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A Total of 1,007 Percutaneous Coronary Interventions Without Onsite Cardiac Surgery

Acute and Long-Term Outcomes

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OBJECTIVES We sought to compare clinical outcomes of elective percutaneous coronary intervention (PCI) and primary PCI for ST-segment elevation myocardial infarction (STEMI) at a community hospital without onsite cardiac surgery to those at a tertiary center with onsite cardiac surgery.

BACKGROUND Disagreement exists about whether hospitals with cardiac catheterization laboratories, but without onsite cardiac surgery, should develop PCI programs. Primary PCI for STEMI at hospitals without onsite cardiac surgery have achieved satisfactory outcomes; however, elective PCI outcomes are not well defined.

METHODS A total of 1,007 elective PCI and primary PCI procedures performed from March 1999 to August 2005 at the Immanuel St. Joseph's Hospital–Mayo Health System (ISJ) in Mankato, Minnesota, were matched one-to-one with those performed at St. Mary's Hospital (SMH) in Rochester, Minnesota. Strict protocols were followed for case selection and PCI program requirements. Clinical outcomes (in-hospital procedural success, death, any myocardial infarction, Q-wave myocardial infarction, and emergency coronary artery bypass surgery) and follow-up survival were compared between groups.

RESULTS Among 722 elective PCIs, procedural success was 97% at ISJ compared with 95% at SMH ($p = 0.046$). Among 285 primary PCIs for STEMI, procedural success was 93% at ISJ and 96% at SMH ($p = 0.085$). No patients at ISJ undergoing PCI required emergent transfer for cardiac surgery. Survival at two years' follow-up by treatment location was similar for patients with elective PCI and primary PCI.

CONCLUSIONS Similar clinical outcomes for elective PCI and primary PCI were achieved at a community hospital without onsite cardiac surgery compared with those at a tertiary center with onsite cardiac surgery using a prospective, rigorous protocol for case selection and PCI program requirements. (J Am Coll Cardiol 2006;47:1713–21) © 2006 by the American College of Cardiology Foundation

More than one million percutaneous coronary interventions (PCIs) are performed annually in the U.S. (1). With contemporary coronary stents and adjunctive pharmacotherapies, procedural success has improved to 90% to 95% (2–4). Concomitantly, the rate of emergency coronary artery bypass surgery (CABG) stemming from a procedural complication has decreased markedly to 1% or less (5–7). Several hospitals with cardiac catheterization laboratories but without onsite cardiac surgery have developed PCI programs and reported satisfactory results in small patient cohorts (8–24), but widespread adoption of this health care delivery model is very controversial.

Guidelines for PCI published by the American College of Cardiology (ACC) and the American Heart Association (AHA) in 2005 explicitly addressed the issue of onsite cardiac surgical back-up for elective PCI and primary PCI for ST-segment elevation myocardial infarction (STEMI) (1). Performance of elective PCI without onsite cardiac surgery was deemed a class III indication (i.e., not indicated). Primary PCI for STEMI was classified as a class IIb indication provided that minimal operator volumes (≥75 total PCIs per year and ≥11 primary PCIs per year) and institutional volumes are met (≥36 primary PCIs per year), as well as requiring a proven, tested plan for rapid transport to a nearby hospital with cardiac surgical capability.

Our hypothesis was that PCI procedures can be performed safely without onsite cardiac surgery by following strict protocols for case selection and PCI program requirements. We report our outcomes in the first 1,007 PCI procedures at a community hospital without onsite cardiac surgery compared with those obtained at a high-volume tertiary care facility with cardiac surgical capability.

METHODS

PCI program: Immanuel St. Joseph's Hospital–Mayo Health System. Immanuel St. Joseph's Hospital–Mayo Health System (ISJ) is a 150-bed community hospital located in Mankato, Minnesota, with a population service region of approximately 300,000. It has a fully equipped cardiac catheterization laboratory (digital biplane acquisition system: Advantx LCN+; General Electric, Fairfield,

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Abbreviations and Acronyms

ACC = American College of Cardiology
AHA = American Heart Association
CABG = coronary artery bypass surgery
CI = confidence interval
ISJ = Immanuel St. Joseph's Hospital–Mayo Health System
MI = myocardial infarction
PCI = percutaneous coronary intervention
SMH = St. Mary's Hospital
STEMI = ST-segment elevation myocardial infarction
TVR = target vessel revascularization

Connecticut) but does not have onsite cardiac surgical capability. St. Mary's Hospital (SMH), located 85 miles away in Rochester, Minnesota, is the nearest tertiary care facility with onsite cardiac surgery. Both ISJ and SMH are part of a vertically and clinically integrated health care delivery system with shared governance by the Mayo Clinic and Foundation.

We developed a PCI program at ISJ and started performing elective PCI and primary PCI for STEMI in March 1999 and March 2000, respectively. We followed a prospective, rigorous protocol at ISJ for case selection for elective PCI and primary PCI for STEMI (Table 1). Case selection protocols were reviewed and approved by the Mayo Clinic Catheterization Laboratory Practice Committee. Informed consent was obtained from the patient and included a discussion of goals, benefits, and risks, as well as the alternative of transfer to another facility for PCI with onsite cardiac surgery.

