

Elective Percutaneous Coronary Intervention Without On-Site Surgical Backup: A Community Hospital Experience

M. Djelmami-Hani, MD; Mouatou Mouanoutoua, MD; Abdelazim Hashim, MD; Joaquin Solis, MD; Lawrence Bergen, PhD; Neil Oldridge, PhD; Leo C. Egbujiobi, MD; Suhail Allaqaband, MD; Masood Akhtar, MD; Tanvir Bajwa, MD

ABSTRACT

Context: The American College of Cardiology guidelines consider elective percutaneous coronary intervention (PCI) without on-site surgical backup (OSB) a Class-III indication.

Objective: Our objective was to determine the safety of elective PCI without OSB.

Design: The study is a prospective analysis of a cohort of patients who underwent elective PCI without OSB at our institution. All patients were at our community satellite institution in Beloit, Wis. Three hundred twenty-one elective interventions were performed (mean age 64 ± 12 , 68% male). The prevalence of diabetes and hypertension was 28% and 82.5% respectively.

Intervention: A predefined protocol was designed to transfer patients to a cardiac surgical facility if necessary. An experienced interventional cardiologist reviewed the diagnostic angiograms. Patients with complex lesions were excluded from the study.

Main Outcome Measure: Any procedure-related death or emergency coronary artery bypass graft surgery.

Results: Three hundred eighty-two vessels were stented. Multi-vessel intervention was performed in 61 patients (19%). Only 5% of lesions were type C. Four hundred thirty-seven stents were deployed. IIB-IIIa inhibitors were used in 77 (24%) cases. Procedural success was 99.7%. There were no deaths, myocardial infarctions

nor need for urgent target vessel revascularization at 6 months.

Conclusion: With careful patient/lesion selection, an experienced interventional cardiologist and a predefined transfer protocol, elective PCI without OSB can be performed safely.

INTRODUCTION

The initial experience with percutaneous coronary intervention (PCI) indicated the need for on-site surgical backup for emergency coronary artery bypass graft surgery (ECABG) in up to 4% of the cases.¹⁻⁵ Therefore, the American College of Cardiology (ACC) recommended on-site surgical backup (OSB) for all coronary interventions at that time. However, after the introduction of stents in the 1990s, the need for ECABG has been reduced significantly to 0.4%-2%.⁶⁻⁸

During the same period, primary PCI has proved to be superior and safer than thrombolytic therapy for patients with ST-elevation myocardial infarction (STEMI), provided it is done in a timely manner by experienced operators.⁹ The recently published C-PORT trial confirms that PCI in STEMI patients can be performed effectively by experienced operators at institutions without on-site surgical backup.¹⁰ As a result, the ACC guidelines regarding PCI have been revised¹¹ and primary PCI for STEMI patients at hospitals without OSB has been given a class IIB recommendation, provided certain criteria are met (see Table 1 for class indication definition). These criteria include specified minimum levels of experience in PCI, both in regard to the individual operator and the facility as a whole and the presence of written protocols for immediate (<1 hour) and efficient transfer of the patient to the nearest cardiac surgical facility. Elective PCI without OSB, however, is still considered unsafe by the ACC and is given a class III recommendation.¹¹

Surveys in community hospitals have shown that

Author Affiliations: Aurora Sinai/Aurora St. Luke's Medical Centers, University of Wisconsin School of Medicine and Public Health, Milwaukee Clinical Campus, Milwaukee, Wis (Djelmami-Hani, Mouanoutoua, Hashim, Solis, Allaqaband, Akhtar, Bajwa); College of Health Sciences, University of Wisconsin-Milwaukee, Milwaukee, Wis (Oldridge); Beloit Memorial Hospital, Beloit, Wis (Bergen, Egbujiobi).

Corresponding Author: Tanvir Bajwa, MD, 2801 W Kinnickinnick River Pkwy #777, Milwaukee, WI 53215; phone 414.649.3390; fax 414.649.5769; e-mail bdanek@hrtcare.com.

Table 1. Class Indication Definition

Class I: Conditions for which there is evidence for and/or general agreement that the procedure/therapy is useful and effective.

Class II: Conditions for which there is conflicting evidence and/or a divergence of opinion about the usefulness/efficacy of performing the procedure/therapy.

Class IIa: Weight of evidence/opinion is in favor of usefulness/efficacy.

Class IIb: Usefulness/efficacy is less well established by evidence/opinion.

Class III: Conditions for which there is evidence and/or general agreement that the procedure/therapy is not useful/effective and in some cases may be harmful.

