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News from the NCDR

NCDR™ National Cardiovascular Data Registry

Percutaneous Coronary Interventions in Facilities Without Cardiac Surgery On Site: A Report From the National Cardiovascular Data Registry (NCDR)

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Since the introduction of percutaneous coronary intervention (PCI) in 1977 by Andreas Gruntzig (1), the presence of cardiac surgery backup on site has been a recommended practice to treat the potential of life-threatening complications. As a result of major improvements in technology and pharmacology, the need for emergency cardiac surgery is now infrequent (0.3% to 0.6%) (2,3). Moreover, primary PCI has been accepted as superior to fibrinolytic therapy for ST-segment elevation myocardial infarction (STEMI) (4). These developments have provided the justification for some hospitals without cardiac surgery to develop PCI programs based on a strategy to provide more rapid care for STEMI (5,6) and to increase the availability of PCI to patients in geographically underserved areas.

Favorable outcomes for primary PCI performed in facilities without cardiac surgery backup on site have been reported (7–9). In addition, smaller observational studies have extended this concept to both primary and elective PCI (10–14), and even PCI limited to elective cases (15). However, there are few large studies that have directly compared the procedural outcomes of both primary and elective PCI at facilities without cardiac surgery on site with those that have traditional surgery on site (16–18). Because of the conflicting literature on this subject, the American College of Cardiology (ACC), American Heart Association (AHA), and Society for Cardiovascular Angiography and Interventions (SCAI) 2005 PCI guidelines continue to designate primary PCI a Class IIb indication (may be considered), and elective PCI a Class III indication (not recommended) when performed at facilities without surgical backup on site (19). The 2007 PCI guideline focused update did not address or change these designations (20). Despite

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these classifications, the number of PCI programs in the U.S. without surgery on site has increased significantly over the past several years (21). Recently, a SCAI expert panel outlined practical consensus principles for PCI performed at facilities without surgery on site, while not specifically encouraging or endorsing this practice (22).

The National Cardiovascular Data Registry (NCDR) was established by the ACC to proactively monitor and assess the clinical practice of cardiology in the U.S. (23). The NCDR CathPCI Registry, cosponsored by the ACC and SCAI, offers its participant institutions data field definitions, uniform data entry, secure transmission requirements, a data quality program, and risk-adjustment algorithms (24–26). Therefore, this registry provides an excellent resource of comparative data, in a relative contemporary clinical setting, to address the controversy over PCI at facilities without surgical backup on site.

Abbreviations and Acronyms

ACC = American College of Cardiology
AHA = American Heart Association
CABG = coronary artery bypass graft surgery
IABP = intra-aortic balloon pump
MI = myocardial infarction
NSTEMI = non–ST-segment myocardial infarction
PCI = percutaneous coronary intervention
SCAI = Society for Cardiovascular Angiography and Interventions
STEMI = ST-segment elevation myocardial infarction

Methods

Study population. Clinical characteristics and in-hospital outcomes were assessed in consecutive PCI cases reported to the NCDR CathPCI Registry from January 1, 2004, to March 30, 2006. Standardized NCDR version 3.04 definitions and data fields were used by all participating sites (27). The analysis cohort consisted of 308,161 patients from 465 PCI-capable facilities. Of these, 8,736 patients had PCI performed at 60 institutions in which it was verified there was no surgical backup on site within the buildings or campus that constituted the facility (off-site facility). The remaining 299,425 patients underwent PCI at 405 facilities that had cardiac surgery on site (on-site facility). Off-site PCI facilities comprised 13% of sites and 3% of patients in the NCDR CathPCI Registry during the study period.

Definitions. The primary outcomes for analysis were the incidence of emergency surgery and in-hospital death from all causes after PCI. Emergency surgery was defined as coronary artery bypass graft (CABG) surgery performed after PCI in which there was evidence of active ischemia or mechanical dysfunction (emergency), or if the patient required cardiopulmonary resuscitation en route to the operating room or before anesthesia (emergent/salvage). Secondary outcomes included procedure success, total complications (any general, bleeding, or vascular complications), and reperfusion time in cases of primary PCI for STEMI.

Off-site data clarification. During initial analysis, variations in 2 data fields unique to off-site PCI programs were noted. The field "CABG during this admission" permitted entry of only 1 category. In off-site centers, there was a disproportionately low incidence of "emergency" surgery, but a proportionately large number of patients "transferred for CABG" entered in this field. In addition, "transfer" patients could be counted as "alive" in the data field "discharge status" from an off-site center, but this opened the potential that a subsequent death after emergency surgery at the outside surgical center may not have been captured.

