JACC Vol. 31, No. 6
May 1998:1234–9

A Clinical Trial Comparing Primary Stenting of the Infarct-Related Artery With Optimal Primary Angioplasty for Acute Myocardial Infarction

Results From the Florence Randomized Elective Stenting in Acute Coronary Occlusions (FRESCO) Trial

DAVID ANTONIUCCI, MD, GIOVANNI M. SANTORO, MD, LEONARDO BOLOGNESE, MD, RENATO VALENTI, MD, MAURIZIO TRAPANI, MD, PIER FILIPPO FAZZINI, MD

Florence, Italy

Objectives. **This study sought to compare stenting of the primary infarct-related artery (IRA) with optimal primary percutaneous transluminal coronary angioplasty (PTCA) with respect to clinical and angiographic outcomes of patients with an acute myocardial infarction.**

Background. **Early and late restenosis or reocclusion of the IRA after successful primary PTCA significantly contributes to increased patient morbidity and mortality. Coronary stenting results in a lower rate of angiographic and clinical restenosis than standard PTCA in patients with angina and with previously untreated, noncomplex lesions.**

Methods. **After successful primary PTCA, 150 patients were randomly assigned to elective stenting or no further intervention. The primary end point of the trial was a composite end point, defined as death, reinfarction or repeat target vessel revascularization as a consequence of recurrent ischemia within 6 months of randomization. The secondary end point was angiographic evidence of restenosis or reocclusion at 6 months after randomization.**

Results. **Stenting of the IRA was successful in all patients randomized to stent treatment. At 6 months, the incidence of the primary end point was 9% in the stent group and 28% in the PTCA group ($p = 0.003$); the incidence of restenosis or reocclusion was 17% in the stent group and 43% in the PTCA group ($p = 0.001$).**

Conclusions. **Primary stenting of the IRA, compared with optimal primary angioplasty, results in a lower rate of major adverse events related to recurrent ischemia and a lower rate of angiographically detected restenosis or reocclusion of the IRA.**

(J Am Coll Cardiol 1998;31:1234–9)

Early and late recurrent ischemia, as a consequence of restenosis or reocclusion of the infarct-related artery (IRA) after successful primary percutaneous transluminal coronary angioplasty (PTCA), is a major pitfall of primary PTCA therapy for acute myocardial infarction (AMI). Within 6 months of infarction, restenosis or reocclusion may occur in >50% of patients (1–3), and the incidence of major adverse events related to recurrent ischemia, such as death, reinfarction or repeat target vessel revascularization, may be as high as 30% (2,4,5).

Unplanned stenting of the IRA for a suboptimal or poor angiographic result after primary PTCA, may be safely performed and results in good clinical outcome (i.e., low rates of in-hospital recurrent ischemia and related major adverse events) (6–9). Primary stenting in AMI would be expected to improve both early and late outcomes if the rate of IRA artery restenosis and reocclusion were reduced compared with that for PTCA.

The extent to which primary stenting of the IRA may improve the long-term patient outcome has not been determined. The Florence Randomized Elective Stenting in Acute Coronary Occlusions (FRESCO) trial is a randomized trial comparing primary stenting of the IRA with optimal PTCA with respect to the clinical and angiographic outcomes of patients with an AMI.

Methods

Patient selection. Criteria for enrollment included 1) chest pain persisting >30 minutes associated with ST segment elevation of at least 0.1 mV in two or more contiguous electrocardiographic (ECG) leads; and 2) admission within 6 h of symptom onset, as well as admission between 6 and 24 h if there was evidence of continuing ischemia. Patients with cardiogenic shock were included. Cardiogenic shock was confirmed at cardiac catheterization by a systolic blood pressure

From Division of Cardiology, Careggi Hospital, Florence, Italy.

Manuscript received November 24, 1997; revised manuscript received February 4, 1998, accepted February 9, 1998.

Address for correspondence: Dr. David Antoniucci, Division of Cardiology, Careggi Hospital, Viale Morgagni, I-50134, Florence, Italy. E-mail: carddept@tin.it.

