JACC: CARDIOVASCULAR INTERVENTIONS
VOL. 2, NO. 1, 2009

ISSN 1936-8798/09/$36.00
PUBLISHED BY ELSEVIER INC.
DOI: 10.1016/j.jcin.2008.08.021

Incomplete Revascularization in the Era of Drug-Eluting Stents

Impact on Adverse Outcomes

Edward L. Hannan, PhD, FACC,* Chuntao Wu, MD, PhD,*† Gary Walford, MD, FACC,‡ David R. Holmes, MD, FACC,§ Robert H. Jones, MD, FACC,|| Samin Sharma, MD, FACC,¶ Spencer B. King III, MD, MACC#

Albany, Syracuse, and New York, New York; Hershey, Pennsylvania; Rochester, Minnesota; Durham, North Carolina; and Atlanta, Georgia

Objectives We sought to compare outcomes for percutaneous coronary intervention patients undergoing complete revascularization (CR) and incomplete revascularization (IR) in the drug-eluting stent era.

Background There have been relatively few studies that have examined the impact of IR in patients undergoing coronary stenting, particularly in the era of drug-eluting stents.

Methods New York State's Percutaneous Coronary Intervention Reporting System was used to identify 11,294 stent patients with multivessel disease undergoing either IR or CR in 39 hospitals between October 1, 2003, and December 31, 2004. These patients were followed through December 31, 2005, and IR patients were subdivided based on the number of IR vessels and presence of a chronic total occlusion. Risk-adjusted mortality and mortality/myocardial infarction (MI) for CR and IR patients were compared at 18 months.

Results Incomplete revascularization was performed in a total of 7,795 patients (69.0%). Incomplete revascularization was associated with higher 18-month mortality (adjusted hazard ratio [HR]: 1.23, 95% confidence interval [CI]: 1.04 to 1.45) and higher 18-month MI/mortality (adjusted HR: 1.27, 95% CI: 1.09 to 1.47). The risk-adjusted survival rates for CR and IR were 94.9% and 93.8% ($p = 0.01$). The risk-adjusted survival/freedom from MI rates were 93.3% and 91.7% ($p = 0.002$). Patients with 2 diseased vessels unattempted with a total occlusion were at highest risk (adjusted survival HR: 1.44, 95% CI: 1.14 to 1.82, risk-adjusted survival 94.9% vs. 92.9%, $p = 0.002$; and adjusted survival/freedom from MI: 1.50, 95% CI: 1.21 to 1.86, rates 93.3% vs. 90.3%, $p < 0.001$).

Conclusions Patients undergoing coronary stenting who receive IR experience more adverse outcomes even in the era of drug-eluting stents. This has implications for choice of procedure and post-procedural monitoring. (J Am Coll Cardiol Intv 2009;2:17–25) © 2009 by the American College of Cardiology Foundation

From the *University at Albany, State University of New York, Albany, New York; †Penn State Hershey College of Medicine, Hershey, Pennsylvania; ‡St. Joseph's Hospital, Syracuse, New York; §Mayo Clinic, Rochester, Minnesota; ||Duke University Medical Center, Durham, North Carolina; ¶Mt. Sinai Medical Center, New York, New York; and #St. Joseph's Hospital, Atlanta, Georgia. Dr. Sharma is the recipient of a research grant from Boston Scientific and has Speakers' Bureau appointments with Boston Scientific, Abbott Vascular, and Lilly. Dr. King receives royalties from Cordis and serves as a consultant/advisory board member of Medtronic. Sotirios Tsimikas, MD, FACC, served as Guest Editor.

Manuscript received July 10, 2008; revised manuscript received August 19, 2008, accepted August 22, 2008.

Unlike coronary artery bypass graft (CABG) surgery, where most patients are completely revascularized and where complete revascularization (CR) has been demonstrated to be associated with better long-term outcomes, the strategy for multivessel disease patients undergoing percutaneous coronary interventions (PCI) frequently involves incomplete revascularization (IR). In IR, balloon angioplasty and stent placement are performed (or performed successfully, depending on the definition) on only some of the patient's diseased vessels. Reasons for not attempting all diseased vessels may include the presence of 1 or more chronic total occlusions, the presence of serious medical conditions such as severe left ventricular dysfunction, or the decision to treat only the "culprit lesion" that is thought to be responsible for the patient's symptoms.

Although multiple studies (1–17) have compared outcomes of patients who have been completely and incompletely revascularized with PCI, few of these are recent. Most of these studies were conducted before the introduction of coronary stenting, and many were conducted in the context of randomized trials in which incompletely revascularized patients were monitored more closely than they would be under normal circumstances.

The purpose of this study was to compare outcomes (18-month mortality, 18-month mortality/myocardial infarction [MI]) for patients with multivessel disease who were completely and incompletely revascularized using stents in the era following the introduction of drug-eluting stents (DES). When significant differences were found, we then focused on groups of IR patients for whom the outcomes were the worst.