To resolve these issues, we conducted a data clarification project. Off-site centers with specific data points in question were queried to clarify whether a "transfer for CABG" data point was for elective or emergency surgery, and to verify the eventual survival at the off-site surgical center. This effort also provided an opportunity to gather additional information by a Capabilities Survey to reaffirm a true off-site status and to assess organization, staffing, and logistics. All of the off-site programs were invited to fill out the survey form, even those sites in which data clarification was not necessary.

Of the 8,736 patients undergoing PCI in off-site centers, 172 (2%) patients from 43 sites required data clarification regarding transfer surgery or mortality status. Of these 43 sites, 38 (88%) sites were able to clarify CABG status and/or mortality information for 154 of the 172 (90%) patients. For the 18 patients (0.2% of 8,736) whose transfer or mortality data were not clarified, if CABG status was uncertain, the original record entry was used for the CABG status-related analysis. If the subsequent mortality at the receiving surgery center could not be clarified, these patients were not included in the analysis of observed or risk-adjusted mortality.

Statistical analysis. Data analysis was performed by the Duke Clinical Research Institute. For descriptive analyses, institutional comparisons between off- and on-site PCI centers were made based on hospital characteristics. Comparisons between patients were made based on clinical characteristics, treatment profiles, procedural details, and clinical outcomes. These aggregates were further divided and analysis performed in patients who underwent primary PCI as first-line therapy for reperfusion in the presence of STEMI, and to the remainder of patients who underwent PCI in a nonprimary setting. Continuous variables are presented as mean with SD or as frequencies with percentages in each pre-specified category. Categorical variables are expressed as frequencies with percentages. To test for independence of patients' baseline characteristics, in-hospital care patterns and outcomes with respect to off-site versus on-site centers, the Wilcoxon rank-sum test was used for continuous variables, and the Pearson chi-square test was used for categorical variables.

A multivariable logistic regression model was then used to estimate the risk-adjusted association between on-site versus off-site PCI center surgical status and primary outcomes. Variables adjusted to mortality in-

cluded age, sex, insulin-treated diabetes mellitus, hypercholesterolemia, hypertension, dialysis, cerebrovascular disease, chronic lung disease, peripheral vascular disease, congestive heart failure, prior CABG, prior PCI, prior myocardial infarction (MI), cardiogenic shock at presentation, MI status (STEMI, non–ST-segment myocardial infarction [NSTEMI], and no MI), pre-operative intra-aortic balloon pump (IABP), PCI status (rescue, emergent, urgent, and elective), subacute thrombosis in a major artery, any treated lesion in left main artery, any treated lesion with pre-procedure stenosis 100%, any treated lesion with pre-procedure Thrombolysis In Myocardial Infarction (TIMI) flow grade 0, any treated lesion with high/C risk characteristics (see definition, bottom legend, Table 1), and total number of lesions treated. Variables adjusted to emergency CABG included cardiogenic shock, MI status (STEMI, NSTEMI, and no MI), pre-operative IABP, PCI status (rescue, emergent, urgent, and elective), and any treated left main artery lesion.

The Generalized Estimate Equation method (28) was applied to account for within-hospital clustering, considering patients at the same hospital are more likely to have similar responses relative to patients in other hospitals (i.e., within-center correlation for response). This method produces estimates comparable to those from ordinary logistic regression, but estimated variances are adjusted for the correlation of outcomes within each hospital.

Because not all off-site PCI center patient mortality data could be clarified, a sensitivity analysis was performed. This analysis utilized the same multivariable logistic regression model but imputed data to either of the following: patients with missing mortality data were considered either as all had died (worst scenario) or as all were alive (best scenario) on discharge.

Results

Institutional characteristics. Institutional characteristics are shown in Table 2. Compared with on-site centers, off-site PCI facilities had smaller bed capacity, were more likely to be located in nonurban areas, and had lower annual total PCI and primary PCI volume ($p < 0.001$). Overall, 43 (72%) of the off-site programs performed <200 total PCIs per year, and only 3 sites (5%) had >400 cases, suggesting that it was unlikely the outcomes were preferentially influenced by a few large-volume centers. The recommended volume standard of 36 or more primary PCIs per year (19) was achieved by 42% of the off-site programs compared with 80% of the on-site centers ($p < 0.001$).