0735-1097/98/$19.00
PII S0735-1097(98)00097-7

Abbreviations and Acronyms

AMI = acute myocardial infarction
CABG = coronary artery bypass graft surgery
ECG = electrocardiographic
FRESCO = Florence Randomized Elective Stenting in Acute Coronary Occlusions (trial)
IRA = infarct-related artery
MLD = minimal lumen diameter
PTCA = percutaneous transluminal coronary angioplasty
TIMI = Thrombolysis in Myocardial Infarction

<90 mm Hg and a left ventricular filling pressure ≥20 mm Hg. No upper age limit was used. The exclusion criteria included previous administration of fibrinolytic treatment and inability to provide informed consent.

Study protocol. Angiographic criteria for exclusion from PTCA included 1) stenosis of the IRA of <70%, and 2) inability to identify the IRA. Primary PTCA had to be attempted in all patients who met inclusion criteria. Primary PTCA was accomplished with the use of standard techniques; an attempt was made to reduce the degree of residual stenosis in all lesions within the IRA to <30% with the use of high pressure inflations and moderately oversized balloons as needed. After an optimal acute angiographic result was achieved (i.e., a residual stenosis <30% with restoration of Thrombolysis in Myocardial Infarction [TIMI] grade 3 flow [10]) and informed consent was obtained, patients were randomly assigned to either primary stenting or no further intervention. Randomization was performed by means of sealed envelopes. The only criterion for exclusion from randomization was a reference vessel diameter <2.5 mm. Patients considered for the study but in whom PTCA was nonoptimal were not randomized. These patients were studied in a separate parallel registry. Stenting of the target lesion was accomplished using the Gianturco-Roubin coronary stent (Cook, Inc.) as the first-choice device; other types of stents could be used after Gianturco-Roubin stent deployment failure or to complete stenting treatment after successful Gianturco-Roubin stent deployment. In patients randomized to stenting, attempted stenting was mandatory irrespective of the coronary anatomy. Evidence of coronary thrombus or the presence of diffuse disease or severe vessel tortuosity was not considered a contraindication to stenting. Coronary stenting was performed using standard techniques, including high pressure (>13 atm) dilations after stent deployment.

In both groups, intravenous heparin was administered for 3 days. Patients were routinely treated with aspirin (325 mg/day indefinitely) and ticlopidine (500 mg/day for 2 months).

For patients who could not be randomized because of a nonoptimal angiographic result after primary PTCA, stenting of the IRA was recommended if there was persistent occlusion or residual stenosis >50% or angiographic evidence of occlusive dissection after one or more dilations with appropriately sized balloons.

Coronary angiography was required for all patients at 48 to 72 h, at 1 month and at 6 months after the procedure. Unscheduled angiography was allowed on the basis of clinical indication. Nonrandomized patients had clinical and angiographic follow-up as well.

The study protocol was approved by the local ethics committee.

Angiographic analysis. Quantitative coronary angiography was performed with the use of an automatic edge detection system (Siemens Ancor). *Coronary occlusion* was assigned a value of 0 mm for minimal lumen diameter (MLD) and 100% for percent diameter stenosis. Coronary flow in the IRA was graded according to TIMI flow grade (10). *Collateral flow* was graded according to the classification developed by Rentrop et al. (11). *Multivessel disease* was defined as at least one major non–infarct-related coronary artery with >50% stenosis. *An optimal acute angiographic result* was defined as residual stenosis <30% associated with TIMI grade 3 flow. *A suboptimal angiographic result* was defined as residual stenosis >30% associated with TIMI grade 3 flow or residual stenosis <30% associated with TIMI grade 2 flow. *Unsuccessful PTCA* was defined as PTCA resulting in TIMI grade 0 or 1 flow, whatever the residual stenosis. Left ventricular ejection fraction was calculated by digitization of the ventricular outline in diastolic and systolic frames from ventriculograms performed in the right anterior oblique projection. Analysis immediately after PTCA, at 48 to 72 h, at 1 month and at 6 months was performed using identical projections.

End points. The primary end point of the trial was a composite clinical end point defined as the occurrence of one of the following events: death, reinfarction, or repeat target vessel revascularization as a consequence of recurrent ischemia within the first 6 months after initial revascularization. Patients with more than one event were assigned the highest ranked event according to the previous list. *Recurrent ischemia* was defined as ischemic chest pain with either new ST segment or T wave changes at rest or on exercise testing. *Reinfarction* was defined as recurrent chest pain with new ST segment elevation and recurrent elevation of cardiac enzymes. *Repeat revascularization* of the target vessel was defined as PTCA or bypass surgery performed because of restenosis or reocclusion of the target lesion in association with objective evidence of recurrent ischemia. *Hemorrhagic and vascular complications* were defined as hemorragic stroke, bleeding requiring transfusion or vascular surgery.