Abbreviations and Acronyms

CABG = coronary artery bypass graft

CR = complete revascularization

CTO = chronic total occlusion

DES = drug-eluting stent(s)

IR = incomplete revascularization

MI = myocardial infarction

PCI = percutaneous coronary interventions

PCIRS = Percutaneous Coronary Intervention Reporting System

Methods

Databases. Data were obtained from New York State's Percutaneous Coronary Interventions Reporting System (PCIRS), a mandatory registry in New York, which was initially developed in 1992, that contains detailed information for each patient undergoing PCI in the state on demographics; pre-procedural risk factors; peri-procedural complications; types of devices used; lesions diseased; dates of admission, discharge, and procedure; discharge disposition and destination; and hospital and operator identifiers. Also, PCIRS contains information on diseased and attempted lesions, including regions of the heart, whether or not a lesion was attempted, and pre- and post-procedural stenosis. These data are matched to New York administrative data and are audited by the New York State Department of Health's utilization review agent to ensure completeness and accuracy.

The PCIRS data were matched to New York's vital statistics data so that patients could be followed after discharge for evidence of subsequent death. Also, PCIRS data were matched to data in New York's acute care administrative database, the Statewide Planning and Research Cooperative System, to identify stent patients readmitted to New York hospitals with a principal diagnosis of MI using unique patient identifiers. Furthermore, data from New York's Cardiac Surgery Reporting System was used along with PCIRS data to identify repeat revascularizations after discharge through December 31, 2005.

Patients. Patients in the study included all patients with multivessel disease (defined as stenosis ≥70% in at least 2 of the 3 main coronary arteries) who underwent stenting in nonfederal New York State hospitals between October 1, 2003, and December 31, 2004, and followed through December 31, 2005, except patients with previous revascularization (n = 5,642), left main disease (defined as stenosis >50%, n = 189), an acute MI during the 24-h period before undergoing PCI (n = 2,254); CABG surgery following PCI during the index admission (n = 44); and non–New York patients (n = 430). The study was limited to New York residents because the New York Vital Statistics Death File only applies to residents of the state.

"Complete revascularization" was defined as successfully attempting all diseased (≥70% stenosis) lesions in major epicardial coronary vessels (proximal, mid, and distal segments; major left anterior descending diagonals; and circumflex marginal branches) with PCI either during the index hospitalization or at any time within 30 days after discharge from the index hospitalization for PCI but before suffering a new MI. Success was defined as a reduction in stenosis of at least 20% and a residual stenosis of less than 50%. Patients not meeting the definition of CR were defined to have IR.

End points. End points in the study were 18-month mortality, mortality/MI, subsequent CABG (new admission more than 30 days after discharge), and repeat PCI (new admission more than 30 days after discharge). Myocardial infarctions occurring after PCI during the index admission were defined in PCIRS as new Q waves and a rise in cardiac enzyme to at least 2.5 times the normal range. Myocardial infarctions occurring after discharge were obtained using Statewide Planning and Research Cooperative System data and were defined as readmissions with *International Classification of Diseases–Ninth Revision–Clinical Modification* code 410.x1 as a principal diagnosis. All adverse outcomes were risk-adjusted to account for differences in baseline risk of CR and IR patients.

Statistical analysis. Differences in baseline characteristics between CR and IR patients (e.g., demographics, comorbidities, left ventricular function, hemodynamic state, vessels diseased, symptoms) were examined using Fisher exact and chi-square tests.

To test for risk-adjusted differences in mortality and mortality/MI, stepwise Cox proportional hazards survival models with a robust covariance matrix that accounts for correlation of survival times for individuals within a hospital or operator cluster (18) were developed for each adverse outcome measure after having confirmed that the proportional hazards assumption was justified (19). Candidate independent variables included the patient risk factors available in PCIRS (demographics, left ventricular function, MI more than 1 day before the procedure, and numerous comorbidities). Type of revascularization (CR, IR) was used in each model as an independent variable with IR treated as the indicator variable, and the CR/IR adjusted hazards ratios were obtained by exponentiation of the coefficient of that variable. Adjusted survival curves were constructed for CR and IR for each of the 2 outcomes using the Cox proportional hazards survival models and methods for calculating adjusted survival (20).

Different types of IR (1-vessel IR/no total occlusion; 1-vessel IR/total occlusion; 2-vessel IR/no total occlusion; 2-vessel IR/at least 1 total occlusion) were then compared with CR for each adverse outcome by creating similar proportional hazards models with each of the IR types as a binary indicator variable and CR as the reference. Patients with total occlusions were examined separately because they are in danger of having worse longer-term outcomes and because IR may sometimes be justified in these patients when there is no viable myocardium to be preserved.

Cox proportional hazards survival models were also used to test for significance of hazards ratios for 4 subsets of patients: 1) patients who were at least 80 years old; 2) were diabetics; 3) had ejection fractions of 40% or less; and 4) had left anterior descending artery disease. For subsequent CABG surgery and repeat PCI, log-rank tests were used to compare Kaplan-Meier survival estimates of survival differences between CR and each type of IR.

To test for selection bias, a propensity model was developed (21,22). The risk factors in Table 1 were used as independent variables in a logistic regression model with a binary dependent variable representing IR. Also, the percentage of patients in which CR was attempted in the hospital in which each patient underwent stenting was used as independent variable in the model in case outcomes were related to the quality of the hospital. The propensity score was subdivided into quartiles and 18-month hazards ratios for IR/CR were examined across quartiles for mortality and mortality/MI to determine if there was any trend or major difference based on the tendency to use CR versus IR. All tests were 2-sided and conducted at the 0.05 level, and all analyses were conducted in SAS 9.1 (SAS Institute, Cary, North Carolina).