Off-site capabilities survey. The survey (Table 3) was completed by 53 of the 60 off-site PCI facilities (88%). Approximately one-quarter of the centers had travel distances >40 miles and transit times (estimated driving or flight) >30 min. This information also reaffirmed that these were true off-site programs and did not have surgery back-up nearby in the next building. Full 24-h, 7-day coverage for PCI was provided by 92% of the sites. Both primary and elective PCI were performed in 79% of the centers, and none of the programs performed only elective PCI. Descriptive demographics regarding the organization of technical staff, interventional cardiologists, and transpor-

Table 1 Clinical Characteristics by PCI Status

	All PCI Patients			Primary PCI Patients			Nonprimary PCI Patients		
Characteristic	Off-Site (n = 8,736)	On-Site (n = 299,425)	p Value	Off-Site (n = 1,934)	On-Site (n = 31,099)	p Value	Off-Site (n = 6,802)	On-Site (n = 268,312)*	p Value
Age, yrs, mean ± SD	63.5 ± 12	64.1 ± 12	<0.001	61.2 ± 13	60.6 ± 13	0.194	64.2 ± 12	64.4 ± 12	0.062
Male	5,817 (67)	198,656 (66)	0.639	1,384 (72)	21,958 (71)	0.371	4,433 (65)	176,688 (66)	0.243
Previous MI >7 days	2,285 (26)	87,521 (29)	<0.001	327 (17)	5,440 (17)	0.509	1,958 (29)	82,077 (31)	0.001
Previous CHF	839 (9.6)	30,953 (10.3)	0.026	80 (4)	1,442 (5)	0.308	759 (11)	29,510 (11)	0.675
Diabetes	2,534 (29)	95,160 (32)	<0.001	361 (19)	6,514 (21)	0.016	2,173 (32)	88,642 (33)	0.058
Previous renal failure	367 (4)	15,868 (5)	<0.001	56 (3)	1,033 (3)	0.308	311 (4.6)	14,835 (5.5)	<0.001
Cerebrovascular disease	817 (9)	33,865 (11)	<0.001	105 (5)	2,165 (7)	0.010	712 (10)	31,700 (12)	<0.001
Peripheral vascular disease	895 (10)	35,519 (12)	<0.001	123 (6)	2,019 (6)	0.818	772 (11)	33,500 (12)	0.005
Hypertension	6,226 (71)	225,404 (75)	<0.001	1,069 (55)	18,275 (59)	0.002	5,157 (76)	207,120 (77)	0.007
Dyslipidemia	5,827 (67)	220,220 (74)	<0.001	974 (50)	17,432 (56)	<0.001	4,853 (71)	202,780 (76)	<0.001
Previous PCI	2,711 (31)	105,133 (35)	<0.001	321 (17)	5,254 (17)	0.735	2,390 (35)	99,875 (37)	<0.001
Previous CABG	1,068 (12)	56,815 (19)	<0.001	99 (5)	1,810 (6)	0.199	969 (14)	55,000 (21)	<0.001
Lesion characteristics									
≥2 lesions in laboratory visit	2,503 (29)	99,309 (33)	<0.001	478 (25)	8,463 (27)	0.048	2,025 (30)	90,843 (34)	<0.001
Segment in SVG	396 (5)	20,644 (7)	<0.001	55 (3)	989 (3)	0.657	341 (5)	19,675 (7)	<0.001
High-risk C lesion†	3,426 (39)	123,207 (41)	<0.001	1,106 (57)	18,933 (61)	0.001	2,320 (34)	104,270 (39)	<0.001

Data are n (%) unless otherwise indicated. *14 patients not included due to missing value for variable "Acute PCI." †High risk C lesion includes any of the following: diffuse (length >20 mm), excessive tortuosity of proximal segment, extremely angulated segments >90 degrees, total occlusions >3 months old and/or bridging collaterals, inability to protect major side branches, and degenerated vein grafts with friable lesions.

CABG = coronary artery bypass grafting; CHF = congestive heart failure; MI = myocardial infarction; PCI = percutaneous coronary intervention; SVG = saphenous vein graft.

tation modalities are further outlined in Table 3. Of note, 81% of the off-site programs reported that their interventional operators also rotated and performed PCI at on-site facilities.

Clinical characteristics. Clinical characteristics are shown in Table 1. In aggregate, on-site PCI centers generally treated patients with more risk factors and performed a greater percentage of PCI in multiple-lesion (33% vs. 29%, $p < 0.001$), saphenous vein graft (7% vs. 5%, $p < 0.001$), and higher lesion-risk cases (41% vs. 39%, $p = 0.001$). This difference was more pronounced in patients who underwent nonprimary PCI. In contrast, off-site facilities had a greater incidence of patients who had a clinical presentation of STEMI or NSTEMI (41% vs. 29%, $p < 0.001$) (Fig. 1).