The secondary end point was angiographic evidence of restenosis or reocclusion, defined as at least 50% stenosis of the target lesion on the scheduled or unscheduled follow-up angiogram.

Statistical analysis. The sample size was calculated on the assumption that the primary end point would occur in 30% of patients who underwent conventional PTCA and in 10% of those who underwent primary coronary stenting. Thus, 59 patients were required in each group to test for an absolute reduction of 20% with p value of .05 and a power of 80%. Accounting for adverse events other than those included in the

primary end point and withdrawal, it was expected that at least 75 patients/group would be available for analysis. Analyses were performed on an intention to treat basis. Continuous data are summarized as mean value ±SD. Chi-square test analysis was used for comparison of categoric variables. Analysis of variance was used to test differences among continuous variables. Kaplan-Meier survival curves were used to characterize the timing of the primary study end point during the follow-up period. Comparison of survival curves was performed using the log-rank test. Multivariate analysis using a logistic regression model was performed to identify correlates of recurrent ischemia. Factors analyzed included age, gender, previous myocardial infarction, anterior location of the current infarction, presence of collateral vessels, time to reperfusion, primary stenting of the IRA, postprocedural MLD. Odds ratios and their 95% confidence intervals were calculated. A p value <0.05 was considered significant. Statistical tests were performed using GB-STAT system (Dynamic Microsystem).

Results

Patients. Between January 1996 and March 1997, 223 patients eligible for primary PTCA were enrolled. Primary PTCA was successful in 220 patients (99%). After successful primary angioplasty, 70 patients (32%) were not randomized because of an initial suboptimal acute angiographic result (66 patients) or a reference vessel diameter <2.5 mm (4 patients), whereas 150 patients with an optimal angiographic result were randomized either to elective stenting or no further intervention. The baseline clinical and angiographic characteristics of all 223 patients are shown in Table 1. There were significant differences between nonrandomized and randomized patients. The former had a greater incidence of anterior AMI, cardiogenic shock, severe left ventricular dysfunction and multivessel disease. Between randomized groups, more patients with an anterior AMI were assigned to the stent group than to the PTCA group, but the two groups were well matched with respect to other clinical and angiographic characteristics.

Procedural data and angiographic analysis. Procedural data are shown in Table 2. Stents were successfully placed in all 75 patients randomly assigned to this therapy, and 17 patients (23%) had multiple-stent implantation. All patients received at least one Gianturco-Roubin stent 20 mm in length. Other types of stents, <20 mm long, were used in 12 patients to complete stenting treatment of the target lesion or other focal lesions within the IRA. Seventy-four patients had a final optimal angiographic result after stent placement. One patient had temporary deterioration of flow (TIMI grade 2 flow) after high pressure balloon stent expansion, without any evidence of residual stenosis or dissection; at the first control angiogram at 72 h, TIMI grade 3 flow was revealed. After the procedure, a larger mean MLD was achieved in the stent group than in the PTCA group (3.33 ± 0.43 vs. 3.03 ± 0.46 mm, $p < 0.01$).

Coronary stenting was attempted in 58 (88%) of 66 nonrandomized patients with a nonoptimal acute angiographic result. There were no stent deployment failures, and 24 patients (41%) had multiple-stent implantation to treat diffuse disease of the IRA. Stenting was not attempted in eight patients with diffuse disease of the IRA and a residual stenosis <50% associated with TIMI grade 3 flow. Overall, a final optimal acute angiographic result was achieved in nonrandomized 62 (85%) patients, and the resulting MLD was similar to that of the stent group and larger than that of the PTCA group (3.31 ± 0.57 vs. 3.03 ± 0.46 mm, $p < 0.01$).

No patient received fibrinolytic agents or glycoprotein IIb/IIIa inhibitors.