Table 1. Baseline Characteristics of Stent Patients (N = 11,294)

Variable	CR (n = 3,499)	IR (n = 7,795)	p Value
Age, yrs			<0.001
<50	10.5	9.0	
50–59	24.0	22.1	
60–69	27.9	27.3	
70–79	26.4	27.1	
80+	11.2	14.5	
Gender			0.71
Male	66.8	67.1	
Female	33.2	32.9	
Race and ethnicity			<0.001
Hispanic	7.5	10.1	
Non-Hispanic Black	7.1	11.2	
Non-Hispanic White	79.4	71.7	
Other	5.9	7.0	
Ejection fraction, %			<0.001
<19	0.3	1.1	
20–29	2.3	3.9	
30–39	5.1	7.6	
40+	87.1	82.2	
Missing	5.1	5.2	
Previous MI			<0.001
1–7 days	19.3	20.1	
8–20 days	1.8	2.9	
≥21 days	7.7	14.7	
No MI prior to procedures	71.2	62.4	
Cerebrovascular disease	7.3	8.2	0.08
Peripheral arterial disease	5.1	8.3	<0.001
Hemodynamically unstable or shock	0.3	0.3	1.0
Congestive heart failure			<0.001
None	91.9	88.2	
This admission	6.0	8.6	
Before this admission	2.1	3.2	
Malignant ventricular arrhythmia	0.4	0.5	0.45
Chronic obstructive pulmonary disease	6.1	6.8	0.15
Diabetes	28.3	34.3	<0.001
Renal failure			<0.001
Requiring dialysis	2.0	2.6	
Creatinine >2.5 mg/dl	0.9	1.7	
No renal failure	97.1	95.7	
Number of diseased vessels (stenosis ≥70%)			<0.001
2	90.1	68.4	
3	9.9	31.6	
Type of stents implanted			<0.001
Bare-metal stents only	8.1	13.7	
Drug-eluting stents only	75.5	80.2	
Other	16.5	6.1	

CR = complete revascularization; IR = incomplete revascularization; MI = myocardial infarction.

Table 2. Adjusted HR (IR and IR Subgroups vs. CR) and 95% CI for 18-Month Mortality and Mortality/MI by Subgroups of IR

			Mortality			Mortality/MI		
Patient Group	No. of Cases	Mean Length of Follow-up (Months)	No. of Events	Adjusted HR* (95% CI)	p Value	No. of Events	Adjusted HR† (95% CI)	p Value
CR	3,499	19.0	165	Reference		216	Reference	
IR	7,795	18.9	551	1.23 (1.04–1.45)	0.01	736	1.27 (1.09–1.47)	0.002
Subgroups of IR								
1 IR vessel with no total occlusion	3,815	18.9	239	1.23 (1.02–1.48)	0.03	316	1.22 (1.04–1.44)	0.02
1 IR vessel with total occlusion	1,725	19.1	112	1.11 (0.87–1.42)	0.39	145	1.14 (0.92–1.41)	0.24
≥2 IR vessels with no total occlusion	1,233	19.1	92	1.18 (0.89–1.56)	0.26	132	1.34 (1.04–1.73)	0.03
≥2 IR vessels with total occlusion	1,022	18.4	108	1.44 (1.14–1.82)	0.002	143	1.50 (1.21–1.86)	<0.001

Note that all the significant predictors were also significant predictors after adjusting for propensity score. *Adjusted for age, race/ethnicity, ejection fraction, history of myocardial infarction prior to procedure, cerebrovascular disease, peripheral arterial disease, hemodynamic state, congestive heart failure, chronic obstructive pulmonary disease, renal failure, and type of stents implanted. †Adjusted for all control variables for the mortality model and diabetes.

CI = confidence intervals; HR = hazard ratios; other abbreviations as in Table 1.

Results

A total of 7,795 patients (69.0%) were classified as IR patients. The range across the 39 hospitals in percentage of patients who were IR was 45% to 89%. Of the IR patients, 48.9% had 1-vessel IR with no chronic total occlusion (CTO), 22.1% had 1-vessel IR with a CTO, 15.8% had 2-vessel IR with no CTO, and 13.1% had 2-vessel IR with a CTO.

Significant predictors of IR include advanced age, race (higher rates for African Americans and Hispanics), lower ejection fractions, previous MI, and several comorbidities: peripheral arterial disease, congestive heart failure, diabetes, renal failure, 3-vessel disease, and the exclusive use of bare-metal stents (see Table 1).

Table 2 indicates that after adjustment for differences in baseline characteristics between IR and CR patients, IR was associated with higher 18-month mortality (adjusted hazard ratio [HR]: 1.23, 95% confidence interval [CI]: 1.04 to 1.45) and higher 18-month MI/mortality (adjusted HR: 1.27, 95% CI: 1.09 to 1.47). The respective risk-adjusted survival rates (Fig. 1A) for CR and IR were 94.9% and 93.8% ($p = 0.01$). The risk-adjusted survival/freedom from MI rates (Fig. 2A) were 93.3% and 91.7% ($p = 0.002$).

