Outcomes of a System-Wide Protocol for Elective and Nonelective Coronary Angioplasty at Sites Without On-site Surgery: The Mayo Clinic Experience

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OBJECTIVE: To compare outcomes of percutaneous coronary interventions (PCIs) at 2 community hospitals without on-site surgery (Franciscan Skemp Healthcare and Immanuel St. Joseph's Hospital) with a center with on-site surgery (Saint Marys Hospital).

PATIENTS AND METHODS: Using a matched case-control design, we studied 1842 elective and 667 nonelective PCI procedures (myocardial infarction [MI]/cardiogenic shock) performed from January 1, 1999, through December 31, 2007. The quality assurance protocol included operator volume and training, application of a risk-adjustment model, transport protocol, and database participation. We compared in-hospital mortality and/or emergent coronary artery bypass surgery after PCI at Franciscan Skemp Healthcare and Immanuel St. Joseph's Hospital, which do not have on-site surgery, with Saint Marys Hospital, a medical center with the capability to perform coronary artery bypass grafting on site.

RESULTS: Of 22 baseline variables, significant imbalances between matched groups were present in only 3 (hyperlipidemia, history of MI, American College of Cardiology/American Heart Association B2/C type lesion) in the elective group and 2 (Canadian Cardiovascular Society class III/IV angina, multivessel disease) in the nonelective group. The primary end point occurred in 0.3%, 0.1%, and 0.6% of patients undergoing elective PCI ($P=.07$) and 3.3%, 3.3%, and 3.7% of patients undergoing nonelective PCI ($P=.65$) at Immanuel St. Joseph's Hospital, Franciscan Skemp Healthcare, and Saint Marys Hospital, respectively. The in-hospital mortality rate at Immanuel St. Joseph's Hospital and Franciscan Skemp Healthcare was comparable to that at Saint Marys Hospital for both elective (0.3%, 0.1%, 0.4%; $P=.24$) and nonelective PCI (2.6%, 2.4%, 3.1%; $P=.49$). No patient undergoing elective PCI required transfer for emergency cardiac surgery. Of the 21 transfers, 20 (95%) were in the setting of MI and cardiogenic shock or left main/3-vessel disease; 18 patients (86%) survived to discharge.

CONCLUSION: Optimal outcomes with PCI have been observed at community hospitals without on-site cardiac surgical programs with application of a prospective, standardized quality assurance protocol.

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ACC = American College of Cardiology; AHA = American Heart Association; CABG = coronary artery bypass grafting; CI = confidence interval; MACE = major adverse cardiovascular event; MCRS = Mayo Clinic risk score; MHS = Mayo Health System; MI = myocardial infarction; OR = odds ratio; PCI = percutaneous coronary intervention

Advances in percutaneous coronary interventions (PCIs) have led to significant improvements in procedural success and notable reductions in the rates of emergency coronary artery bypass grafting (CABG).¹⁻⁴ These improvements have allowed the expansion of indications to higher-risk patients and the performance of PCIs at centers without on-site cardiac surgical programs.^{5,6}

Several hospitals without on-site cardiac surgical programs have reported their results with PCI.⁷⁻¹¹ Despite satisfactory PCI outcomes at selected centers without surgical backup, concerns remain regarding the implementation of a program that ensures safety, efficacy, and outcomes comparable to those obtained at centers with on-site surgical programs. First, most data are limited to small, single-center observational registries, and data from more than 1 center are urgently needed to demonstrate wider generalizability. Second, some prior studies using administrative data showed worse outcomes for patients undergoing elective PCI without on-site surgery, especially at centers with low annual angioplasty volumes.⁹ Outcomes analyses from centers with comprehensive data collection and risk-adjustment tools will likely overcome the limitations inherent in administrative datasets. Third, the mortality rate after emergent CABG due to failed PCI continues to be high despite a dramatic decrease in the incidence.^{4,12} Few data are available regarding the indications and outcomes of patients requiring transfer to a surgical institution after PCI. Fourth, the lack of a protocol that provides the necessary framework to ensure procedural safety and effectiveness poses an important barrier.

Previously, we reported the programmatic requirements and initial results of PCI at Immanuel St. Joseph's Hospital, which does not have an on-site surgical program; we found that outcomes were comparable to those at a center with an on-site surgical program.^{7,8,13} The current article reports the in-hospital outcomes of PCI programs at 2 community hospitals without on-site surgery and with similar models of care and compares them with those of a large-volume, tertiary center with on-site surgical capability.