As a quality assurance measure for this new model of health care delivery, the catheterization laboratory at ISJ was linked to SMH through a high-speed telemedicine link, a dedicated T3 fiberoptic line. This T3 line enables real-time transfer of angiographic and ultrasonographic images and hemodynamic data as well as audio and video images to review terminals at the catheterization laboratory and cardiac surgery operating suites at SMH. The T3 line possesses a maximal data transfer rate of 45 megabits/s. Digital angiographic images can be transmitted in real time without appreciable delay by using a 6:1 compression algorithm, and uncompressed images are transmitted with a 30- to 60-s delay depending on the length of the angiographic sequence. Lossy data compression at ratios >6:1 decreases the sensitivity and accuracy of detecting coronary angiographic features (25). For the first 12 months of the PCI program, an interventional cardiologist at SMH observed and provided real-time consultation for every elective PCI procedure. After the first 12 months, telemedicine consultation with cardiology or cardiac surgery colleagues at SMH was used on an as-needed basis and at the discretion of the operator at ISJ. Real-time review during PCI was rarely used after the first 12 months.

All operators performing PCI at ISJ received formal interventional training in U.S.-accredited programs and maintained procedural volumes compliant with ACC/AHA guidelines. All operators at ISJ were credentialed and rotated through the SMH catheterization laboratory on a periodic basis. Allied health staff at ISJ involved with PCI patient care also received training at SMH. Staff at ISJ and SMH followed the same protocols for periprocedural and postprocedural patient care.

Immediate access to emergency cardiac surgery was ensured with a tested transport protocol, which included access to three helicopters as well as ground ambulances for urgent patient transfer with intra-aortic balloon pump capability for hemodynamic support, if necessary. This transport system was available for all patient transfers at Mayo Clinic but was not solely developed for or dedicated to the PCI program. In rare circumstances during which inclement weather prohibited ambulance transport by air or ground, an elective PCI procedure at ISJ was delayed or cancelled. We evaluated this system with unscheduled and unrehearsed "test" cases and transport times of <60 min were reliably achieved.

Data sources and outcome measures. All patients undergoing PCI at ISJ and SMH were followed prospectively according to a well-established protocol, the Mayo Clinic PCI Registry (26). This database contains demographic, clinical, and angiographic data, as well as information on patient outcomes during follow-up. An independent reviewer adjudicated clinical and angiographic data. All patients were interviewed in person or by telephone 6 and 12

Table 1. Case Selection Protocol at ISJ

Elective PCI
1. For the first 12 months, only ACC/AHA type A and B1 lesions were eligible for elective PCI at ISJ. Cases, outcomes, and adverse events were reviewed every quarter.
2. After the first 12 months, eligibility was expanded beyond ACC/AHA type A and B lesions to include all low-to-moderate risk cases except:
   a. ISJ operator's assessment that coronary anatomy may preclude easy stent deployment (including diffuse disease, severe calcification, severe tortuosity, chronic total occlusion, ostial lesion involving left anterior descending or left circumflex artery, degenerated saphenous vein graft, or poor coronary guide catheter support).
   b. Planned use of rotational atherectomy or directional atherectomy devices.
   c. Poor baseline left ventricular function that may require hemodynamic support with intra-aortic balloon pump or ventricular assist device.
3. In the past 12 months, cases with a Mayo Clinic Risk Score >10 were not eligible for elective PCI at ISJ.

Primary PCI
1. Cases with cardiogenic shock refractory to vasopressors were not eligible for primary PCI at ISJ.
2. Cases with persistent, refractory ventricular arrhythmias were not eligible for primary PCI at ISJ.

ACC/AHA = American College of Cardiology/American Heart Association; ISJ = Immanuel St. Joseph's Hospital–Mayo Health System; PCI = percutaneous coronary intervention.

months after PCI and yearly thereafter to assess major adverse cardiovascular events. Records from subsequent visits and hospitalizations were obtained for review with the patient's written informed authorization. In accordance with Minnesota statute, we excluded all patients who did not grant authorization for use of their medical records for research. This study was approved by the institutional review boards of both institutions.

Data from this registry were electronically available and used to identify our study population, to assess patient and procedural characteristics, as well as to track patient outcomes. The primary outcomes of interest included in-hospital angiographic success and procedural success. Definition of end points, including angiographic success, procedural success, and myocardial infarction, are listed in Table 2. Creatine kinase-MB fraction isoenzymes were drawn before the procedure and every 8 h × 3 after the procedure. Additional creatine kinase-MB fraction isoenzymes were drawn in the event of any clinical events suspicious for myocardial ischemia. Emergency CABG was defined as CABG performed within 24 h of PCI for a procedural-related complication.