Table 2. Exclusion Criteria

Diffuse disease
 Excessive tortuosity of proximal segment
 Extremely angulated segments (>90°)
 Total occlusions >3 months old
 Inability to protect major side branches
 Unprotected left main
 Degenerated vein grafts with friable lesions
 Poor coronary guide catheter support
 Planned use of rotational atherectomy or directional atherectomy devices
 Poor baseline left ventricular function
 Peripheral vascular disease precluding the use of intra-aortic balloon pump
 Mayo Clinic Risk Score >10

Table 3. TIMI Grade Flow Definition

TIMI 0 refers to the absence of any antegrade flow beyond a coronary occlusion.

TIMI 1 flow is faint antegrade coronary flow beyond the occlusion, although filling of the distal coronary bed is incomplete.

TIMI 2 flow is delayed or sluggish antegrade flow with complete filling of the distal territory.

TIMI 3 flow is normal flow, which fills the distal coronary bed completely.

patients prefer and demand care close to home and avoid travel unless necessary. There are numerous reasons why people prefer to stay close to home. It interferes less with their work schedules, it lets them stay in the comfort of familiar surroundings, and it keeps them near their support system of family and friends.

Several centers with PCI programs without OSB have reported satisfactory results with careful patient and lesion selection as well as a well-predefined protocol to transfer patients to a surgical site in case of emergency.¹²⁻¹⁷ We report our experience with elective PCI at a community hospital without OSB.

METHODS

We developed and started a PCI program at Beloit Memorial Hospital (BMH) in January 2003. Beloit, Wis is located 55 miles south of Madison, Wis and 75 miles southwest of Milwaukee, Wis. The program was fully supported by the hospital administration and approved by the internal review board (IRB). The catheterization laboratory is well-equipped and staffed with interventional equipment. Intra-aortic balloon pump (IABP) is available as well as a code cart. The nursing and catheterization laboratory staff are well-trained and comfortable with the interventional equipment and with the handling of acutely ill patients. A clearly defined, written protocol was put in place for immediate transfer of patients to a nearby cardiac surgical facility and tested with drills. Dedicated ambulance was available during all interventions. The transfer time from lab to ambulance was 6 minutes and the transit time door-to-door averaged 23 minutes.

We prospectively followed all patients who presented to the hospital and underwent an elective PCI. Patients with acute ST segment elevation myocardial infarction (STEMI) and patients who required an immediate or emergency PCI, however, were excluded. Study patients underwent a diagnostic cardiac catheterization prior to the procedure. All catheterizations were done by the same invasive staff cardiologist. Coronary angiography films were reviewed by a cardiologist with high-volume interventional experience.

Patients with high-risk lesions, as described in Table 2, were transferred for intervention to a tertiary hospital with on-site surgical backup. Patients who underwent CABG were excluded. The decision as to which revascularization method to employ (PCI versus CABG) and whether to transfer the patient for on-site surgical backup PCI was left to the discretion of the interventional cardiologist. Appropriate informed consent was obtained from all patients. Eligible patients were brought back to the catheterization laboratory for elective PCI. Unless contraindicated, all patients received a loading dose of 325 mg of aspirin and 300 mg of plavix prior to the intervention. Heparin and glycoprotein IIb/IIIa inhibitors were used when indicated during the intervention. Active coagulation time was measured during and after the intervention.

Choice of stent type (drug-eluting or bare metal) was left to the discretion of the operator. All patients were observed at least overnight in the coronary intensive care unit. Successful PCI with stenting was defined as a residual diameter stenosis of <20% with thrombolysis in myocardial infarction (TIMI) 3 flow establishment (see TIMI flow grade

Table 4. Patients' and Lesions' Characteristics

	N (%), Mean [SD]
Total	321 Patients
Age	64 [±12]
Gender	218 Male (68%)
Diabetes	90 (28%)
Hypertension	265 (82.5%)
Hyperlipidemia	263 (82%)
Chronic renal failure	16 (5%)
Smoker	112 (35%)
Chronic obstructive pulmonary disease	29 (9%)
History of prior MI	40 (12.2%)
History of cerebrovascular accident	18 (6%)
LVEF (Mean)	56% [±10]
Acute coronary syndrome	132 (41%)
Unstable angina	55 (17%)
NSTEMI	77 (24%)
Number of diseased vessels per patient	
1	135 (42%)
2	112 (35%)
3 or more	74 (23%)
Lesion Morphology	(100%)
Type A	252 (66%)
Type B	99 (26%)
Type B2	11 (2.8%)
Type C	20 (5.2%)
Mean lesion stenosis	86% [±9]