There were 2 IR groups for which IR patients had significantly higher mortality: patients with 1-vessel disease with no occlusion (adjusted HR: 1.23, 95% CI: 1.02 to 1.48), risk-adjusted survival 94.9% versus 93.8%, $p = 0.03$ (Fig. 1B), and patients with 2 diseased vessels unattempted with a total occlusion (adjusted HR: 1.44, 95% CI: 1.14 to 1.82), risk-adjusted survival 94.9% versus 92.9%, $p = 0.002$ (Fig. 1B).

Incomplete revascularization patients had significantly higher mortality/MI rates for 3 of the 4 groups of IR patients: 1-vessel IR with no total occlusion (adjusted HR: 1.22, 95% CI: 1.04 to 1.44), risk-adjusted survival/freedom from MI, 93.3% versus 91.9%, $p = 0.02$; 2-vessel IR with no total occlusion (adjusted HR: 1.34, 95% CI: 1.04 to 1.73), risk-adjusted survival/freedom from MI, 93.3% versus 91.3%, $p = 0.03$; and 2-vessel IR with total occlusion (adjusted HR: 1.50, 95% CI: 1.21 to 1.86), risk-adjusted survival/freedom from MI, 93.3% versus 90.3%, $p < 0.001$ (Fig. 2B).

For stent patients with CR, a total of 1.6% had subsequent CABG surgery within 18 months (Kaplan-Meier estimate). Compared with CR, the need for subsequent CABG surgery was significantly higher for patients with 2-vessel IR with a total occlusion (3.4%, $p < 0.001$) and patients with 2-vessel IR and no total occlusion (2.7%, $p = 0.02$). Patients with 1-vessel IR with or without total occlusions did not have significantly different rates of subsequent CABG surgery (2.2% and 1.5%, respectively).

A total of 13.5% of stent patients with CR had repeat PCI within 18 months. Patients with 2-vessel IR with and without a total occlusion both had higher rates of repeat PCI (20.3% and 29.5%, respectively, $p < 0.001$ for both groups). Patients with 1-vessel IR and a total occlusion did not have a significantly different rate of repeat PCI (11.7%, $p = 0.09$) and patients with 1-vessel IR and no total occlusion had a significantly higher rate (22.1%, $p < 0.001$).

Of the patients in the study, 9,936 (88.0%) had at least 1 DES. Of those patients, IR patients were trending toward higher 18-month mortality compared with 18-month mortality in CR patients (adjusted HR: 1.21, 95% CI: 0.99 to 1.46) and IR had higher mortality/MI (adjusted HR: 1.30, 95% CI: 1.09 to 1.53). Two IR subgroups had significantly higher mortality, with the highest HR for patients with 2 diseased vessels unattempted with a total occlusion (adjusted HR: 1.34, 95% CI: 1.01 to 1.77). Of the 4 groups, 3 groups had higher mortality/MI rates for IR patients, with the largest HR for patients with 2 diseased vessels unattempted with a total occlusion (adjusted HR: 1.49, 95% CI: 1.17 to 1.89).

With respect to selected subgroups of patients, Table 3 indicates that there were no significant differences in adjusted mortality between CR and IR for diabetics, patients with ejection fractions that were at most 40%, or patients at least 80