PATIENTS AND METHODS

MAYO CLINIC REGIONAL PCI PROGRAM

Outcome data from March 1999 to August 2005 for the PCI program at Immanuel St. Joseph's Hospital, a 150-bed com-

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FIGURE 1. Hub-and-spoke quality assurance model that focuses on operator volume, training, and accreditation; predefined processes and structures of care for protocols, including transport; use of risk-adjustment tool for case selection, outcomes, and benchmarking of operator performance; and use of database for analyses. CABG = coronary artery bypass grafting; PCI = percutaneous coronary intervention.

community hospital in Mankato, MN, that is part of the Mayo Health System (MHS), have been reported previously.¹³ The current report updates results for Immanuel St. Joseph's Hospital through December 2007 and also reports outcomes at Franciscan Skemp Healthcare, a 160-bed MHS hospital in La Crosse, WI, from January 1, 1999, to December 31, 2007. Both community hospitals serve a population of approximately 300,000 and have a fully equipped cardiac catheterization laboratory. Both lack an on-site cardiac surgical program and are 85 miles (Immanuel St. Joseph's Hospital) and 65 miles (Franciscan Skemp Healthcare) from Saint Marys Hospital, which offers on-site cardiac surgery. Approval for the current study was obtained from the Mayo Clinic Institutional Review Board.

The PCI program at Franciscan Skemp Healthcare is modeled on the program at Immanuel St. Joseph's Hospital and, like it, was started in 1999. Program details have been discussed previously.^{7,13} Informed consent includes a discussion with the patient about the absence of on-site sur-

gery. An option of transfer to a facility with on-site cardiac surgery is provided to every patient.

EVOLUTION OF PCI PROGRAM AT FRANCISCAN SKEMP HEALTHCARE

The development of the PCI program at Franciscan Skemp Healthcare has paralleled that at Immanuel St. Joseph's Hospital.¹³ Since 2005, we have used store-and-forward technology for telemedicine and have added the Mayo Clinic risk score (MCRS) adjustment model to determine eligibility for PCI. Patients with an MCRS greater than 10 were ineligible for elective PCI at Immanuel St. Joseph's Hospital and Franciscan Skemp Healthcare.¹⁴

HUB-AND-SPOKE QUALITY ASSURANCE MODEL

Since 2005, the "hub-and-spoke" model has allowed PCI to be performed on the basis of predefined structures and processes of care at Immanuel St. Joseph's Hospital, Franciscan Skemp Healthcare, and Saint Marys Hospital (Figure 1, Table 1). All operators performing PCI at Franciscan Skemp

TABLE 1. **Hub-and-Spoke Model^a**

Participation in database and collaborative care	Mandatory participation in prospective data repository Presence of store-and-forward telemedicine technology for consultation with colleagues at center with on-site surgery
Operators	Accredited training in coronary interventions Maintenance of minimum PCI volumes as per the ACC/AHA guidelines Annual performance review Periodic rotation through high-volume centers to perform higher-risk cases
Use of risk-adjustment tool	Outcomes after PCI Case selection Benchmarking of operator performance
Processes and structures of care	Similar pre- and post-PCI protocols between tertiary and community hospitals Similar staffing responsibilities and integrated hospital organization Provision of training, education, and accreditation of physicians and allied health staff Expedition transport availability

^a ACC = American College of Cardiology; AHA = American Heart Association; PCI = percutaneous coronary intervention.

Healthcare received formal interventional training in accredited programs and have maintained volumes compliant with the current American College of Cardiology (ACC)/American Heart Association (AHA) guidelines.¹⁵ All interventional consultants working at the MHS rotate through Saint Marys Hospital to gain experience with more complex PCIs. Staff members at both Franciscan Skemp Healthcare and Saint Marys Hospital follow the same protocols for periprocedural and postprocedural patient care. As a requirement of the program, data on all PCI procedures are prospectively entered in the Mayo PCI Registry, a databank maintained since 1979. Annual review of the hospitals and individual operators includes assessment of and feedback regarding the risk-adjusted outcomes using the MCRS. Access to emergency cardiac surgery was ensured with a tested transport protocol. Elective PCI was postponed or canceled if transport was unavailable because of weather or other problems.

OUTCOMES OF INTEREST

The primary end point was in-hospital mortality and/or need for emergent CABG. Another outcome of interest was major adverse cardiovascular events (MACEs), defined as 1 or more of the following: (1) in-hospital death, (2) Q-wave myocardial infarction (MI), (3) urgent or emergent CABG during the index hospitalization, or (4) stroke.