Statistical analyses. We report continuous variables as means ± standard deviation and categorical variables as frequencies and percentages. Because of the observational study design, a matched cohort approach was used in analysis to minimize confounding due to varying patient characteristics by treatment facility. Each PCI procedure at ISJ was matched one-to-one with a SMH procedure. Matching was accomplished separately between primary PCIs and elective PCIs. For primary PCIs, matching was based on procedure date (within 1 year), age (within 5 years), gender, a propensity score based on 32 covariates and 9 interactions, Mayo Clinic Risk Score (27), congestive heart failure on presentation, previous CABG, and number of diseased vessels. For elective PCIs, matching was based on procedure date (within 1 year), age (within 5 years), the previously mentioned propensity score, Mayo Clinic Risk Score, prior PCI, any myocardial infarction (MI) within the previous seven days, renal disease (defined as serum creatinine ≥3 mg/dl), number of diseased vessels, current smoking status, ACC/AHA type B2 and C lesions, and metastatic cancer. This matching process was conducted electronically using a computer algorithm designed to reduce the total (weighted) difference between groups in the matching variables sets (28,29).

Patient characteristics were compared between groups using *t*-tests and chi-square tests, as appropriate. We used the Wilcoxon rank-sum test to compare ordered categorical variables (for example, number of diseased vessels treated during PCI). Conditional logistic regression was used to compare in-hospital outcomes, accounting for the matched structure of the data. Survival free of cardiac events during follow-up was estimated using the Kaplan-Meier method and tested using a Cox regression model with separate baseline hazards for each ISJ and SMH matched patient pair. Because the matching was based on procedures, some patients at ISJ with multiple procedures were in the cohort more than once. The survival analysis included the earliest successful PCI of the patients treated at ISJ. The survival analysis start point was defined as the day of discharge from the hospital (in-hospital events were excluded). All statistical tests were two-sided, and p values <0.05 were considered significant. We used SAS version 9.1 (SAS Institute Inc., Cary, North Carolina) for all analyses.

Table 2. Definition of In-Hospital Clinical Outcomes

Elective PCI
1. Angiographic success
   a. <20% residual stenosis (stent-treated lesion) or
   b. <50% residual stenosis (non–stent-treated lesion)
2. Procedural success = angiographic success without death, any MI, or emergency CABG
3. Any MI
   a. Development of new Q waves in ≥2 contiguous leads or
   b. If pre-procedure CK-MB is normal, then require CK-MB >3× ULN or
   c. If pre-procedure CK-MB is > ULN, then require both an increase in CK-MB of at least 50% over previous value and documentation that CK-MB was decreasing before the suspected recurrent MI

Primary PCI for STEMI
1) Angiographic success
   a. <20% residual stenosis (stent-treated lesion) or
   b. <50% residual stenosis (non–stent-treated lesion)
2) Procedural success = angiographic success without death, any recurrent MI, or emergency CABG
3) Any recurrent MI
   a. Within 24 h of qualifying MI, then require typical chest pain ≥20 min and new or recurrent ST-segment elevation ≥0.10 mV in ≥2 contiguous leads or new LBBB or
   b. After 24 h of qualifying MI, then require typical chest pain ≥20 min and new or recurrent ST-segment elevation ≥0.10 mV in ≥2 contiguous leads or new LBBB or
   c. After 24 h of qualifying MI, then require typical chest pain ≥20 min and both an increase in CK-MB of at least 50% over previous value and documentation that CK-MB was decreasing before the suspected recurrent MI

CABG = coronary artery bypass surgery; CK = creatine kinase; LBBB = left bundle branch block; MI = myocardial infarction; PCI = percutaneous coronary intervention; STEMI = ST-segment elevation myocardial infarction; ULN = upper limit of normal.

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Table 3. Elective PCI Clinical and Angiographic Characteristics

Variable	SMH (n = 722)	ISJ (n = 722)	p Value
Age, yrs	64.9 ± 12.5	64.9 ± 12.7	0.97
Male gender, n (%)	476 (66%)	504 (70%)	0.11
MI 1 to 7 days before procedure, n (%)	98 (14%)	118 (16%)	0.14
Canadian Cardiovascular Class ≥3, n (%)	325 (45%)	305 (42%)	0.29
Mayo Clinic Risk Score, median (Q1, Q3)	4.0 (3.0, 6.0)	4.0 (3.0, 6.0)	0.18
Diabetes, n (%)	170 (24%)	176 (24%)	0.73
Hypertension, n (%)	480 (69%)	496 (69%)	1.00
History of cholesterol ≥240 mg/dl, n (%)	544 (82%)	475 (79%)	0.28
Current smoker, n (%)	147 (21%)	165 (23%)	0.27
CHF on presentation, n (%)	38 (5%)	39 (5%)	0.91
CHF class IV, n (%)	6 (1%)	8 (1%)	0.59
History of CHF, n (%)	56 (8%)	61 (9%)	0.86
Prior MI, n (%)	273 (39%)	248 (34%)	0.10
Prior PCI, n (%)	245 (34%)	244 (34%)	0.96
Prior CABG, n (%)	84 (12%)	74 (10%)	0.40
Peripheral vascular disease, n (%)	72 (10%)	86 (12%)	0.29
History of stroke or TIA, n (%)	80 (11%)	69 (10%)	0.31
Renal disease (creatinine ≥3.0 mg/dl), n (%)	18 (2%)	18 (3%)	0.95
Metastatic cancer, n (%)	11 (2%)	11 (2%)	0.99
Left ventricular ejection fraction (mean)	54 ± 16	56 ± 13	0.18
Left ventricular ejection fraction ≤0.40, n (%)	92 (13%)	74 (10%)	0.14
Multivessel disease, n (%)	423 (62%)	429 (61%)	0.86
Type B2 or C lesion, n (%)	269 (38%)	268 (38%)	0.94
Type C lesion, n (%)	112 (16%)	116 (16%)	0.72
Maximum device size (mm)	3.3 ± 0.6	3.3 ± 0.6	0.80
Total number of vessels treated, n (%)			0.39
1	646 (90%)	636 (88%)	
2	68 (9%)	83 (11%)	
3	7 (1%)	3 (0%)	
Number of stents placed	1.3 ± 0.9	1.5 ± 1.0	<0.001
Glycoprotein IIb/IIIa use, n (%)	323 (45%)	548 (76%)	<0.001
Vein graft intervention, n (%)	22 (3%)	24 (3%)	0.77