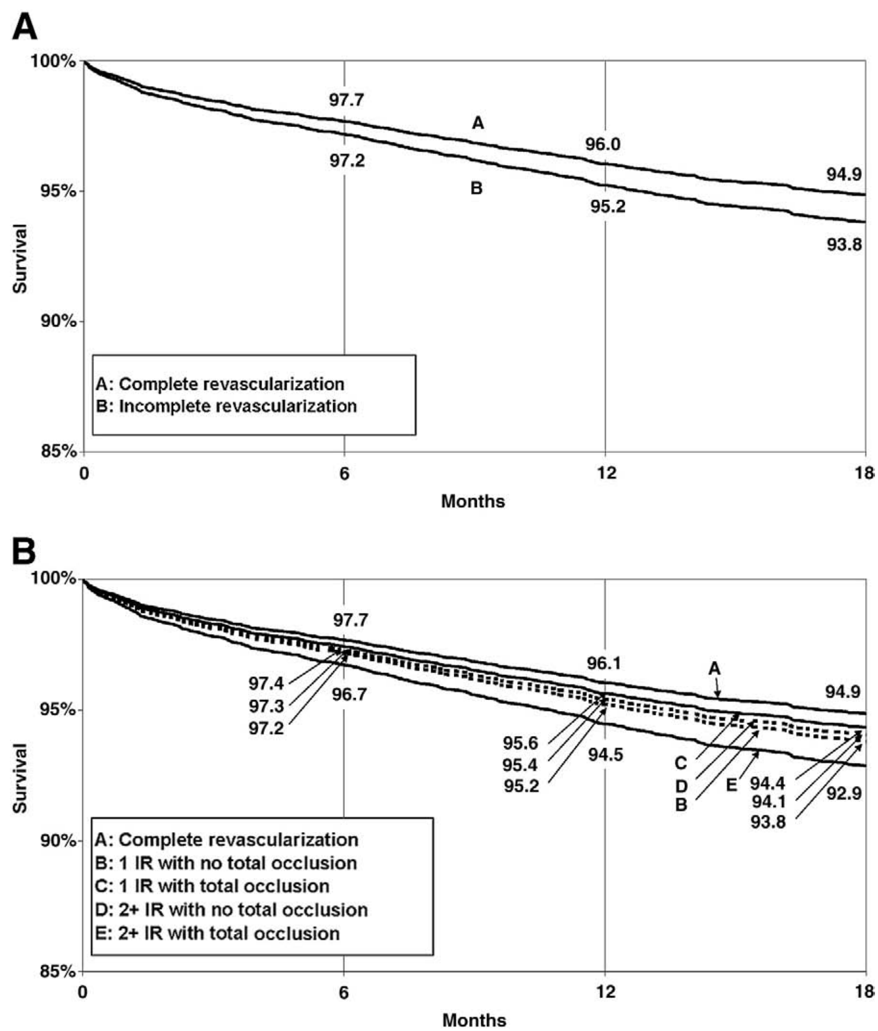

Figure 1. Adjusted 18-Month Survival Curves

(A and B) Adjusted for age, race/ethnicity, ejection fraction, history of myocardial infarction prior to procedure, cerebrovascular disease, peripheral arterial disease, hemodynamic state, congestive heart failure, chronic obstructive pulmonary disease, renal failure, and type of stents implanted. IR = incomplete revascularization.

years old. Patients with a diseased left anterior descending artery fared better with CR (adjusted HR: 1.25, 95% CI: 1.02 to 1.54). There were no significant differences between CR and IR in mortality/MI rates for patients with ejection fractions that were at most 40%, but IR patients who were diabetic or who had left anterior descending artery disease had significantly higher rates (adjusted HR: 1.29, 95% CI: 1.01 to 1.65, and adjusted HR: 1.28, 95% CI: 1.05 to 1.56, respectively), and IR patients who were age 80 years or older had borderline higher rates (adjusted HR: 1.32, 95% CI: 1.00 to 1.75).

In the propensity model, the C statistic was in the appropriate range—reasonably high (0.73) but not so high as to be indicative of 2 groups of patients with no commonality. Hazards ratios in order of increasing tendency to use IR for the quartiles related to mortality were 1.14, 1.24, 1.23, and 1.01. Hazards ratios for mortality/MI were 1.42, 1.12, 1.35, and 1.01. Although the HR in the last quartile for each outcome was the lowest, there was no evidence of a trend toward lower HRs with increasing tendency to use IR. Also, all patients in the last quartile were removed from the database for each outcome, and 2 new sets of analyses were conducted. The resulting HRs were nearly identical to the original HRs (1.23 for mortality compared with the original 1.23, and 1.27 for mortality/MI compared with the original 1.29).

Discussion

Surprisingly few studies have compared outcomes for patients completely and incompletely revascularized for