DEFINITIONS USED

Nonelective PCI was defined as PCI performed either for patients with acute MI within 24 hours or for patients presenting with cardiogenic shock. Myocardial infarction was

diagnosed if 2 of the following 3 criteria were present: (1) typical chest pain for 20 or more minutes, (2) a creatine kinase (or the MB fraction) level less than 2 times normal, and (3) a new Q wave on electrocardiography. In-hospital deaths included all deaths during the index hospital admission. All MACEs occurring in patients originating at Immanuel St. Joseph's Hospital or Franciscan Skemp Healthcare were attributed to Immanuel St. Joseph's Hospital/ Franciscan Skemp Healthcare in the event of transfer to Saint Marys Hospital to prevent double counting and misclassification. Procedural success was defined as a decrease in residual luminal diameter stenosis to 20% or less without in-hospital death, Q-wave MI, or emergent CABG (<24 hours). The records of all patients transferred to Saint Marys Hospital were individually reviewed, and the reasons for transfer and outcomes were noted.

STATISTICAL ANALYSES

Continuous variables are reported as mean $\pm$ SD and categorical variables as percentages. Because of the observational study design, a matched case-control approach was used to minimize confounding. Each PCI at Immanuel St. Joseph's Hospital and Franciscan Skemp Healthcare was matched one-to-one with a Saint Marys Hospital procedure. Matching was accomplished separately for nonelective and elective PCI and within Immanuel St. Joseph's Hospital and Franciscan Skemp Healthcare sites. To facilitate matching across many characteristics, a propensity score was constructed based on 31 variables. A logistic regression model predicting case/control probability was fit to patient characteristics, such as age, sex, body mass index, cardiovascular history (eg, diabetes, hypertension, chronic heart failure, smoking), comorbidities (eg, renal disease, chronic obstructive pulmonary disease, metastatic cancer), urgency of procedure (eg, MI within 24 hours, preprocedural shock), and angiographic characteristics (number of diseased vessels, presence of thrombus, worst ACC/AHA lesion type). The linear predictor (log-odds) from the logistic regression model was used as the propensity score.¹⁶ The matching criteria included age (within 5 years), date of procedure (within 1 year), the propensity score, and nonelective PCI. This matching process was conducted using a computer algorithm designed to minimize the total (weighted) "distance" between groups in the matching variables sets. Distance is calculated by a weighted sum of the absolute differences in the matching variables between a case and control. Hence, if all matching variables are exactly the same, the distance is zero. After a matching attempt, only the clinical and angiographic characteristics of the groups were compared; if these were thought to be too imbalanced, other variables were added to the matching criteria (and thus to the formula for calculating distances between a case and

TABLE 2. Patient Exclusions by Study Site^a

	SMH	FSH	ISJ
Total No. of PCIs during study period	14,903	1330	1695
No. of PCIs excluded because patients refused research authorization	-414	-0	-94
Remaining	14,489	1330	1601
No. of PCIs excluded because patients had multiple PCIs per hospitalization	-294	-6	-23
Remaining	14,195	1324	1578
No. of patients seen at MHS sites	-248	NA	NA
No. of patients available as controls	13,947		
Elective PCIs	10,425	951	1053
With matched control		887	955
Without matched control		64	98
Nonelective PCIs	3522	373	525
With matched control		246	421
Without matched control		127	104

^a FSH = Franciscan Skemp Healthcare; ISJ = Immanuel St. Joseph's Hospital; MHS = Mayo Health System; NA = not applicable; PCI = percutaneous coronary intervention; SMH = Saint Marys Hospital.

control), or variable weights in the distance calculation were modified until satisfactory matches were attained. At most, 5 variables were added to the matching criteria to produce acceptable matches. Conditional logistic regression was used to compare patient characteristics and outcomes, thus accounting for the matched structure of the data. As a secondary analysis, multiple logistic regression was used to assess the risk differences at Saint Marys Hospital vs Immanuel St. Joseph's Hospital and Franciscan Skemp Healthcare so that all patients could be analyzed. The models contained the new MCRS (for either death or MACE, as appropriate),¹⁷ an indicator for nonelective PCI, and separate indicators for MHS in elective PCI and nonelective PCI. All statistical tests were 2-sided, and *P* values <.05 were considered significant. We used SAS version 9.1 (SAS Institute, Cary, NC) for all analyses.

RESULTS

At Saint Marys Hospital, Franciscan Skemp Healthcare, and Immanuel St. Joseph's Hospital, 14,903, 1330, and 1695 PCIs were performed, respectively. The mean annual PCI case volume was 164 PCIs for Franciscan Skemp Healthcare and 193 for Immanuel St. Joseph's Hospital. The median yearly volume for individual operators at these sites was 122 PCIs (minimum-maximum, 85-167 PCIs). Exclusions are listed in Table 2. A total of 1842 elective PCIs (887 at Franciscan Skemp Healthcare, 955 at Immanuel St. Joseph's Hospital) and 667 nonelective PCIs (246 at Franciscan Skemp Healthcare, 421 at Immanuel St. Joseph's Hospital) were available for comparison with Saint Marys Hospital controls.