Observed unadjusted procedural outcomes. Observed unadjusted procedural outcomes are shown in Table 4. Off-site facilities had slightly higher aggregate procedural success (94% vs. 93%, $p = 0.010$), predominantly due to higher success rates in nonprimary PCI cases. Aggregate total complications were similar in both off- and on-site facilities (6.5% vs. 6.3%), but off-site programs tended to have more bleeding events, and on-site more vascular complications. Off-site programs had fewer total complications in primary PCI (11.6% vs. 13.4%, $p = 0.029$) and had lower general (2.6% vs. 3.3%, $p = 0.001$) and vascular (0.8% vs. 1.1%, $p = 0.017$) complication rates in nonprimary PCI patients compared with on-site facilities.

In the overall PCI cohort, there was no significant difference in the incidence of emergency CABG surgery (0.3% vs. 0.4%, $p = 0.271$) or mortality with emergency CABG (13.6% vs. 12.8%, $p = 0.907$) between off- and on-site facilities, respectively. There was no difference in either of these variables when the analysis was stratified into primary PCI and nonprimary PCI patients. Although the unadjusted aggregate mortality rate was higher in off-site facilities (1.7% vs. 1.2%, $p < 0.001$) and appeared to be confined to patients who did not require emergency surgery, this difference did not persist when stratified by primary or nonprimary PCI. This increased unadjusted aggregate mortality was most likely due to a higher proportion of primary PCI patients (22% vs. 10%, $p < 0.001$) and STEMI and NSTEMI presentations (41% vs. 29%, $p < 0.001$) in off-site compared with on-site programs, respectively.

Primary PCI reperfusion times in nontransferred patients were significantly shorter in off-site PCI centers (mean 2.1 ± 5.1 h, median 1.4 h) compared with on-site (mean 2.6 ± 8.4 h, median 1.5 h, $p < 0.001$). These "reperfusion times" were defined as the time of arrival at the facility to the time of first treatment device deployment (27). Although both groups followed the same definition, these data were collected before there were major national quality

Table 2 Institutional Characteristics

Variable	Off-Site (n = 60)	On-Site (n = 405)	p Value
Number of CMS-certified beds			
Median	198	371	<0.001
Mean ± SD	212 ± 109	403 ± 188	
<200	31 (52%)	40 (10%)	<0.001
≥200 and <400	27 (45%)	178 (44%)	
≥400	2 (3%)	185 (46%)	
Location/community type			
Rural	21 (35%)	67 (17%)	<0.001
Suburban	24 (40%)	115 (28%)	
Urban	15 (25%)	223 (55%)	
Average annual PCI volume			
Median	134	612	<0.001
Mean ± SD	166 ± 138	745 ± 551	
<200	43 (72%)	23 (6%)	<0.001
≥200 and <400	14 (23%)	98 (24%)	
≥400	3 (5%)	284 (70%)	
Average annual primary PCI volume			
Median	32	66	<0.001
Mean ± SD	35 ± 22	78 ± 52	
≥36	25 (42%)	324 (80%)	<0.001

Two sites had missing Centers for Medicare and Medicaid Services (CMS) bed data. Primary percutaneous coronary intervention (PCI) indicates PCI performed as first-line therapy for reperfusion in the presence of ST-segment elevation myocardial infarction (STEMI), and does not include rescue or facilitated PCI or PCI for non-STEMI.