JACC: CARDIOVASCULAR INTERVENTIONS, VOL. 2, NO. 1, 2009
JANUARY 2009:17–25

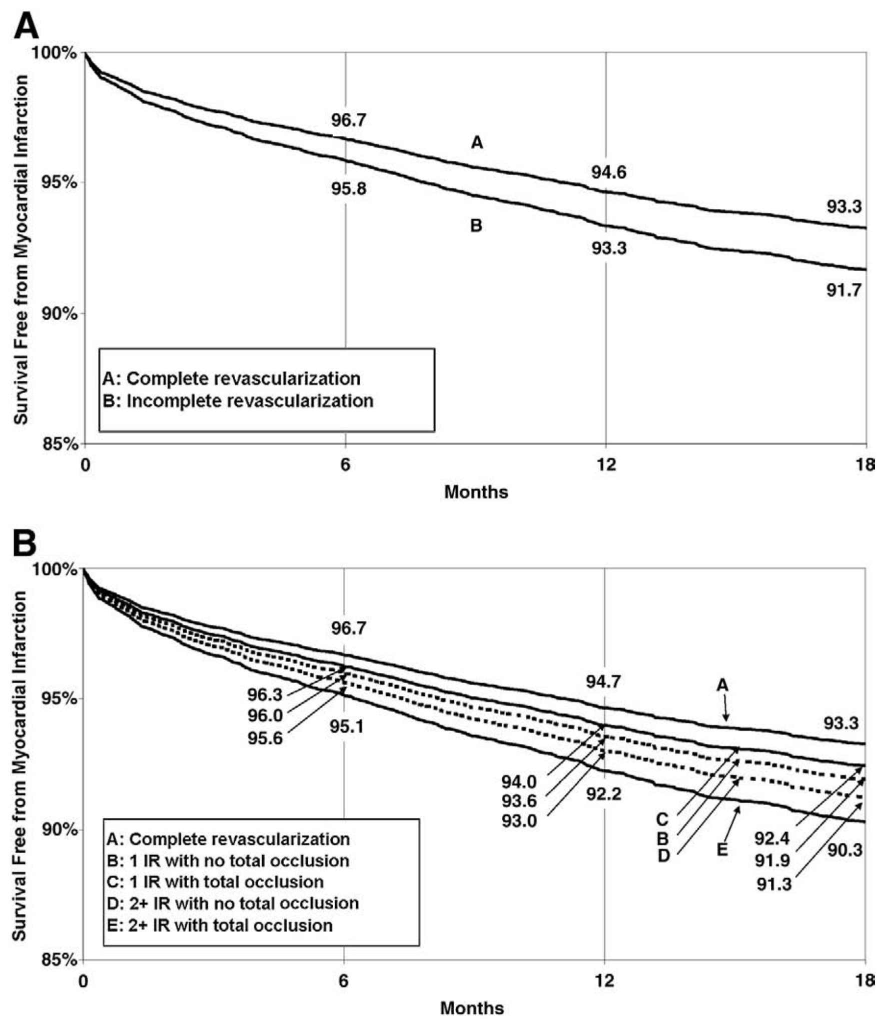

Figure 2. Adjusted 18-Month Curves for Survival Free From MI

(A and B) Adjusted for age, race/ethnicity, ejection fraction, history of myocardial infarction (MI) prior to procedure, cerebrovascular disease, peripheral arterial disease, hemodynamic state, congestive heart failure, chronic obstructive pulmonary disease, renal failure, and type of stents implanted. IR = incomplete revascularization.

PCI. Most of those pre-date the use of stents, particularly DES.

Most earlier studies that examined the impact of IR for PCI were considerably smaller and were conducted before the DES era. Some of these studies found no differences in outcomes between IR and CR patients, but these studies were quite small. For example, Mariani et al. (1) and Ijsselmuiden et al. (17) found that there was no difference in major adverse cardiac event rates between CR and IR patients, but both studies had very low statistical power. In the Ijsselmuiden et al. (17) study, major adverse cardiac event rates were found to be the same at 4.6 $\pm$ 1.2 years (34.6% for CR vs. 40.4% for IR) and repeat PCI rates were also found to be the same (21.2% vs. 31.2%, $p = 0.06$). However, the lack of statistical significance may be because there were only 108 CR patients and 111 IR patients in the study. Similarly, the Mariani et al. (1) study had only 49 CR patients and 159 IR patients.

Of the other studies, 2 found significantly higher rates of subsequent CABG surgery among IR patients. In the ARTS (Arterial Revascularization Therapies Study) trial, van den Brand et al. (3) found that after 1 year, patients undergoing IR with stenting experienced significantly lower event-free survival (freedom from death, MI, cerebrovascular accident, and repeat revascularization) than stent patients with CR did (69.4% vs. 76.6%, $p < 0.05$), and that this difference was due to a higher use of subsequent CABG surgery (10.0% vs. 2.0%, $p < 0.05$).

Bourassa et al. (4) found in the BARI (Bypass Angioplasty Revascularization Investigation) trial that among

Table 3. Adjusted HR (IR vs. CR) and 95% CI for Mortality and Mortality/MI for Selected Subgroups of Patients

Patient Group	Completeness of Revascularization	No. of Cases	Mean Length of Follow-up (Months)	Mortality			Mortality/MI		
				No. of Events	Adjusted HR* (95% CI)	p Value	No. of Events	Adjusted HR† (95% CI)	p Value
Diabetes	CR	991	18.7	66	Reference		84	Reference	
	IR	2,673	18.7	216	1.11 (0.85–1.44)	0.46	317	1.29 (1.01–1.65)	0.04
Ejection fraction <40%	CR	273	18.4	31	Reference		36	Reference	
	IR	976	18.1	149	1.18 (0.78–1.79)	0.42	183	1.29 (0.88–1.89)	0.20
Age ≥80 yrs	CR	393	18.2	43	Reference		50	Reference	
	IR	1,132	18.1	184	1.28 (0.94–1.73)	0.12	218	1.32 (1.00–1.75)	0.05
Left anterior descending artery disease	CR	2,634	18.7	125	Reference		166	Reference	
	IR	3,362	18.5	254	1.25 (1.02–1.54)	0.04	338	1.28 (1.05–1.56)	0.02

Note that all the significant predictors were also significant predictors after adjusting for propensity score. *Adjusted for age, race/ethnicity, ejection fraction, history of myocardial infarction prior to procedure, cerebrovascular disease, peripheral arterial disease, hemodynamic state, congestive heart failure, chronic obstructive pulmonary disease, renal failure, and type of stents implanted. †Adjusted for all control variables for the mortality model and diabetes.
Abbreviations as in Tables 1 and 2.

nondiabetic patients who were candidates for CABG surgery, 5-year rates of death, cardiac death, repeat revascularization, and angina were similar in all PCI patients with CR and IR. However, there was a trend for higher rates of freedom from subsequent CABG surgery among CR patients (70.3% vs. 64.0%, p = 0.08).

Three other studies found that CR was superior to IR with regard to mortality as well as other outcomes. In a single center observational study, Kalarus et al. (13) found that among PCI patients with acute MI, remote mortality (18.5% vs. 7.2%, p < 0.001) and major adverse cardiac event (53.1% vs. 24.3%, p < 0.001) rates were both higher for IR patients than for CR patients.

Nikolsky et al. (5) examined 658 consecutive diabetic patients (94 CR patients and 258 IR patients) who underwent PCI and found that CR patients had a significantly higher survival rate at 5 years (94.5% vs. 83.0%, p < 0.001). Also, the rate of MI-free survival was significantly higher for CR patients (92.9% vs. 79.9%, respectively).