Multivessel disease defined as ≥70% stenosis in the target vessel and ≥50% stenosis in the other vessels. Left ventricular ejection fraction was available in 68% of SMH and 76% of ISJ patients.

CABG = coronary artery bypass surgery; CHF = congestive heart failure; ISJ = Immanuel St. Joseph's Hospital–Mayo Health System; MI = myocardial infarction; PCI = percutaneous coronary intervention; SMH= St. Mary's Hospital; TIA = transient ischemic attack.

RESULTS

A total of 1,048 consecutive PCI procedures were performed on 908 patients at ISJ. In this report, we analyzed a cohort of 1,007 PCI procedures at ISJ, including 722 elective PCIs performed from March 1999 to August 2005 and 285 primary PCIs performed from March 2000 to August 2005. Thirty procedures were excluded because patients refused consent for research, and 11 procedures (4 elective PCIs and 7 primary PCIs) were excluded because a suitable match was not available. There were no in-hospital deaths or CABG among the 11 PCI procedures excluded for no suitable match. These 1,007 PCI procedures from ISJ were matched one-to-one to SMH procedures from a cohort of 8,622 PCIs performed during the same time period at SMH. Median follow-up time was 22.6 and 24.5 months for elective PCI patients at ISJ and SMH, respectively. Median follow-up time was 30.6 and 32.0 months for the primary PCI patients at ISJ and SMH, respectively.

The total volume of PCI procedures per year performed at ISJ from 1999 to 2005 were as follows: 55 (1999; extrapolated for 12 months), 137 (2000), 243 (2001), 158 (2002), 141 (2003), 223 (2004), and 221 (2005). The number of operators at ISJ varied from one to three during the specified time period.

Clinical and angiographic characteristics for the 722 elective PCI procedures are shown in Table 3 according to treatment site. By design, the two cohorts (ISJ vs. SMH) were similar in terms of age (65 years), gender distribution (approximately 70% men), diabetes (24%), congestive heart failure on presentation (5%), multivessel disease (61%), and other baseline characteristics. The ISJ cohort used more stents per procedure (1.5 vs. 1.3) and had more frequent use of glycoprotein IIb/IIIa inhibitors (76% vs. 45%) compared with the SMH cohort. The greater use of glycoprotein IIb/IIIa inhibitors at ISJ was protocol-driven, with the objective of reducing acute and subacute thrombosis and other ischemic events.

Clinical and angiographic characteristics for the 285 primary PCI procedures are shown in Table 4. The two cohorts were similar in terms of age (63 years), gender distribution (approximately 74% men), diabetes (approximately 17%), multivessel disease (68%), and other baseline

Table 4. Primary PCI Clinical and Angiographic Characteristics

Variable	SMH (n = 285)	ISJ (n = 285)	p Value
Age, yrs	63.3 ± 12.9	63.1 ± 13.1	0.80
Male gender, n (%)	208 (73%)	210 (74%)	0.85
Mayo Clinic Risk Score, median (Q1, Q3)	8.0 (6.0, 9.0)	8.0 (6.0, 10.0)	0.79
Diabetes, n (%)	59 (21%)	49 (17%)	0.28
Hypertension, n (%)	168 (64%)	151 (55%)	0.03
History of cholesterol ≥240 mg/dl, n (%)	178 (75%)	109 (53%)	<0.001
Current smoker, n (%)	109 (39%)	93 (33%)	0.13
CHF on presentation, n (%)	20 (7%)	18 (6%)	0.74
CHF class IV, n (%)	10 (4%)	9 (3%)	0.82
History of CHF, n (%)	26 (10%)	21 (7%)	0.27
Prior MI, n (%)	44 (15%)	62 (22%)	0.05
Prior PCI, n (%)	41 (14%)	45 (16%)	0.64
Prior CABG, n (%)	10 (4%)	9 (3%)	0.82
Peripheral vascular disease, n (%)	21 (8%)	24 (9%)	0.67
History of stroke or TIA, n (%)	22 (8%)	22 (8%)	0.96
Renal disease (creatinine ≥3.0 mg/dl), n (%)	2 (1%)	4 (1%)	0.40
Metastatic cancer, n (%)	4 (1%)	3 (1%)	0.72
Intra-aortic balloon pump, n (%)	4 (1%)	6 (2%)	0.52
Left ventricular ejection fraction (mean)	49 ± 16	50 ± 14	0.55
Left ventricular ejection fraction ≤0.40, n (%)	30 (11%)	76 (27%)	<0.001
Multivessel disease, n (%)	188 (69%)	191 (68%)	0.77
TIMI flow grade 0 or 1 pre-procedure, n (%)	137 (60%)	187 (66%)	0.22
Maximum device size (mm)	3.4 ± 0.6	3.4 ± 0.6	0.74
Total number of vessels treated, n (%)			0.06
1	261 (92%)	272 (95%)	
2	23 (8%)	13 (5%)	
3	1 (0%)	0 (0%)	
Number of stents placed	1.4 ± 1.0	1.5 ± 1.1	0.19
Glycoprotein IIb/IIIa use, n (%)	236 (83%)	246 (86%)	0.25
Vein graft intervention, n (%)	4 (1%)	4 (1%)	1.00