Clinical and angiographic outcomes of randomized patient groups. Clinical follow-up data were available for all patients and are shown in Table 3. The 1-month recurrent ischemia rate was 3% in the stent group, and 15% in the PTCA group ($p = 0.009$). In the stent group, recurrent ischemia resulted in nonfatal reinfarction in one patient and emergency repeat PTCA in another. In the angioplasty group, recurrent ischemia resulted in nonfatal reinfarction in two patients, and nine, all with angiographic evidence of occlusive or subocclusive dissection, had repeat PTCA and rescue stenting. In the PTCA group, three patients (4%), all with cardiogenic shock on admission, died of refractory cardiogenic shock, without any clinical or ECG evidence of IRA reocclusion. The incidence of bleeding and vascular complications was identical in the two groups (4%).

Table 1. Baseline Clinical and Angiographic Patient Characteristics

	Nonrandomized Group (n = 73)	PTCA Group (n = 75)	Stent Group (n = 75)
Age (yr)	64 ± 11	61 ± 12	62 ± 12
Range	39–89	28–86	34–87
>75 yr	10 (14%)	10 (13%)	12 (16%)
Men	58 (79%)	60 (80%)	56 (75%)
Diabetes	11 (15%)	6 (8%)	13 (17%)
Killip class ≥II	34 (47%)*	23 (31%)	25 (33%)
Prior CABG	0	0	0
Prior PTCA	1 (1%)	3 (4%)	1 (1%)
Prior MI	9 (12%)	6 (8%)	6 (8%)
Current ant MI	43 (59%)	29 (39%)*	41 (55%)
Cardiogenic shock	18 (25%)*	7 (9%)	7 (9%)
Multivessel disease	46 (63%)*	33 (44%)	34 (45%)
LVEF†	44 ± 14‡	52 ± 12	50 ± 14
IRA			
LAD	44 (60%)*	29 (39%)	40 (54%)
LCx	6 (8%)	6 (8%)	4 (5%)
RCA	23 (32%)*	40 (53%)	31 (41%)
Ref vessel diam (mm)	3.19 ± 0.48	3.19 ± 0.47	3.19 ± 0.43
Time to admission (min)	162 ± 95	137 ± 74	152 ± 95
Time to treatment (min)	30 ± 24	28 ± 18	28 ± 21

*$p < 0.05$ by chi-square test for comparison among the three groups. †Baseline left ventricular angiography was available for 189 patients. ‡$p < 0.05$ by analysis of variance for comparison among the three groups. Data presented are mean value ± SD, range or number (%) of patients. ant = anterior; CABG = coronary artery bypass graft surgery; diam = diameter; IRA = infarct-related artery; LAD = left anterior descending coronary artery; LCx = left circumflex coronary artery; LVEF = left ventricular ejection fraction; MI = myocardial infarction; PTCA = percutaneous transluminal coronary angioplasty; RCA = right coronary artery; Ref = reference.

Table 2. Procedural Data

	Nonrandomized Group (n = 73)	PTCA Group (n = 75)	Stent Group (n = 75)
Primary PTCA failure	3	0	0
IRA stenting	58 (79%)	—	75 (100%)
Single stent	34 (59%)	—	58 (77%)
Multiple stents	24 (41%)	—	17 (23%)
Type of stent			
Gianturco-Roubin	55 (63%)	—	87 (88%)
Palmaz-Schatz	19 (22%)	—	6 (6%)
Microstent	12 (14%)	—	3 (3%)
Freedom	1 (1%)	—	3 (3%)
Stent deployment failure	0	—	0
Final balloon inflation pressure (atm)	14 ± 3	9 ± 2*	15 ± 2
Intraaortic balloon pump	20 (28%)‡	8 (11%)	9 (12%)
Procedural duration (min)	51 ± 25†	34 ± 28	40 ± 19
Final result			
Optimal result	62 (85%)‡	75 (100%)	74 (99%)
Suboptimal result	8 (11%)	0	1 (1%)
Postprocedural QCA			
MLD (mm)	3.31 ± 0.57	3.03 ± 0.46*	3.33 ± 0.43
Residual %DS	−3 ± 12	5 ± 8*	−4 ± 8

*$p < 0.01$, †$p < 0.05$ by analysis of variance for comparison among the three groups. ‡$p < 0.05$ by chi-square test for comparison among the three groups. Data presented are mean value ± SD or number (%) of patients. MLD = minimal lumen diameter; QCA = quantitative coronary angiography; %DS = percent diameter stenosis; — = not applicable; other abbreviations as in Table 1.