An earlier study in New York also identified better outcomes for CR patients. In an era before the use of DES, Hannan et al. (12) found that patients undergoing bare-metal stenting for whom IR was intended were significantly more likely to die at any time than other patients (adjusted HR: 1.15, 95% CI: 1.01 to 1.30). Furthermore, IR patients with total occlusions and 2 or more vessels IR comprised 14% of all IR patients and had the highest risk compared with CR patients (adjusted HR: 1.36, 95% CI: 1.12 to 1.36). Incomplete revascularization patients with a single total occlusion IR comprised 21% of all IR patients and had the second highest risk (adjusted HR: 1.35, 95% CI: 1.14 to 1.59).

The study reported here found that that the percentage of stent patients who were classified as IR in the era of DES was 69.0%. Incomplete revascularization was associated with significantly higher 18-month mortality (adjusted HR: 1.23, 95% CI: 1.04 to 1.45) and higher 18-month MI/mortality (adjusted HR: 1.27, 95% CI: 1.09 to 1.47). The risk-adjusted survival rates for CR and IR were 94.9% and 93.8% (p = 0.01) and the risk-adjusted survival/freedom from MI rates were 93.3% and 91.7% (p = 0.002).

Subsequent analyses subdivided patients on the basis of the number of diseased vessels IR and on the basis of whether they had total occlusions. Patients with total occlusions were examined separately because they are in danger of having worse longer-term outcomes and because IR may sometimes be justified in these patients when there is no viable myocardium to be preserved. Because we were unable to identify when this is the case, we wanted to see if the benefit of CR relative to IR was restricted to patients with total occlusions. The results demonstrated that although the benefit of CR was highest for patients with 2 diseased vessels IR and a total occlusion, patients with 1-vessel IR and no total occlusion had significantly higher mortality and mortality/MI than CR patients did, and patients with 2 vessels IR and no total occlusion had significantly higher mortality/MI than CR patients did.

Study limitations. There are a few caveats to the study. First, it is an observational study, and differences among patients in characteristics related to outcomes may have been the reason for differences in outcomes between CR and IR. This potential bias was controlled for by risk-adjusting the outcomes by using patient characteristics that were significantly related to the outcomes. Also, a propensity analysis was used to test for selection bias, and the conclusions were that there was no tendency for the outcome advantages for CR patients to have been concentrated in the group of patients who were far more likely to receive CR. However, patient characteristics such as cancer and the need for noncardiac surgery were not available in the database, and to the extent that they are related to outcomes and more likely to be present in IR patients, this introduces an uncontrolled bias (23).

Moreover, we were unable to determine why CR was not attempted, and many patients may not have undergone CR because they were not amenable to it, such as patients with a diseased vessel that supplies an infarcted territory, or because it was not judged to be beneficial. However, as noted previously, even IR patients without total occlusions had significantly worse outcomes than CR patients did. The very low percentage of CR (31%) and the large variation in IR rates across the 39 hospitals in the study (from 45% to 89%) may be a result of differences in patient mix across hospitals, but we believe it suggests that there was considerable variation in practice pattern and that many more CRs could have been attempted and would have been beneficial.

It is conceivable that a planned CR may have been aborted and turned into an IR when the procedure was more complex than anticipated or if adverse events occurred. To account for this possibility, we repeated the analyses with any attempted CR assigned to the CR group rather than the IR group. However, the outcomes were essentially the same because only 6.8% of the attempted CRs were unsuccessful. For example, the respective risk-adjusted 18-month survival rates for CR and IR when success is part of the definition were 94.9% and 93.8%, and when success was not part of the definition of CR, these rates were 94.7% and 93.9%.

It is also possible that the period we used to allow for CR when procedures were staged (30 days) was too short, but we found here and elsewhere (12) that extending that period to 60 days did not change the essence of the findings. We were unable to control for differences in post-procedural use of dual antiplatelet therapy, but there is no reason to believe there should be utilization differences between CR and IR patients, particularly because the time frame was the same for both groups.

In addition, there is a possibility that the results could be biased as a result of incomplete follow-up of post-discharge MIs and deaths. New York state vital statistics data were used to identify patients who died after discharge. Because of this, the study was limited to patients residing in New York at time the procedure was performed. We were not able to capture deaths or subsequent revascularizations for MI for patients who moved to another state or after discharge, but results from a similar study comparing outcomes of CABG surgery and PCI in New York indicate that very few deaths are missed because of patients moving out of state (24). Also, it seems unlikely that the percentages of CR and IR patients who move out of state would differ substantially.

Another caveat is that DES use in the time interval chosen for analysis was not mature, and bias of DES versus bare-metal stent use existed, which may have affected the study outcomes.

Conclusions

As noted by Ong and Serruys (15), "complete revascularization is an important factor in the decision-making process that requires careful thought before a patient is recommended for either treatment option. The goal should always be complete revascularization, because the overall trend supports it, whether the treatment choice is surgery or percutaneous intervention." The results reported here suggest that if CR is not being contemplated for PCI, outcomes may not be optimal. Also, although it is not always clear before the procedure which patients are amenable to CR, our results suggest that if it is not achieved, it may be wise to monitor those patients more intensively after discharge.

Acknowledgments
The authors would like to thank the members of New York State's Cardiac Advisory Committee for their encouragement and support of this study; and Paula Waselauskas, Kimberly S. Cozzens, Rosemary Lombardo, Cynthia Johnson; and the cardiac surgery departments and cardiac catheterization laboratories of the participating hospitals for their tireless efforts to ensure the timeliness, completeness, and accuracy of the registry data.