Multivessel disease defined as ≥70% stenosis in the target vessel and ≥50% stenosis in the other vessels. Left ventricular ejection fraction was available in 41% of SMH and 93% of ISJ patients.

CABG = coronary artery bypass surgery; CHF = congestive heart failure; ISJ = Immanuel St. Joseph's Hospital–Mayo Health System; MI = myocardial infarction; PCI = percutaneous coronary intervention; SMH = St. Mary's Hospital; TIA = transient ischemic attack; TIMI = Thrombolysis In Myocardial Infarction.

characteristics. Intra-aortic balloon pump use was similar at ISJ and SMH (2% vs. 1%). The ISJ cohort had a higher frequency of left ventricular ejection fraction ≤0.40 (27% vs. 11%) compared with SMH. Utilization of glycoprotein IIb/IIIa inhibitors was similar for ISJ and SMH procedures at 86% and 83%, respectively.

Clinical outcomes in elective PCI. In-hospital clinical outcomes for elective PCI procedures are shown in Table 5 according to treatment site. Procedural success was 97% at ISJ (95% confidence interval [CI] 96% to 98%) and 95% at SMH (p = 0.046). In-hospital death, any MI, and emergency CABG after elective PCI were rare and similar between ISJ and SMH. Postprocedural Q-wave MI was higher at SMH compared with ISJ (1% vs. 0%, p = 0.019). Only two (0.3%) in-hospital deaths occurred at ISJ and one (0.1%) in-hospital death occurred at SMH (p = 0.56). At ISJ, the first death was a patient who underwent successful stenting of both the left anterior descending and left circumflex arteries 10 days after anterior wall MI. Two days after PCI, the patient suffered a large embolic stroke, and echocardiography documented a left ventricular thrombus associated with an akinetic anterior wall. The family decided a do-not-resuscitate code status, and the patient died. The second death occurred in a patient who had successful stenting of a left anterior descending artery and diagonal branch bifurcation lesion who subsequently developed respiratory failure. Patient and family declined intubation/ventilator support. No patients at ISJ required emergency transfer for cardiac surgery. At SMH, the only death occurred in a patient who had previous CABG and chronic renal failure requiring hemodialysis. The patient had a drug-eluting stent placed in the right posterior descending artery for in-stent restenosis of a prior bare-metal stent. Six days after the procedure, the patient suffered an acute anterior wall MI with cardiogenic shock and could not be resuscitated. One patient at SMH required emergency CABG related to the procedure. This patient experienced perforation of the left anterior descending artery associated with cardiac tamponade. Immediate pericardiocentesis was performed; however, covered stent grafts were not available in 2001, and the patient underwent successful emergency cardiac surgery.

The Kaplan-Meier estimated probabilities of survival and of remaining free from recurrent MI or target vessel revascularization (TVR) during a median follow-up of 22.6 months are shown in Figures 1A and 1B, respectively. Treatment location (ISJ vs. SMH) was not significantly associated with survival during follow-up (p = 0.89) or

Table 5. In-Hospital Clinical Outcomes

Variable	Elective PCI		p Value
	SMH (n = 722)	ISJ (n = 722)	
Angiographic success, n (%)	707 (98%)	717 (99%)	0.035
Procedural success, n (%)	686 (95%)	701 (97%)	0.046
In-hospital death, n (%)	1 (0.1%)	2 (0.3%)	0.56
Any in-hospital MI, n (%)	21 (3%)	15 (2%)	0.27
In-hospital Q-wave MI, n (%)	4 (1%)	0 (0%)	0.019
In-hospital emergency CABG, n (%)	1 (0.1%)	0 (0%)	0.24
Variable	**Primary PCI**		**p Value**
	SMH (n = 285)	ISJ (n = 285)	
Angiographic success, n (%)	279 (98%)	280 (98%)	0.76
Procedural success, n (%)	274 (96%)	266 (93%)	0.085
In-hospital death, n (%)	4 (1%)	10 (4%)	0.050
Any recurrent in-hospital MI, n (%)	1 (0.4%)	4 (1%)	0.17
Recurrent in-hospital Q-wave MI, n (%)	1 (0.4%)	2 (1%)	0.56
In-hospital emergency CABG, n (%)	0 (0%)	0 (0%)	—

Angiographic success defined as <20% residual stenosis (stent-treated lesion) or <50% residual stenosis (non–stent-treated lesion). Procedural success defined as angiographic success and without in-hospital death, any MI, or emergency CABG.
Abbreviations as in Table 4.

remaining free of recurrent MI or TVR (p = 0.75). Survival at one year and two years after elective PCI was 97% (14 deaths) and 94% (23 deaths), respectively, for patients treated at ISJ compared with 97% (14 deaths) and 95% (22 deaths) for patients treated at SMH, respectively.