The 3 groups were matched for both clinical and angiographic variables and for patients undergoing elective

and nonelective PCIs (Table 3). By protocol, the 3 cohorts (Immanuel St. Joseph's Hospital and Franciscan Skemp Healthcare vs Saint Marys Hospital) were similar in terms of most baseline characteristics.

Higher prevalence of prior MI, multivessel disease, and stent use was noted among patients treated at the Immanuel St. Joseph's Hospital and Franciscan Skemp Healthcare sites. The use of glycoprotein IIb/IIIa inhibitors was significantly higher in patients undergoing elective PCI at Immanuel St. Joseph's Hospital and Franciscan Skemp Healthcare but lower in patients undergoing nonelective PCI at those sites; however, the latter difference did not reach statistical significance.

IN-HOSPITAL OUTCOMES FOR ELECTIVE PCI

The primary end point of in-hospital mortality and/or emergent CABG was 0.3%, 0.1%, and 0.6% at Immanuel St. Joseph's Hospital, Franciscan Skemp Healthcare, and Saint Marys Hospital, respectively (*P*=.07) (Table 4). Procedural success was higher at Immanuel St. Joseph's Hospital and Franciscan Skemp Healthcare than at Saint Marys Hospital. No patient at the Immanuel St. Joseph's Hospital and Franciscan Skemp Healthcare sites required transfer for emergent cardiac surgery. Rates of MACEs were similar for patients undergoing PCIs across the 3 sites. Among the 162 elective PCIs at the MHS for whom no control could be obtained, no in-hospital deaths occurred and no emergent CABG was needed; 1 patient (0.6%) had Q-wave MI. Thus, exclusion of unmatched PCIs did not bias the analysis.

NONELECTIVE PCI

The primary end point was observed in 3.3%, 3.3%, and 3.7% of patients undergoing PCIs at the Immanuel St. Joseph's Hospital, Franciscan Skemp Healthcare, and Saint Marys Hospital, respectively (*P*=.65) (Table 4). Procedural success for nonelective PCIs at Immanuel St. Joseph's Hospital and Franciscan Skemp Healthcare was similar to that at Saint Marys Hospital (93.3% and 92.3% vs 90.9%; *P*=.16), and in-hospital mortality was low (2.6% and 2.4% vs 3.1%; *P*=.49). The MACE rates in patients undergoing PCIs were similar at Immanuel St. Joseph's Hospital, Franciscan Skemp Healthcare, and Saint Marys Hospital sites (5.2% and 5.7% vs 4.2%; *P*=.30). Among the 231 nonelective PCIs at MHS sites that did not have a suitable control, 10 patients (4.3%) died in-hospital, but none required emergent CABG.

LOGISTIC REGRESSION ANALYSIS

Logistic regression was used in analyzing data from all patients, including those excluded from the matching process. The MCRS and nonelective PCI were used to adjust for baseline risk differences.¹⁷ For the outcome of death or

TABLE 3. Comparison of Clinical and Angiographic Characteristics for 2 Community Hospitals (ISJ and FSH) and a Tertiary Hospital With On-site Surgery (SMH)^{a,b}