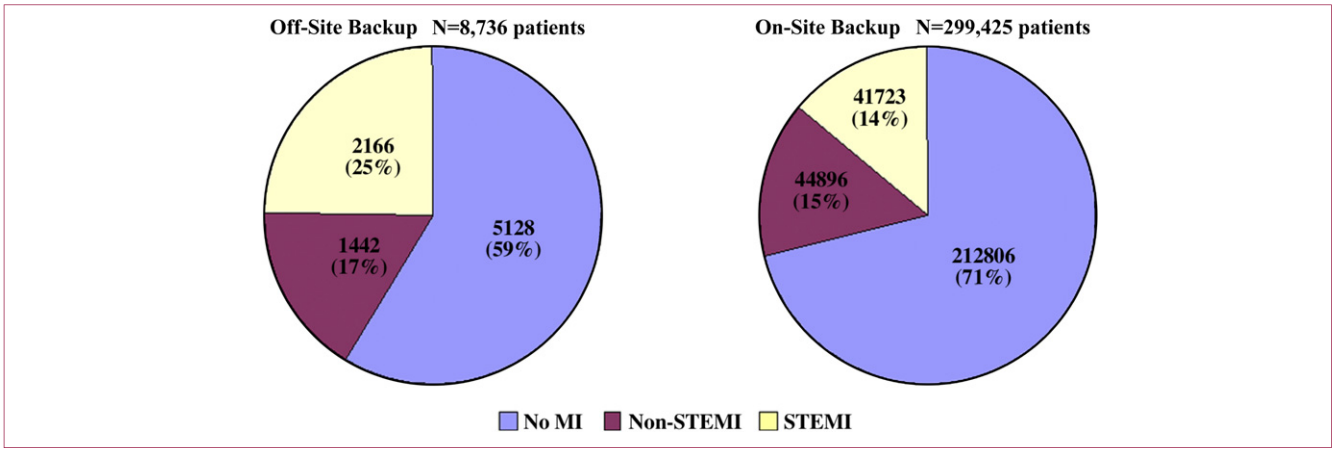
Table 3 Off-Site Capabilities Survey

Characteristic	Off-Site (n = 53)
Average travel distance to surgical facility, miles	
Mean ± SD	36 ± 59
<10	11 (21%)
≥10 and <20	18 (34%)
≥20 and <40	11 (21%)
≥40	13 (25%)
Average transit time to surgical facility, min	
Mean ± SD	25 ± 17
<10	4 (8%)
≥10 and <20	16 (30%)
≥20 and <30	19 (36%)
≥30	14 (26%)
Predominant transportation mechanism	
Ground ambulance	28 (53%)
Helicopter	11 (21%)
Fixed wing aircraft	1 (2%)
Combination of ground or air	13 (25%)
Dedicated staff and facilities for PCI	
24 h, 7 days a week	49 (92%)
Daytime during weekdays only	3 (6%)
Variable time frames	1 (2%)
Type of PCI provided	
Only primary PCI for acute MI	11 (21%)
Both primary PCI and elective PCI	42 (79%)
Only elective PCI	0 (0%)
Catheterization laboratory staff experience*	
Work only at off-site PCI center	41 (77%)
Rotate between off- and on-site PCI centers	11 (21%)
Interventional operators at facility	
Mean ± SD	5 ± 4
1	5 (9%)
2 to 3	18 (34%)
4 to 5	11 (21%)
6 or more	19 (36%)
Interventional operators' experience*	
Work only at off-site PCI center	9 (17%)
Rotate between off- and on-site PCI centers	43 (81%)

*One site did not respond.
Abbreviations as in Table 1.

Figure 1 MI Presentation Status

Pie charts showing the relative distribution of myocardial infarction (MI) presentation within centers with on- or off-site surgical backup. **Blue areas** indicate no MI; **purple areas** indicate non–ST-segment elevation myocardial infarction (non-STEMI); **yellow areas** indicate STEMI. $p < 0.001$.



improvement initiatives and attention to the detailed measurements of true "door-to-balloon" times. Therefore, these times do not reflect the current door-to-balloon standards.

Risk-adjusted outcomes. After risk adjustment, there were no mortality differences between off- and on-site facilities among total PCI patients, primary PCI patients, nonprimary PCI patients, or patients who did not require emergency surgery (Fig. 2). There was a higher risk-adjusted odds of emergency surgery in on-site PCI centers (odds ratio: 0.60 [95% confidence interval: 0.37 to 0.98], $p = 0.042$).

A sensitivity analysis was performed comprising models that imputed missing mortality from off-site centers to 2 potential scenarios. Although the point estimate changed from 0.88 to 1.21, the confidence intervals surrounding these estimates were not statistically significant between off- and on-site facilities under either of these extreme assumptions.

Discussion

This study represents the largest and most comprehensive clinical comparison of PCI centers in the U.S. with and without cardiac surgery support on site. Despite lower annual PCI procedural volumes and more patients presenting with MI subsets, off-site PCI facilities reporting to the NCDR CathPCI Registry had similar rates of procedural success, morbidity, emergency surgery, and risk-adjusted mortality when compared with on-site PCI centers. These results persisted whether PCI was performed as primary therapy for STEMI or in a less urgent nonprimary PCI setting. In addition, the off-site Capabilities Survey in this study provided more descriptive information than has been previously reported in the literature regarding the organization and logistics of established off-site PCI programs.

It is important to contrast this study with the few large comparative reports in the literature. Wennberg et al. (16) found no difference in risk-adjusted mortality for primary PCI at facilities without surgery backup on site, but an increase in mortality for nonprimary/rescue PCI, particularly at very low-volume programs (<50 Medicare PCIs per year). Although their study had more hospitals without surgery on site (n = 178) and similar patient volumes (n = 8,168), the time period was from 1999 to 2001, and the data were derived from coded admission/discharge billing diagnoses confined to the Medicare population. In contrast, our study was based on well-defined contemporary clinical parameters and included clarification of ambiguous transfer data from the off-site PCI programs. We found no significant difference for risk-adjusted mortality between centers with and without surgery on site, in either primary or nonprimary PCI patients.