Clinical outcomes in primary PCI. In-hospital clinical outcomes for primary PCI procedures also are shown in Table 5. Procedural success was 93% at ISJ (95% CI 90% to 96%) and 96% at SMH (p = 0.085). In-hospital any recurrent MI, recurrent Q-wave MI, and emergency CABG after primary PCI were rare, and their rates were similar at ISJ and SMH. In-hospital deaths occurred in 10 (4%) patients at ISJ compared with 4 (1%) patients at SMH (p = 0.050). Among the 10 deaths at ISJ, three patients died from respiratory failure related to severe chronic obstructive pulmonary disease, one patient died from respiratory failure related to pulmonary hemorrhage in the setting of severe chronic obstructive pulmonary disease and abciximab use, one patient died after ventilator support was withdrawn because there was no neurologic recovery after a prolonged out-of-hospital cardiac arrest associated with the index MI, two patients died from progressive shock and were not candidates for CABG because of patient and family decision, one patient had acute mitral regurgitation from a ruptured papillary muscle and was not a candidate for CABG because of patient and family decision, one patient suffered free-wall rupture after the procedure and could not be resuscitated, and one patient had ventricular fibrillation after the procedure and could not be resuscitated. No patients at ISJ or SMH required emergency CABG for a procedural-related complication.

The Kaplan-Meier estimated probabilities of survival and of remaining free from recurrent MI or TVR during a median follow-up of 30.6 months are shown in Figures 2A and 2B, respectively. Treatment location (ISJ vs. SMH) was not significantly associated with survival during follow-up (p = 0.84) or remaining free of recurrent MI or TVR (p = 0.30). Survival at one year and two years after primary PCI was 96% (8 deaths) and 94% (11 deaths), respectively, for patients treated at ISJ compared with 96% (10 deaths) and 93% (15 deaths), respectively, for patients treated at SMH.

DISCUSSION

We systematically developed a PCI program at ISJ, a community hospital with a catheterization laboratory but without onsite cardiac surgery. Main features of the program were cross-training and cross-credentialing of all operators, a telemedicine link for consultation, and strict protocols for case selection and PCI program requirements. Our objective was to compare clinical outcomes associated with performing elective PCI and primary PCI at ISJ to those obtained at SMH, a tertiary center with onsite cardiac surgical capability. For elective PCI, procedural success (97% vs. 95%, p = 0.046) was statistically better at ISJ compared with SMH and in-hospital death (0.3% vs. 0.1%, p = 0.56) was similar. We would caution that this observed difference in procedural success, albeit statistically significant, may not be clinically relevant. A matched cohort analysis is not a substitute for a randomized controlled trial, and our matching may not have adjusted for residual non-measured, non-quantified variables. For primary PCI, procedural success (93% vs. 96%, p = 0.085) was similar at ISJ compared with SMH, and in-hospital death (4% vs. 1%, p = 0.050) was statistically higher at ISJ. The majority of deaths observed at ISJ for primary PCI were not related to a procedural complication or absence of onsite cardiac surgery. No patients at ISJ undergoing elective PCI or primary PCI required emergent transfer for cardiac surgery. Our results suggest that elective PCI and primary PCI can be performed safely at a community hospital without onsite cardiac surgery if