Characteristic	Elective PCI					Nonelective PCI				
	ISJ (N=955)	FSH (N=887)	ISJ & FSH (N=1842)	SMH (N=1842)	P value ^c	ISJ (N=421)	FSH (N=246)	ISJ & FSH (N=667)	SMH (N=667)	P value ^c
Demographics										
Age (y)	65±12	64±12	65±12	65±12	.69	64±13	62±13	63±13	63±13	.60
Male sex	68	66	67	68	.48	73	69	71	69	.43
Comorbid conditions										
Diabetes mellitus	25	29	27	29	.14	18	24	20	21	.45
Hypertension	71	75	73	75	.26	57	68	61	63	.42
Hyperlipidemia (total cholesterol ≥240 mg/dL) ^d	82	71	76	79	.04	61	61	61	64	.35
Current smoker	21	24	22	20	.06	33	37	35	34	.67
Peripheral vascular disease	12	9	11	11	.73	9	8	9	8	.57
CVA/TIA	9	5	7	7	>.99	8	9	8	7	.85
Moderate/severe renal disease	3	4	3	4	.29	1	3	2	1	.36
MCRS for MACE ^e	2.4±2.3	2.3±2.3	2.3±2.3	2.4±2.3	.40	4.7±3.4	4.9±3.7	4.7±3.57	4.7±3.5	.78
Cardiac history										
History of MI	33	31	32	28	.005	16	18	17	15	.47
History of CHF	8	11	10	10	.79	10	14	11	11	.86
Prior PTCA	36	35	36	36	.55	18	22	19	17	.21
Prior CABG	13	16	14	15	.61	6	11	8	9	.41
Priority and indication										
Preprocedural shock	0	0	0	0	NA	5	9	6	6	>.99
Canadian Cardiovascular Society class (III, IV)	35	36	35	38	.08	9	35	18	24	.006
CHF at presentation	5	8	6	6	.50	8	11	9	9	.81
NYHA class III or IV	3	3	3	3	.84	4	8	5	4	.26
Cardiac anatomy and function										
Multivessel disease ^f	46	45	45	42	.11	52	58	54	49	.03
ACC/AHA type B2/C lesion	46	55	50	54	.03	86	82	85	83	.76
LMCA stenosis ≥70%	0.1	0.7	0.4	0.5	.62	0.0	2	0.6	0.9	.53
Thrombus in any lesion	14	19	17	14	.09	75	70	73	71	.28
Procedural										
No. of vessels treated					.02					.03
1	88	86	87	85		94	93	93	91	
2	11	13	12	14		6	7	7	9	
3	1	1	1	1		0	0	0	1	
No. of segments treated	1.5±0.8	1.5±0.8	1.5±0.8	1.4±0.7	.12	1.4±0.7	1.5±0.9	1.5±0.8	1.4±0.7	.03
Glycoprotein IIb/IIIa inhibitors	66	43	55	49	<.001	86	75	82	85	.16
Stent use	95	93	94	91	<.001	93	93	93	91	.12
Medications on discharge										
Aspirin	99	98	98	96	<.001	96	97	96	96	.88
β-Blocker	83	85	84	81	.004	89	89	89	92	.08
ACE inhibitor	45	59	52	52	.76	62	78	68	69	.49
Lipid-lowering agent	69	50	60	65	<.001	60	48	55	62	.002

^a ACC = American College of Cardiology; ACE = angiotensin-converting enzyme; AHA = American Heart Association; CABG = coronary artery bypass grafting; CHF = chronic heart failure; CVA = cerebrovascular accident; FSH = Franciscan Skemp Healthcare; ISJ = Immanuel St. Joseph's Hospital; LMCA = left main coronary artery; MACE = major adverse cardiovascular event; MCRS = Mayo Clinic risk score; MI = myocardial infarction; NA = not available; NYHA = New York Heart Association; PCI = percutaneous coronary intervention; PTCA = percutaneous transluminal coronary angioplasty; SMH = Saint Marys Hospital; TIA = transient ischemic attack.

^b Continuous variables are expressed as mean ± SD and categorical data as percentages. Missing values are excluded from the denominator in the calculation of percentages.

^c P values refer to the comparison of FSH and ISJ vs SMH.

^d SI conversion factor: To convert total cholesterol values to mmol/L, multiply by 0.0259.

^e The components of the MCRS include age, presentation with shock, serum creatinine level, CHF on presentation, MI within 24 hours before PCI, peripheral vascular disease, and left ventricular ejection fraction.¹⁷

^f More than 1 vessel with at least 70% stenosis.

urgent CABG, risk was significantly lower at the MHS sites than at Saint Marys Hospital for nonelective PCI (adjusted odds ratio [OR], 0.58; 95% confidence interval [CI], 0.38-0.87) but not for elective PCI (adjusted OR, 1.14; 95%

CI, 0.31-4.17). Results were similar for death but were not statistically significant, with ORs of 0.64 (95% CI, 0.40-1.01) and 0.86 (95% CI, 0.22-3.39) for nonelective and elective PCIs, respectively. For the end points of death, Q-