AMI=acute myocardial infarction; LVEF=left ventricular ejection fraction; NSTEMI=non-ST elevation myocardial infarction.

definition in Table 3). Non-ST elevation myocardial infarction (NSTEMI) was defined by elevation of cardiac enzymes creatine kinase MB (CK-MB) and troponin-I above the upper normal value per our laboratory norms without ST segment elevation on the electrocardiogram (EKG). ST-elevation MI was defined as at least 2 mm elevation in at least 2 contiguous leads with reciprocal changes with angina or angina equivalent with or without troponin-I elevation. The normal troponin-I level in our laboratory was <0.2 ng/ml. Renal failure was defined as baseline creatinine >1.5 mg/dl. Unstable angina was defined as new-onset angina, rest angina, angina of increasing frequency or intensity, or angina lasting longer than 20 minutes. Coronary lesions were defined according to the ACC/AHA Classification Task Force.¹⁰ ECABG was defined as an emergency surgery for failed or complicated PCI. All patients were followed in-hospital and post discharge in the cardiology clinic.

Endpoints

The primary endpoints were any procedure-related death or complications requiring an ECABG.

Table 5. Characteristics of ACC/AHA Type A, B, and C Lesions

Type A Lesions (High Success, >85%, low risk)
Discrete (<10 mm length)
Concentric
Readily accessible
Nonangulated segment <45°
Smooth contour
Little or no calcification
Less than totally occlusive
Not ostial in location
No major branch involvement
Absence of thrombus
Type B Lesions (Moderate Success, 60%-85%, moderate risk)
Tubular (10-20 mm length)
Eccentric
Moderate tortuosity of proximal segment
Moderately angulated segment, 45-90°
Irregular contour
Moderate to heavy calcification
Ostial in location
Bifurcation lesions requiring double guidewires
Some thrombus present
Total occlusion <3 months old
Type C Lesions (Low Success, <60%, high risk)
Diffuse (>2 cm length)
Excessive tortuosity of proximal segment
Extremely angulated segments, >90°
Inability to protect major side branches
Degenerated vein grafts with friable lesions
Total occlusion >3 months old

Statistical Analysis

Continuous data are reported as the mean ± SD, unless otherwise specified. Categorical data are presented as absolute values and percentages.

Results

From January 2003 to April 2006, 382 vessels were stented in 321 procedures. Patient demographics and angiographic characteristics are shown in Table 4. The mean age was 64±12 with 68% males. The prevalence of diabetes and hypertension was 28% and 82.5% respectively. Forty patients (12.2%) had history of prior myocardial infarction and 18 (6%) had history of cerebrovascular accident. One hundred twelve patients (35%) were active smokers while 29 (9%) had chronic obstructive pulmonary disease (COPD). One hundred thirty-two (41%) procedures were in patients with acute coronary syndrome (17% unstable angina and 24% NSTEMI). The number of patients who had 1 vessel-disease was 135 (42%) while 112 (35%) had 2-vessel disease and 74 (23%) had 3-vessel disease or more.

Table 6. Interventional Data

Intervention	N (%) or Mean [SD]
Total number of PCIs	321
Multi-vessel PCI	61 (19%)
Vessels Stented	
Total	382
Right coronary artery	145 (37.9%)
Left anterior descending	149 (39%)
Left circumflex	76 (20%)
Left main	2 (0.5%)
Left internal mammary artery	2 (0.5%)
Marginal	3 (0.8%)
Ramus	3 (0.8%)
Posterior descending artery	2 (0.5%)
Number of Stents per Vessel	
1 stent	223 (69.5%)
2 stents	80 (24.9%)
3 stents	18 (5.6%)
Stents Used	
Total	437
Bare metal	35 (8%)
Cypher	149 (34%)
Taxus	253 (58%)
Mean stent diameter	3mm [±0.5]
Mean stent length	23mm [±7]
Dissection	9 (2.8%)
TIMI III flow achieved	321 (100%)
DeNovo	296 (92.2%)
Flouro Time (min)	6 [±3.5]
Sheath size (F)	6.29 [±0.7]
Anticoagulation	
Heparin	59 (18.4%)
Bivalirudin	262 (81.6%)
GP IIb/IIIa inhibitor	77 (24%)
Aspirin	289 (90%)
Clopidogrel	319 (99.4%)
Statins	289 (90%)
B-blockers	277 (86.3%)

Lesion morphology, as defined in Table 5, was Type A in 252 (66%), Type B in 99 (26%), Type B2 in 11 (2.9%), and Type C in 20 (5.1%). The mean left ventricle ejection fraction was 56% ±10 and the mean lesion stenosis was 86% ±9.