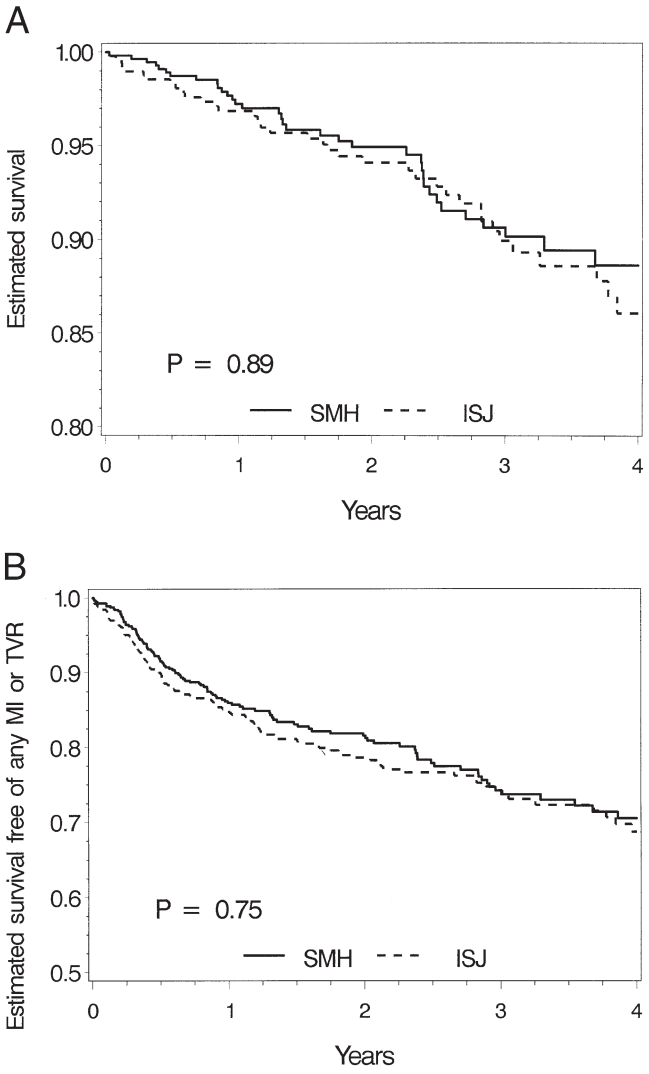

Figure 1. Kaplan-Meier curves relating treatment location to **(A)** survival and to **(B)** freedom from recurrent myocardial infarction (MI) or target vessel revascularization (TVR) for matched patients undergoing elective percutaneous coronary intervention. ISJ = Immanuel St. Joseph's Hospital–Mayo Health System; SMH = St. Mary's Hospital.

strict protocols for case selection and PCI program requirements are followed (Tables 1 and 6).

There is considerable disagreement about whether hospitals with cardiac catheterization laboratories, but without onsite cardiac surgery, should develop PCI programs (30–34). Opposing viewpoints have debated trade-offs between quality and outcomes versus convenience, cost implications for an institution versus the health care system, perceived versus real barriers to access, and patient-centered versus financial and political motives. Concerns raised against proliferation of PCI programs without onsite cardiac surgery argue that low-volume programs may result in poor outcomes as well as dilute procedural volume at current, high-volume institutions. Concern exists that patients are not provided sufficient information to evaluate whether a trade-off exists between convenience versus the quality and cost of the care they receive. Moreover, community hospitals face competitive and market pressures to offer comprehensive cardiovascular services and improve financial performance.

On the other hand, previous studies have shown that primary PCI for STEMI achieves similar outcomes at hospitals with or without cardiac surgery if performed in a timely manner and by experienced operators and institutions (17,24). Performing primary PCI at community hospitals may benefit patients who are not eligible for thrombolysis or who experience significant delays for transport to a hospital with onsite cardiac surgery. Because it will be difficult for operators and hospitals to maintain adequate volumes performing solely primary PCI, some community hospitals have expanded to performing low-risk elective PCI. Developing PCI programs without onsite cardiac surgery may also improve access to care for patients living in medically underserved regions or who face geographic or socioeconomic barriers to access at tertiary facilities. Patients also may prefer to be treated at facilities

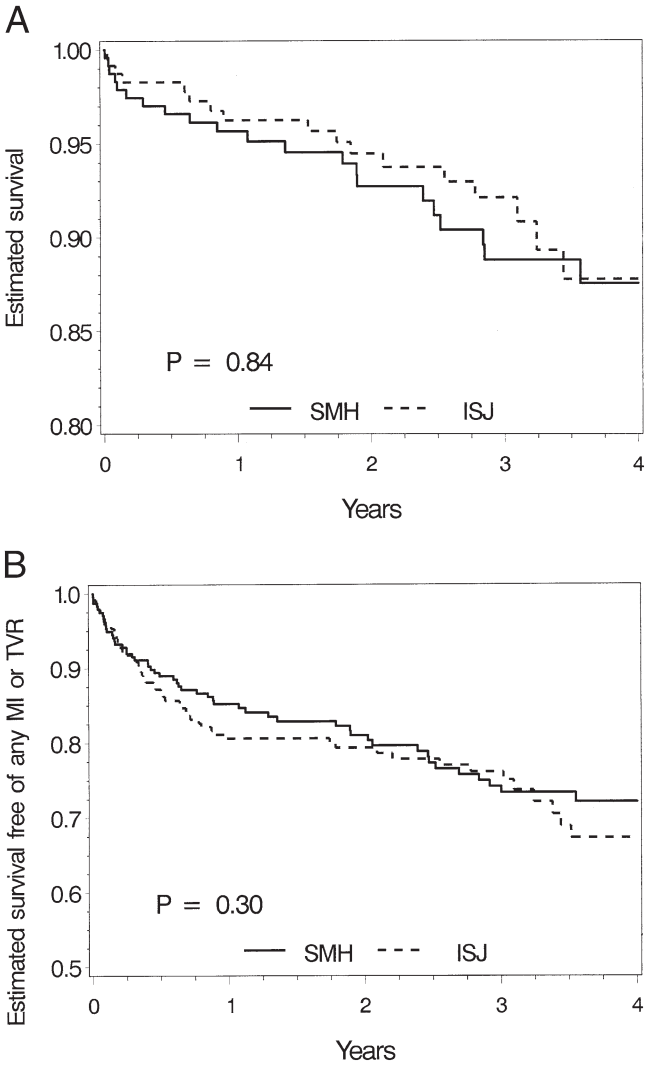

Figure 2. Kaplan-Meier curves relating treatment location to **(A)** survival and to **(B)** freedom from recurrent myocardial infarction (MI) or target vessel revascularization (TVR) for matched patients undergoing primary percutaneous coronary intervention. ISJ = Immanuel St. Joseph's Hospital–Mayo Health System; SMH = St. Mary's Hospital.