TABLE 4. In-Hospital Outcomes^{a,b}

Outcome	Elective PCI					Nonelective PCI				
	ISJ (N=955)	FSH (N=887)	ISJ & FSH (N=1842)	SMH (N=1842)	P value ^c	ISJ (N=421)	FSH (N=246)	ISJ & FSH (N=667)	SMH (N=667)	P value ^c
Procedural success	929 (97.3)	860 (97.0)	1789 (97.1)	1756 (95.3)	.004	393 (93.3)	227 (92.3)	620 (93.0)	606 (90.9)	.16
Death	3 (0.3)	1 (0.1)	4 (0.2)	8 (0.4)	.24	11 (2.6)	6 (2.4)	17 (2.5)	21 (3.1)	.49
Emergent CABG for failed PCI	0 (0.0)	0 (0.0)	0 (0.0)	3 (0.2)	.041	3 (0.7)	2 (0.8)	5 (0.7)	4 (0.6)	.74
Death or emergent CABG	3 (0.3)	1 (0.1)	4 (0.2)	11 (0.6)	.07	14 (3.3)	8 (3.3)	22 (3.3)	25 (3.7)	.65
Q-wave MI	5 (0.5)	2 (0.2)	7 (0.4)	2 (0.1)	.09	4 (1.0)	1 (0.4)	5 (0.7)	2 (0.3)	.25
In-hospital target revascularization	5 (0.5)	4 (0.5)	9 (0.5)	9 (0.5)	>.99	7 (1.7)	2 (0.8)	9 (1.3)	15 (2.2)	.21
MACE (death, Q-wave MI, emergency CABG, stroke)	9 (0.9)	5 (0.6)	14 (0.8)	14 (0.8)	>.99	22 (5.2)	14 (5.7)	36 (5.4)	28 (4.2)	.30

^a CABG = coronary artery bypass grafting; FSH = Franciscan Skemp Healthcare; ISJ = Immanuel St. Joseph's Hospital; MACE = major adverse cardiovascular event; MI = myocardial infarction; PCI = percutaneous coronary intervention; SMH = Saint Marys Hospital.

^b Data are provided as number (percentage) of patients.

^c P values refer to the comparison of the ISJ & FSH column vs the SMH column.

wave MI, urgent CABG, or stroke, the ORs were 0.83 (95% CI, 0.59-1.17) and 0.91 (95% CI, 0.38-2.17) for nonelective and elective PCI, respectively.

TRANSFER OF PATIENTS

The indications for transfer, need for surgery, and outcomes of patients after transfer to a facility with an on-site

surgical program (Saint Marys Hospital) are summarized in Figure 2. Overall, 21 (0.69%) of 3025 patients undergoing PCIs were transferred during the study period. No patient undergoing elective PCI was transferred emergently. Most patients who needed transfer were patients with ST-segment elevation MI (16/20, 80%). Eighteen (86%) of 21 transferred patients survived to hospital discharge.

FIGURE 2. Indications for transfer of patients from Immanuel St. Joseph's Hospital and Franciscan Skemp Healthcare (hospitals without on-site surgery) to Saint Marys Hospital (hospital with on-site surgery). CABG = coronary artery bypass grafting; LAD = left anterior descending; LVAD = left ventricular assist device; MHS = Mayo Health System; MR = mitral regurgitation; NSTEMI = non-ST-segment elevation myocardial infarction; PCI = percutaneous coronary intervention; STEMI = ST-segment elevation myocardial infarction; VT = ventricular tachycardia.

DISCUSSION

This study demonstrates excellent outcomes for patients undergoing PCI at 2 community hospitals without on-site surgical capability using predetermined case selection criteria. One unique feature of the current study was the “hub-and-spoke” model of care, which likely helped make the outcomes at these community hospitals comparable to those at a hospital with an on-site surgical program. The high procedural success rate and low in-hospital mortality rate were comparable to those at a facility with on-site surgical capability. Previous studies have shown favorable results for primary and elective PCIs at centers without cardiac surgical backup, but most were limited because they had small numbers, were single-center experiences, and lacked comparison with centers with on-site surgery.¹⁸ Recent data from a Swedish national registry showed no differences in the outcomes for elective and primary PCIs between hospitals with and without surgical programs.¹⁹ Despite excellent PCI results, use of valid risk-adjustment tools and quality assurance protocols are notably lacking.

Our study, one of the largest to date, documents outcomes at 2 Mayo community hospitals without surgical programs and extends our previous observations.^{7,8,13} The demonstration of excellent and comparable outcomes after PCI underscores the feasibility of offering such technology at sites without surgical backup. These community hospitals followed the recommendations of the ACC/AHA for quality assurance¹⁵; that is, they adhered to a valid peer-review process, set minimum volume thresholds for the operators, provided a fully equipped cardiac catheterization laboratory facility, and participated in a PCI database. For case selection and for the benchmarking of operator performance, the Mayo Clinic risk-adjusted model was used,^{14,17} which predicts PCI complications more accurately than the older ACC/AHA lesion classification scheme.²⁰ Our results suggest that PCI can be safely performed at community hospitals without on-site cardiac surgery. More data and longer follow-up are required to further confirm the usefulness and robustness of the model. Our results do not support a cause-and-effect relationship or allow for generalization of PCI without an on-site surgical program in the absence of the critical programmatic requirements described herein.