A total of 382 vessels underwent PCI including 149 (39%) left anterior descending, 145 (38%) right coronary, 76 (20%) left circumflex and 2 (0.5%) protected left main coronary arteries (see Table 6 for percent of other vessels stented). Multi-vessel PCI was performed in 61 patients (19%). De novo lesions comprised 92.3%, and 7.7 % were in-stent restenosis.

A total of 437 stents were deployed; 35 (8%) bare metal, 149 (34%) Cypher (Cordis Corp., Miami Lakes,

Fla) and 253 (58%) Taxus (Boston Scientific Corporation, Natick, Mass). The mean stent diameter was 3 mm ±0.5. The mean stent length was 23 mm ±7. During the procedure, 59 patients (18.4%) received heparin while 262 (81.6%) received bivalirudin. A glycoprotein IIb-IIIa inhibitor was used in 77 (24%) of cases. Groin hematomas after PCI occurred in 3 patients, none of which required surgical intervention or transfusion. Aspirin and clopidogrel were used in 289 (90%) and 319 (99.4%) cases respectively.

Procedural success, as defined above, was achieved in 99.7% of patients. In one patient, PCI was unsuccessful, as the lesion was heavily calcified and could not be dilated with a balloon. The patient was stable, the procedure was stopped and the patient was electively transferred and treated at a hospital with OSB with rotational atherectomy followed by stenting. Non flow-limiting dissections occurred in 9 vessels (2.3%) during PCI but were successfully treated with stenting. None of the patients required ECABG. The mean hospital stay after the procedure was 2 days. There were no deaths, cardiac arrests, reinfarction, or target vessel revascularizations during the hospital stay or at 30-days post procedure.

DISCUSSION

Coronary interventions have evolved significantly since the first reports of PCI.⁶⁻⁸ Before the introduction of stents in the mid 1990s, PCI carried a significant risk of serious complications such as flow-limiting dissections, abrupt vessel closure and perforation of the target vessel¹⁻⁵ and up to 4% of patients eventually required ECABG. With the introduction of stents, ECABG has seen a continuous and remarkable decline.⁶⁻⁸ Surgical backup has evolved from a formal in-house surgical team and an operating room on standby to a simple arrangement that the surgical team be available if needed. Even with the marked decline in need for ECABG after years of stenting experience, elective PCI without OSB is still considered a class III indication by the ACC in its latest guidelines published in 2005.¹¹ The ACC argues that some important clinical concerns are not yet addressed, such as timely management of ischemic complications, the adequacy of specialized post-interventional care, as well as accreditation questions.

We certainly agree that starting an angioplasty program without OSB could be risky if done without strict guidelines and protocols, the most important of which would be the presence of an experienced operator, able to perform PCIs safely and deal with any unforeseen complications. The support staff in the laboratory must be equally well-trained to assist in these interventions.

Availability of appropriate equipment in the lab to perform these interventions safely and effectively and to deal with any complications must also be a high priority. A staff of well-trained nurses capable of taking care of the patients after the intervention is also critical to the success of such a program. Finally, a formal protocol for transferring patients emergently, in a timely manner, to a facility with OSB if the need arises, must be in place and well tested prior to the start of such a program.

However, daily and practical experience has proved the safety of PCI without OSB. Many centers have reported their experience, including the large prospective study by Ting et al¹⁷ at the Mayo Clinic. We believe the ACC guidelines are more politically motivated than based on scientific data. Tertiary care centers have seen a decline in referrals for PCI from community hospitals with programs using PCI without OSB.

PCI programs in community hospitals are needed in rural areas where there are limited or no cardiovascular surgical facilities or surgeons. Patients in these areas benefit from the proximity of care available near home with less stress and disruption to their personal lives and lower travel-related expense. Careful patient follow-up is important and being able to accomplish this in close proximity to the patient's home boosts compliance as well. By allowing community hospitals that meet the criteria to start an elective PCI program without OSB, we will increase physicians' experience and comfort with the procedure and will improve the skill level of the nursing and catheterization laboratory staff. This should also result in improved outcomes for primary PCI without OSB in these community hospitals, which is presently considered a IIb indication by the ACC.

With careful patient and lesion selection, elective PCI without OSB can be safely performed in community hospitals with an experienced operator and nursing staff and a well pre-defined protocol for immediate transfer to surgery.

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