify as target-vessel revascularization when it was performed as an initial procedure (i.e., for participants who did not undergo the intended index PCI), the rates of major adverse cardiac events at 9 months among participants at hospitals with-

Table 3. Trial Outcomes.*

Outcome	No On-Site Cardiac Surgery	On-Site Cardiac Surgery	Difference in Rate (Asymptotic One-Sided 95% CI)	P Value	
				Noninferiority	Superiority
	no./total no. (%)		*percentage points*		
Primary end point (intention-to-treat population)					
Death at 6 wk	132/14,149 (0.9)	46/4718 (1.0)	–0.04 (–0.31 to 0.23)	0.004	
9-mo outcomes					
Death	454/14,149 (3.2)	150/4718 (3.2)			
TVR	915/14,149 (6.5)	255/4718 (5.4)			0.01
Q-wave myocardial infarction	434/14,149 (3.1)	144/4718 (3.1)			
Major adverse cardiac event	1716/14,149 (12.1)	529/4718 (11.2)	0.92 (0.04 to 1.80)	0.05	
Exploratory analyses (intention-to-treat population)					
Major adverse cardiac event, including withdrawal and loss to follow-up	2026/14,149 (14.3)	653/4718 (13.8)	0.48 (–0.48 to 1.44)	0.01	
CABG as initial procedure not included in TVR definition					
TVR	873/14,149 (6.2)	218/4718 (4.6)			<0.001
Major adverse cardiac event	1678/14,149 (11.9)	495/4718 (10.5)	1.37 (0.51 to 2.23)	0.21	
TVR according to stent type					
DES only	484/10,074 (4.8)	120/3343 (3.6)			0.005
BMS only	223/2790 (8.0)	53/877 (6.0)			
Both DES and BMS	39/596 (6.5)	8/156 (5.1)			
Balloon only	138/550 (25.1)	34/162 (21.0)			
Per-protocol analyses					
Death at 6 wk	129/13,967 (0.9)	38/4508 (0.8)	0.08 (–0.18 to 0.34)	0.03	
TVR	860/13,967 (6.2)	202/4508 (4.5)			<0.001
Major adverse cardiac event at 9 mo	1676/13,967 (12.0)	467/4508 (10.4)	1.64 (0.77 to 2.51)	0.42	

* Major adverse cardiac events included death, target-vessel revascularization (TVR), and Q-wave myocardial infarction. BMS denotes bare-metal stent, and DES drug-eluting stent.

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out and those with on-site cardiac surgery were 11.9% and 10.5%, respectively. In per-protocol analyses (excluding participants who crossed over), the death rates at 6 weeks were 0.9% and 0.8%, respectively, and the rates of major adverse cardiac events at 9 months were 12.0% and 10.4%, respectively.

CABG was performed more frequently among trial participants at hospitals with on-site cardiac surgery than among participants at hospitals without such access (Table 4). The incidence of unplanned catheterization at 6 weeks and 9 months and the incidence of any subsequent revascularization at 9 months were higher among participants at hospitals without on-site cardiac surgery (Table 4).

DISCUSSION

We compared clinical outcomes between trial participants undergoing PCI at a hospital with on-site access to cardiac surgery and participants undergoing PCI at a hospital without such access. We found that outcomes at hospitals without on-site cardiac surgery were noninferior to those at hospitals with cardiac surgery on site, with respect to all-cause mortality at 6 weeks and major adverse cardiac events at 9 months. There were no significant differences between the two study groups at 9 months with respect to rates of death or Q-wave myocardial infarction, but trial participants treated at hospitals without on-site cardiac surgery more frequently required target-vessel revascularization.

The short-term results from this trial are concordant with the findings in previous registry studies and meta-analyses.[17,18] The longer-term outcomes are similar to those in a small randomized trial of low-risk PCI at two hospitals,[19] which showed equivalent safety at the hospitals with and those without on-site cardiac surgery but more frequent target-vessel revascularization at 6 months among participants treated at the sites without cardiac surgery.

The definition of target-vessel revascularization used in the CPORT-E trial included any revascularization (PCI or CABG) after the index PCI. In addition, for randomly assigned participants who did not undergo an index PCI, any subsequent revascularization of the target vessel, whether by PCI or CABG, was considered a target-vessel revascularization. The inclusion of initial CABG as a target-vessel revascularization is consistent with the intention-to-treat approach, which is based on randomized treatment assignments, regardless of the treatment received. When CABG was not counted as a target-vessel revascularization in these trial participants, hospitals without on-site cardiac surgery were inferior to those with on-site access with respect to the rate of major adverse cardiac events at 9 months (Table 3). The per-protocol analysis also showed a higher rate of major adverse cardiac events in hospitals without on-site cardiac surgery. These differences are small and within the range of noninferiority margins used in recent comparative trials of stent types, from 1.5 percentage points (relative difference, 19%)[20] to 3.5 percentage points (relative difference, 43%).[21]

In all analyses, the rate of target-vessel revascularization was higher among participants who underwent PCI at a hospital without cardiac surgery on-site, regardless of the definition of target-vessel revascularization and regardless of stent type. The reason for this is not clear from the current study but may reflect a lower initial success rate and a more conservative approach by interventionalists practicing at relatively inexperienced centers that began PCI programs only as part of the CPORT-E trial.

There are a number of important limitations arising from the design and conduct of the CPORT-E trial. Participants were carefully selected and were excluded if they were deemed to be at high risk. It is possible that the population studied is different from the general population requiring PCI, although a comparison of baseline characteristics with those reported in the National Cardiovascular Data Registry[17] suggests that this is not the case (Table S4 in the Supplementary Appendix). For outcomes of PCI at hospitals without on-site cardiac surgery to be similar to those at hospitals with on-site cardiac surgery, it may be necessary for such centers to participate in a formal PCI development program and for interventionalists who perform the procedures to meet the criteria for competency developed by the ACC, AHA, and SCAI.

In summary, the CPORT-E trial compared the clinical outcomes of PCI performed at hospitals with access to on-site cardiac surgery with outcomes of PCI performed at hospitals without such access. Outcomes at hospitals without on-site cardiac surgery were noninferior to those at hospi-

Table 4. Adverse Events.

Event	6 Wk			9 Mo		
	On-Site Cardiac Surgery (N=14,149)	No On-Site Cardiac Surgery (N=4718)	P Value	On-Site Cardiac Surgery (N=14,149)	No On-Site Cardiac Surgery (N=4718)	P Value
	no. (%)			*no. (%)*		
CABG						
All	88 (0.6)	69 (1.5)	<0.001	216 (1.5)	107 (2.3)	<0.001
Emergency	15 (0.1)	10 (0.2)		18 (0.1)	11 (0.2)	
Bleeding	486 (3.4)	150 (3.2)		754 (5.3)	247 (5.2)	
Vascular repair	52 (0.4)	20 (0.4)		151 (1.1)	55 (1.2)	
Stroke	40 (0.3)	8 (0.2)		87 (0.6)	23 (0.5)	
Renal insufficiency	72 (0.5)	20 (0.4)		131 (0.9)	37 (0.8)	
Unplanned catheterization	613 (4.3)	150 (3.2)	<0.001	2102 (14.9)	566 (12.0)	<0.001
Any subsequent revascularization	378 (2.7)	127 (2.7)		1200 (8.5)	329 (7.0)	0.001

tals with cardiac surgery on site, with respect to all-cause mortality at 6 weeks and major adverse cardiac events at 9 months.

Disclosure forms provided by the authors are available with the full text of this article at NEJM.org.

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