NONELECTIVE VS ELECTIVE PCIs

The indications and need for performance of elective, low-risk PCIs are different, but inclusion of both elective and nonelective PCIs improves access to care by removing geographic barriers and ensuring higher overall PCI volumes, which are important outcome determinants after PCI.²⁰⁻²³ Percutaneous coronary intervention is generally

viewed as the preferred method of restoring vessel patency in patients with ST-segment elevation MI. Application of such quality-of-care models might help extend the reach of primary PCI into smaller communities, thus partially obviating the need for thrombolytic therapy and time-consuming transfers. Involvement of a tertiary care center for oversight, data monitoring, benchmarking of operator performance, and help with transfers, as needed, would be paramount. Wennberg et al⁹ noted that the adjusted mortality rate for patients undergoing elective PCI was 38% higher at hospitals without on-site cardiac surgery. Higher mortality rates have been observed in very low-volume hospitals performing fewer than 50 PCIs annually, emphasizing the need to maintain higher procedural volumes at community hospitals. Our results were achieved with a coordinated system approach in a “hub-and-spoke” model of care that requires complete integration of hospitals (community and tertiary care) in terms of processes, delivery of care, training, oversight, and exposure of operators to complex cases.

TRANSFER OF PATIENTS TO CENTERS WITH ON-SITE SURGERY

Given that transport delays lead to worse outcomes and that mortality is higher after emergent cardiac surgery, the potential need for emergent cardiac surgery due to failed PCI remains a barrier to widespread adoption of PCIs at hospitals without surgical backup.^{4,24} Fortunately, the need for emergent CABG after failed PCI is rare with the availability of stents.^{3,4} In the current study, no patient undergoing elective coronary interventions required emergent CABG, underscoring the safety of PCI in carefully selected patients. This is one of the few studies to document the indications and outcomes of patients after transfer to a surgical facility. Surprisingly, no patients had dissection or abrupt closure after PCI that required transfer.

STUDY LIMITATIONS

We made every effort to match the 2 groups for observed clinical and angiographic variables and for baseline risk. However, some unaccounted for and residual biases may have influenced the results of the current study. Despite following similar post-PCI protocols, differences were noted in the use of medications during hospitalization that may influence outcomes on follow-up. The mortality rates of patients undergoing nonelective PCIs whose matching controls could not be found were slightly higher. Therefore, we analyzed the data for all patients using multiple regression methods to allow for analysis of all patients and found comparable outcomes at the hospitals with and without on-site cardiac surgery. Although the study is one of the largest reported to date, adverse outcomes are rare, indicating the need for additional data before definitive conclusions can be drawn.

CONCLUSION

Excellent outcomes for nonelective and elective PCIs at hospitals without surgery on site can be obtained by adherence to a prospective, standardized protocol for operator training, patient risk assessment, and case selection. Our results do not support generalization of PCI without an on-site surgical program in the absence of these critical programmatic requirements.