Ting et al. (17) previously reported comparable acute and long-term outcomes for both primary and elective PCI in a propensity score analysis of 1,007 cases from a PCI center without surgery on site matched to the same number of patients from a center with surgery on site. Of note, these Mayo Clinic facilities did not participate in the NCDR, and thus their patients were not included in our analysis.

Finally, in a recent report based on SCAAR (Swedish Coronary Angiography and Angioplasty Registry), Carlsson et al. (18) compared 8,838 PCI procedures from 14 PCI facilities that did not have cardiac surgery on site to 25,525 procedures from 10 PCI centers that did have surgery on site. Their analysis was adjusted for baseline variables, and demonstrated comparable 30-day and 1-year mortality and morbidity outcomes for both primary PCI and nonacute PCI. Although different variables were used in our risk-

Table 4 Observed Unadjusted Procedural Outcomes

Outcome	All PCI Patients			Primary PCI Patients			Nonprimary PCI Patients		
	Off-Site (n = 8,736)	On-Site (n = 299,425)	p Value	Off-Site (n = 1,934)	On-Site (n = 31,099)	p Value	Off-Site (n = 6,802)	On-Site (n = 268,312)*	p Value
PCI procedure success	8,194 (94)	278,844 (93)	0.010	1,756 (92)	27,909 (91)	0.139	6,438 (95)	250,923 (94)	<0.001
Total complications	567 (6.5)	18,796 (6.3)	0.399	222 (11.6)	4,104 (13.4)	0.029	345 (5.1)	14,692 (5.5)	0.150
General complications	320 (3.7)	11,629 (3.9)	0.304	144 (7.5)	2,792 (9.1)	0.021	176 (2.6)	8,837 (3.3)	0.001
Bleeding complications	261 (3.0)	7,036 (2.4)	<0.001	104 (5.4)	1,620 (5.3)	0.749	157 (2.3)	5,416 (2.0)	0.093
Vascular complications	66 (0.8)	3,198 (1.1)	0.005	14 (0.7)	344 (1.1)	0.115	52 (0.8)	2,854 (1.1)	0.017
Overall mortality	151 (1.7)	3,632 (1.2)	<0.001	97 (5.1)	1,607 (5.2)	0.869	54 (0.8)	2,025 (0.8)	0.700
Emergency CABG	26 (0.3)	1,110 (0.4)	0.271	14 (0.7)	357 (1.2)	0.091	12 (0.2)	753 (0.3)	0.107
Mortality									
Emergency CABG	3/22† (13.6)	142/1,110† (12.8)	0.907	2/12† (16.7)	59/357† (16.5)	0.990	1/10† (10.0)	83/753† (11.0)	0.918
No emergency CABG	148/8,669† (1.7)	3,488/298,293† (1.2)	<0.001	95/1,894† (5.0)	1,547/30,741† (5.0)	0.975	53/6,775† (0.8)	1,941/267,538† (0.7)	0.587
Reperfusion times (h), nontransfer patients				(n = 1,678)	(n = 19,708)				
Mean ± SD				2.1 ± 5.1	2.6 ± 8.4	<0.001			
Median				1.4	1.5				

Procedure success was defined as residual stenosis <50% with Thrombolysis In Myocardial Infarction flow grade 3 and minimal decrease in stenosis ≤20% in all lesions attempted. Total complications was defined as any of the following complications: general complications: periprocedural MI, cardiogenic shock, congestive heart failure, cerebrovascular accident, tamponade, thrombocytopenia, contrast reaction, renal failure; bleeding complications: bleeding at the access site, retroperitoneal, gastrointestinal, genitourinary, or other; vascular complications: access site occlusion, peripheral embolization, arterial dissection, arterial pseudoaneurysm, or arterio-venous fistula. Primary PCI was defined as PCI performed as first-line therapy for reperfusion in the presence of STEMI; does not include rescue or facilitated PCI or PCI for non-STEMI. Reperfusion time indicates time of arrival to facility to time of first intracoronary treatment device deployment. *14 patients not included due to missing value for variable "Acute PCI." †Clarified data.

Abbreviations as in Tables 1 and 2.

adjusted model, the in-hospital mortality/morbidity results are similar to these 2 studies.

The nonprimary PCI patient cohort in our study is not a reflection of purely elective PCI, as this group includes some patients who presented with acute coronary syndromes, NSTEMI, or after STEMI. However, the consideration of this group as "nonurgent" and a reasonable surrogate for elective PCI is consistent with the analyses done in the literature cited in the preceding text. In our study, the differentiation of patients in off-site versus on-site PCI centers into primary PCI and nonprimary PCI permitted a more comprehensive assessment and risk-adjustment analysis of the major clinical end points.