Table 6. Requirements for a PCI Program Without Onsite Cardiac Surgery

1. Experienced operators and team that perform minimal volumes. (Operator ≥75 total PCIs per year and ≥11 primary PCIs per year; institution ≥36 primary PCIs per year).
2. Operator is "cross"-trained, "cross"-credentialed, and "cross"-practicing PCI at a high-volume institution.
3. Well-equipped cardiac catheterization laboratory with a digital imaging system and full range of interventional equipment, including intra-aortic balloon pump for hemodynamic support.
4. Rigorous protocol for case selection (low-to-moderate lesion risk and clinical risk) that is continuously reviewed and approved by the relevant institutional practice committees.
5. Proven, tested protocol for rapid ambulance transport for patients with procedural complications requiring emergency cardiac surgery.
6. Formal quality assurance process for data collection, analysis, and review to evaluate procedural and clinical outcomes and benchmark with national standards.

PCI = percutaneous coronary intervention.

closer to home; furthermore, transferring patients to another hospital may incur errors from poor communication of medical information as well as increased costs if unnecessary tests are repeated (30,31).

Wennberg et al. (35) compared in-hospital and 30-day mortality for PCIs performed in Medicare enrollees (Medicare Provider Analysis and Review claims database) older than 65 years of age at hospitals with and without onsite cardiac surgery. For primary PCI, there was no difference in the adjusted mortality among hospitals without and with onsite cardiac surgery (11.3% vs. 12.2%, respectively, $p = 0.34$). For elective PCI, the adjusted mortality was 38% higher at hospitals without onsite cardiac surgery compared to those with onsite cardiac surgery (4.6% vs. 2.8%, respectively, $p = 0.001$). However, the observed increase in mortality for elective PCI was confined to low volume hospitals that performed fewer than 50 PCIs per year. Among the 10% of hospitals without onsite cardiac surgery with an annual volume of >50 PCIs per year, the observed mortality for elective PCI was similar without or with onsite cardiac surgery (adjusted odds ratio 1.04, 95% CI 0.76 to 1.41, $p = 0.83$).

The important relationship between operator/hospital volume and PCI outcomes has been documented by multiple investigators (36–42). The 2005 ACC/AHA PCI Guidelines provide class I recommendations for minimal operator volume (≥75 total PCIs per year and ≥11 primary PCIs per year) as well as minimal hospital volume (≥400 total PCIs per and ≥36 primary PCIs per year) for a high-volume institution (1). For a low-volume institution, the class IIa recommendation is for a hospital volume of ≥200 total PCIs per year.

The rationale for the ACC/AHA PCI Guidelines' current recommendation of onsite cardiac surgery for elective PCI is based on two assumptions: 1) immediate availability to cardiac surgery for hemodynamic or ischemic complications resulting from PCI, and 2) a surrogate measure of an institution's overall capability to provide appropriate care for emergency scenarios in the cardiac catheterization laboratory (1). However, efficacy and safety of performing elective and primary PCI are not simply related to the availability of onsite cardiac surgery per se; rather, they are more likely associated with the staff, infrastructure, and processes to provide the service. To ensure optimal quality and clinical outcomes, we recommend standard prerequisites for developing a PCI program without onsite cardiac surgery (Table 6). Our results should not be used to justify proliferation of low-volume PCI programs without onsite cardiac surgical capability. Conversely, we believe that health care systems must determine how best to concentrate their cognitive and capital resources, including PCI programs, to provide the safest and highest quality of care to a population.

Study limitations. As an observational, matched cohort analysis, we adjusted for observed clinical and angiographic differences between patient cohorts. However, we acknowledge that unaccounted differences may remain that may have influenced our findings. Although we tested the emergency transport system, no patients at ISJ actually required emergency cardiac surgery. Hence, we cannot definitively conclude that our transport system is adequate. Our findings may not be generalizable and are restricted to the experience of a single, high-volume referral center and a community hospital which are closely linked with regard to clinical care processes as well as the skill and training of physician and allied health staff.

Conclusions. Comparable clinical outcomes for elective PCI and primary PCI for STEMI can be achieved at a community hospital without onsite cardiac surgery and a tertiary care facility with onsite cardiac surgery. These results were obtained by developing and following strict protocols for case selection (Table 1) and PCI program requirements (Table 6). Additional research is warranted to assess whether this model of healthcare delivery is generalizable to other institutions and to study healthcare policy implications of where, when, and what PCI services "should" be provided to optimize quality, access, and cost for our patients.

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