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REFERENCES

1. Altmann DB, Racz M, Battleman DS, et al. Reduction in angioplasty complications after the introduction of coronary stents: results from a consecutive series of 2242 patients. *Am Heart J*. 1996;132(3):503-507.
2. Anderson KM, Califf RM, Stone GW, et al. Long-term mortality benefit with abciximab in patients undergoing percutaneous coronary intervention. *J Am Coll Cardiol*. 2001;37(8):2059-2065.
3. Singh M, Rihal CS, Gersh BJ, et al. Twenty-five-year trends in in-hospital and long-term outcome after percutaneous coronary intervention: a single-institution experience. *Circulation*. 2007 Jun 5;115(22):2835-2841. Epub 2007 May 28.
4. Yang EH, Gumina RJ, Lennon RJ, Holmes DR Jr, Rihal CS, Singh M. Emergency coronary artery bypass surgery for percutaneous coronary interventions: changes in the incidence, clinical characteristics, and indications from 1979 to 2003. *J Am Coll Cardiol*. 2005 Dec 6;46(11):2004-2009. Epub 2005 Nov 4.
5. Hochman JS, Sleeper LA, Webb JG, et al; SHOCK Investigators. Early revascularization in acute myocardial infarction complicated by cardiogenic shock. *N Engl J Med*. 1999;341(9):625-634.
6. Singh M, Mathew V, Garratt KN, et al. Effect of age on the outcome of angioplasty for acute myocardial infarction among patients treated at the Mayo Clinic. *Am J Med*. 2000;108(3):187-192.
7. Ting HH, Garratt KN, Singh M, et al. Low-risk percutaneous coronary interventions without on-site cardiac surgery: two years' observational experience and follow-up. *Am Heart J*. 2003;145(2):278-284.
8. Singh M, Ting HH, Gersh BJ, et al. Percutaneous coronary intervention for ST-segment and non-ST-segment elevation myocardial infarction at hospitals with and without on-site cardiac surgical capability. *Mayo Clin Proc*. 2004;79(6):738-744.
9. Wennberg DE, Lucas FL, Siewers AE, Kellett MA, Malenka DJ. Outcomes of percutaneous coronary interventions performed at centers without and with onsite coronary artery bypass graft surgery. *JAMA*. 2004;292(16):1961-1968.
10. Wharton TP Jr, McNamara NS, Fedele FA, Jacobs MI, Gladstone AR, Funk EJ. Primary angioplasty for the treatment of acute myocardial infarction: experience at two community hospitals without cardiac surgery. *J Am Coll Cardiol*. 1999;33(5):1257-1265.
11. Wharton TP Jr, Grines LL, Turco MA, et al. Primary angioplasty in acute myocardial infarction at hospitals with no surgery on-site (the PAMI-No SOS study) versus transfer to surgical centers for primary angioplasty. *J Am Coll Cardiol*. 2004;43(11):1943-1950.
12. Seshadri N, Whitlow PL, Acharya N, Houghtaling P, Blackstone EH, Ellis SG. Emergency coronary artery bypass surgery in the contemporary percutaneous coronary intervention era. *Circulation*. 2002;106(18):2346-2350.
13. Ting HH, Raveendran G, Lennon RJ, et al. A total of 1,007 percutaneous coronary interventions without onsite cardiac surgery: acute and long-term outcomes. *J Am Coll Cardiol*. 2006 Apr 18;47(8):1713-1721. Epub 2006 Mar 13.
14. Singh M, Lennon RJ, Holmes DR Jr, Bell MR, Rihal CS. Correlates of procedural complications and a simple integer risk score for percutaneous coronary intervention. *J Am Coll Cardiol*. 2002;40(3):387-393.
15. Smith SC Jr, Dove JT, Jacobs AK, et al. ACC/AHA guidelines of percutaneous coronary interventions (revision of the 1993 PTCA guidelines)—executive summary. *J Am Coll Cardiol*. 2001;37(8):2215-2239.
16. D'Agostino RB Jr. Propensity score methods for bias reduction in the comparison of a treatment to a non-randomized control group. *Stat Med*. 1998;17(19):2265-2281.
17. Singh M, Rihal CS, Lennon RJ, Spertus J, Rumsfeld JS, Holmes DR. Bedside estimation of risk from percutaneous coronary intervention: the new mayo clinic risk scores. *Mayo Clin Proc*. 2007;82(6):701-708.
18. Melberg T, Nilsen DW, Larsen AI, et al. Nonemergent coronary angioplasty without on-site surgical backup: a randomized study evaluating outcomes in low-risk patients. *Am Heart J*. 2006;152(5):888-895.
19. Carlsson J, James SN, Ståhle E, Höfer S, Lagerqvist B. Outcome of percutaneous coronary intervention in hospitals with and without on-site cardiac surgery standby. *Heart*. 2007 Mar;93(3):335-338. Epub 2006 Sep 15.
20. Singh M, Rihal CS, Lennon RJ, Garratt KN, Holmes DR Jr. Comparison of Mayo Clinic risk score and American College of Cardiology/American Heart Association lesion classification in the prediction of adverse cardiovascular outcome following percutaneous coronary interventions. *J Am Coll Cardiol*. 2004;44(2):357-361.
21. Hannan EL, Racz M, Ryan TJ, et al. Coronary angioplasty volume-outcome relationships for hospitals and cardiologists. *JAMA*. 1997;277(11):892-898.
22. Hannan EL, Wu C, Walford G, et al. Volume-outcome relationships for percutaneous coronary interventions in the stent era. *Circulation*. 2005 Aug;112(8):1171-1179. Epub 2005 Aug 15.
23. Malenka DJ, McGrath PD, Wennberg DE, et al; Northern New England Cardiovascular Disease Study Group. The relationship between operator volume and outcomes after percutaneous coronary interventions in high volume hospitals in 1994-1996: the northern New England experience. *J Am Coll Cardiol*. 1999;34(5):1471-1480.
24. Lotfi M, Mackie K, Dzavik V, Seidelin PH. Impact of delays to cardiac surgery after failed angioplasty and stenting. *J Am Coll Cardiol*. 2004;43(3):337-342.