Within our study cohort, the aggregate incidence of emergency surgery was comparably low at off- and on-site PCI facilities (0.3% to 0.4%, respectively) and consistent with contemporary studies (2,3). When emergency surgery was necessary, the mortality rate was similarly high between off- (13.6%) and on-site (12.8%) facilities, and comparable to that reported in prior literature (2,3).

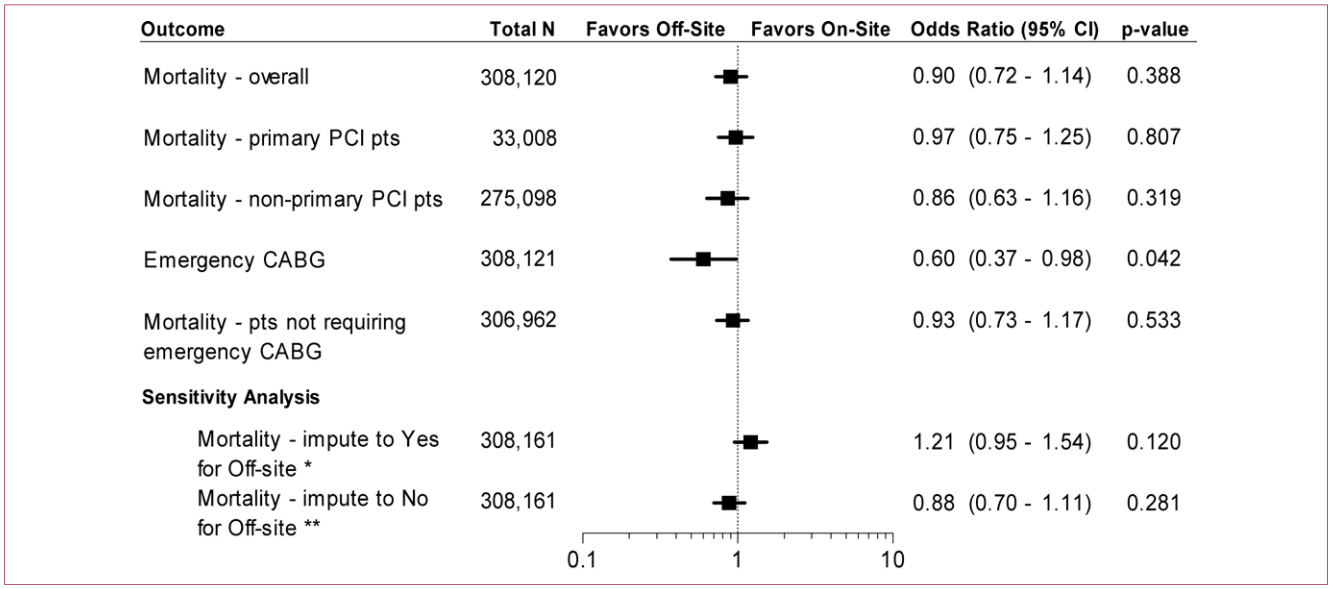
There have been concerns that off-site PCI facilities may tend to keep some borderline stable patients with suboptimal procedural results rather than initiate the logistics of emergency transfer to an outside surgical center. These patients may have adverse outcomes, as seems to be suggested by the aggregate unadjusted mortality rate in our study. However, in the risk-adjusted analyses, there was comparable in-hospital mortality for those off-site patients who were not transferred for emergency surgery.

Conversely, the 1.5-fold higher risk-adjusted incidence of emergency surgery at on-site PCI centers could reflect a lower threshold to opt for emergency surgery if there is any doubt about a suboptimal result, as surgery is available without the added logistics of transfer. An alternative explanation could be that on-site centers perform higher risk elective cases, as is suggested by the clinical and lesion characteristics profiles in this study. In addition, it is possible that patients may have had initial angiography at off-site facilities, found to have complex coronary anatomy and/or high-risk MI subsets with a higher predisposition to emergency surgery, then deferred and transferred to an on-site center for PCI. These complicated potential scenarios and the detailed reasons for case selection were beyond the scope of the NCDR database elements. Regardless, the increased risk-adjusted incidence of emergency surgery at on-site PCI programs did not translate into an increase in mortality.

Data from the Capabilities Survey revealed a mean transit time of 25 ± 17 min from off-site facilities. The British Cardiovascular Interventional Society has recommended a 90 min to emergency surgery standard (29).

Figure 2 Risk-Adjusted Analysis of Outcomes

Odds ratio plot of risk-adjusted outcomes, including sensitivity analysis for missing mortality data. Odds ratio: outcomes for patients at off-site (vs. on-site) facilities, adjusting for within site correlations and potential confounding variables. *Worst case scenario: all patients with missing mortality data were considered to have died. **Best case scenario: all patients with missing mortality data were considered as alive. CABG = coronary artery bypass graft surgery; CI = confidence interval; PCI = percutaneous coronary intervention; pts = patients.