Reprint requests and correspondence: Dr. Edward L. Hannan, Distinguished Professor and Associate Dean for Research, School of Public Health, State University of New York, University at Albany, One University Place, Rensselaer, New York 12144-3456. E-mail: elh03@health.state.ny.us.

REFERENCES

1. Mariani G, De Servi S, Dellavalle A, et al. Complete or incomplete percutaneous coronary revascularization in patients with unstable angina in stent era: are early and one-year results different? Catheter Cardiovasc Interv 2001;54:448–53.
2. Bourassa MG, Yeh W, Holubkov R et al., for the Investigators of the NHLBI PTCA Registry. Long-term outcome of patients with incomplete vs. complete revascularization after multivessel PTCA: a report from the NHLBI Registry. Eur Heart J 1998;19:103–11.
3. van den Brand MJ, Rensing BJ, Morel MA, et al. The effect of completeness of revascularization on event-free survival at one year in the ARTS trial. J Am Coll Cardiol 2002;19:559–64.
4. Bourassa MG, Kip KE, Jacobs AK, et al. Is a strategy of intended incomplete percutaneous transluminal coronary angioplasty revascularization acceptable in nondiabetic patients who are candidates for coronary artery bypass graft surgery? J Am Coll Cardiol 1999;33:1627–36.
5. Nikolsky E, Gruberg L, Patil CV, et al. Percutaneous coronary interventions in diabetic patients: is complete revascularization important? J Invasive Cardiol 2004;16:102–6.
6. Faxon DP, Ghalilli K, Jacobs AK, et al. The degree of revascularization and outcome after multivessel coronary angioplasty. Am Heart J 1992;123:854–9.
7. Cowley MJ, Vandermael M, Topol EJ et al. Is traditionally defined complete revascularization needed for patients with multivessel disease treated by elective coronary angioplasty? J Am Coll Cardiol 1993;22:1289–97.
8. Samson M, Meester HJ, de Feyter PJ, Strauss B, Serruys PW. Successful multiple segment coronary angioplasty: effect of complete-

ness of revascularization in single-vessel multilesions and multivessels. Am Heart J 1990;120:1–12.
9. Bell MR, Bailey KR, Reeder GS, Lapeyre AC, Holmes DR. Percutaneous transluminal angioplasty in patients with multivessel disease: how important is complete revascularization for cardiac-event free survival? J Am Coll Cardiol 1990;16:553–62.
10. Vandormael MG, Chaitman BR, Ischinger T, et al. Immediate and short-term benefit of multi-lesion coronary angioplasty: influence of degree of revascularization. J Am Coll Cardiol 1985;6:983–91.
11. Reeder GS, Holmes DR, Detre KM, Kostigan T, Kelsey SF. Degree of revascularization in patients with multivessel coronary disease: a report from the National Heart, Blood, and Lung Institute Percutaneous Transluminal Coronary Angioplasty Registry. Circulation 1988;77: 638–44.
12. Hannan EL, Racz M, Holmes DR, et al. The impact of completeness of revascularization on long-term outcomes in the stent era. Circulation 2006;113:2406–12.
13. Kalarus Z, Lenarczyk R, Kowalczyk J, et al. Importance of complete revascularization in patients with acute myocardial infarction treated with percutaneous coronary intervention. Am Heart J 2007:153:304–12.
14. McLellan CS, Ghali WA, Labinaz M, et al. Association between completeness of percutaneous coronary revascularization and postprocedure outcomes. Am Heart J 2005;150:800–6.
15. Ong AT, Serruys PW. Complete revascularization: coronary artery bypass graft surgery versus percutaneous coronary intervention. Circulation 2006;114:249–55.
16. Kip KE, Bourassa MG, Schwartz L, et al. Influence of pre-PTCA strategy and initial PTCA result in patients with multivessel disease: the Bypass Angioplasty Revascularization Investigation (BARI). Circulation 1999;100:910–7.
17. Ijsselmuiden AJ, Ezechiels J, Westendorp IC, et al. Complete versus culprit vessel percutaneous coronary intervention in multivessel disease: a randomized comparison. Am Heart J 2004;148:467–74.
18. Zeger SL, Liang KY, Albert PS. Models for longitudinal data: a generalized estimating equation approach. Biometrics 1988;42:1049–60.
19. Ellison P. Survival Analysis Using the SAS System. Cary, NC: The SAS Institute, 1995.
20. Ghali WA, Quan H, Brant R, et al. Comparison of two methods for calculating adjusted survival curves from proportional hazards. JAMA 2001;286:1494–7.
21. Rosenbaum PR, Rubin DR. Reducing bias in observational studies using subclassification on the propensity score. J Am Stat Assoc 1984;79:516–24.
22. Rosenbaum PR, Rubin DB. The central role of the propensity score in observational studies for causal effects. Biometrika 1983;70:41–55.
23. Teirstein PS. The dueling hazards of incomplete revascularization and incomplete data. Circulation 2006;113:2380–2.
24. Hannan EL, Racz MJ, McCallister BD, et al. A comparison of three-year survival after coronary artery bypass surgery and percutaneous transluminal coronary angioplasty. J Am Coll Cardiol 1998;33:63–72.

Key Words: stent ■ incomplete revascularization ■ mortality.