This includes not only the transit time, but also the total time from the initial decision to transport (including call time, transfer of patient from catheterization laboratory to vehicle, vehicle to operating suite), to the actual time of initiating cardiopulmonary bypass at the receiving surgical center. The transit time in the NCDR survey was an estimate of basic travel time and did not include the above additional time elements. However, based on the transit time, most off-site PCI programs in our study may be able to meet this global standard of 90 min by having a clear decision process and heightened logistical coordination with ambulance services and the receiving surgical center.

The demographics of the off-site centers in our study suggests these facilities conform to the stated goals of lowering geographic barriers and facilitating access to PCI, particularly for those patients presenting with STEMI (5,6). The Capabilities Survey also indicates these programs are well staffed and organized with good logistical plans. The fact that 81% of the off-site center operators rotated to an on-site PCI center suggests that most of the off-site facilities were hub-and-spoke centers staffed by large group practices. Overall, the information suggests that the off-site PCI programs in this study have demonstrated a strong commitment to the classic Donabedian triad of structure, process, and outcomes measurements (30).

Study limitations. First, this study is subject to the usual concerns regarding observational registry data. There may be an inherent bias in off-site PCI programs that are either mandated by regulatory agencies or choose on their own to participate in the NCDR. Participants in any registry may be prone to "game" the system, particularly if score carding and public disclosure is an issue.

Second, this study includes outcomes up to the time of hospital discharge. Data regarding long-term outcomes are not currently captured in the NCDR CathPCI Registry. In addition, outcomes are assessed and analyzed on an institutional level, not on an individual operator level.

Third, specific in-depth details regarding clinical presentation, case selection, procedural complications, morbidity, and mortality were sometimes beyond the purview of the basic datasets. However, a special data clarification effort was utilized to resolve the 172 of 8,736 off-site patients (2%) for whom mortality or transfer data were questioned, resulting in clarification of 154 of these patients (90%), leaving 18 of 8,736 (0.2%) not clarified. A sensitivity analysis confirmed that the unclarified data would not have affected the risk-adjusted mortality analysis results.

Fourth, although this NCDR study indicates that nonprimary PCI can be done safely at off-site facilities, the efficacy of truly elective PCI at off-site facilities can perhaps be best addressed by a large randomized prospective trial such as the C-PORT (Cardiovascular Patient Outcome Research Team) Elective Angioplasty Study, which is under way. However, such studies are difficult to conduct, and results may not be forthcoming for some time. In the interim, a comprehensive large database such as the NCDR CathPCI Registry offers a realistic and

relative contemporary quality assurance standard to monitor these issues. Based on the experiences gained with this current study, the NCDR plans to sponsor a proactive comprehensive working group of off-site PCI centers to further communicate and track outcomes. This effort will coincide with the upcoming transition to the next CathPCI database version 4.0.

Finally, a participation bias cannot be excluded. The total number of PCI centers in the U.S. that do not have surgery on site is not definitively known (22) but may number ≈250. Of these, it is estimated that one-third submit data to another peer-reviewed registry, a spoke and hub partner database, or a multicenter trial. Thus, the 60 off-site PCI facilities in this NCDR study may represent a minority of such programs in the nation and are probably in the upper tier of quality. With this perspective, the results reported here may not be applicable to all PCI centers without surgical backup on site, particularly those that do not participate in any formal data registry or clinical trial.

Conclusions

Compared with on-site PCI centers, off-site PCI programs in the NCDR were predominantly located in nonurban areas, had lower annual PCI volume, treated a higher percentage of patients who presented with subsets of MI, and had better reperfusion times in primary PCI. Off-site PCI centers had similar observed procedure success, morbidity, emergency cardiac surgery rates, and mortality in cases that required emergency surgery. The risk-adjusted mortality rates in off-site PCI facilities were comparable to those of PCI centers that had cardiac surgery on site, regardless of whether PCI was performed as primary therapy for STEMI or in a nonprimary setting.

These findings should not be extrapolated to encourage the widespread proliferation of more PCI programs without surgery on site to fulfill a political or an economic agenda. Rather, our study does confirm the safety of an off-site strategy at PCI centers where rigorous clinical, operator, and institutional criteria are in place and where data are submitted and reviewed in a comprehensive multicenter registry such as the NCDR.

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Key Words: percutaneous coronary intervention ■ cardiac surgery ■ outcomes analysis.

APPENDIX

For supplemental NCDR information, please see the online version of this article.