Table 3. Clinical Outcome of Randomized Patients

	PTCA Group	Stent Group	p Value
Early events (0–30 d)	n = 75	n = 75	
Recurrent ischemia	11 (15%)	2 (3%)	0.009
Death	0	0	
Reinfarction	2	1	0.560
Repeat target vessel revasc	9	1	0.009
PTCA	9	1	
CABG	0	0	
Other causes of cardiac death	3 (4%)	0	0.080
Noncardiac death	0	0	
Bleeding and vascular compl	3 (4%)	3 (4%)	
Late events (31–180 d)	n = 61	n = 73	
Recurrent ischemia	10 (16%)	5 (7%)	0.081
Death	0	1	0.359
Reinfarction	0	0	
Repeat target vessel revasc	10 (16%)	4 (5%)	0.040
PTCA	8	4	0.123
CABG	2	0	0.119
Other causes of cardiac death	0	0	
Noncardiac death	1 (2%)	0	0.272
All events (0–180 d)	n = 75	n = 75	
Recurrent ischemia	21 (28%)	7 (9%)	0.003
Death	0	1 (1%)	0.316
Reinfarction	2 (3%)	1 (1%)	0.560
Repeat target vessel revasc	19 (25%)	5 (7%)	0.002
PTCA	17 (23%)	5 (7%)	0.006
CABG	2 (3%)	0	0.154
Other causes of cardiac death	3 (4%)	0	0.080
Noncardiac death	1 (1%)	0	0.316
Bleeding and vascular compl	3 (4%)	3 (4%)	

Data presented are number (%) of patients. compl = complications; d = days; revasc = revascularization; other abbreviations as in Table 1.

Late recurrent ischemia occurred in five stent group patients (7%). Four patients underwent repeat PTCA, and repeat stenting was performed in three of them. One patient in the stent group died suddenly 3 months after the procedure, and this event was attributed to recurrent ischemia. Late recurrent ischemia occurred in 10 patients (16%) in the PTCA group, resulting in repeat PTCA in 8 and elective coronary artery bypass graft surgery (CABG) in 2.

The cumulative early and late recurrent ischemia rate was lower in the stent group than in the PTCA group (9% vs. 28%, p = 0.003). At 6 months, freedom from the composite primary end point was 87% for the stent group and 68% for the PTCA group (p = 0.002) (Fig. 1). Multivariate analysis showed that the only independent predictor of freedom from recurrent ischemia was stenting of the IRA (odds ratio 0.304, 95% confidence interval 0.110 to 0.839, p = 0.021).

Angiographic outcomes are shown in Table 4. One-month angiographic follow-up data were available for 143 (97%) of 147 randomized patients eligible for follow-up. The 1-month restenosis or reocclusion rate was 3% in the stent group and 17% in the PTCA group (p = 0.004). At the 1-month follow-up visit, the mean MLD was larger in the stent group than in the PTCA group (3.06 ± 0.71 vs. 2.58 ± 1.08 mm, p = 0.002). Six-month angiographic follow-up data were available for 124 (95%) of 131 patients eligible for follow-up. The restenosis or reocclusion rate was lower in the stent group than in the PTCA group (15% vs. 30%, p = 0.036). At 6 months, the mean MLD was larger in the stent group than in the PTCA group (2.36 ± 0.88 vs. 2.00 ± 1.05 mm, p = 0.040). At 6-months, the cumulative incidence of early and late restenosis or reocclusion was 17% in the stent group and 43% in the PTCA group (p = 0.001).

Figure 1. Kaplan-Meier curves for freedom from the clinical composite end point according to treatment group.

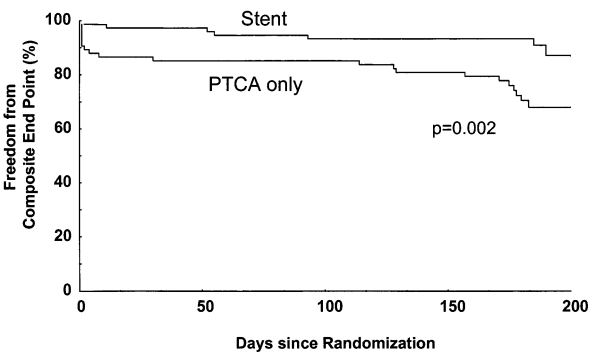

Table 4. Angiographic Outcome of Randomized Patient Groups

	PTCA Group	Stent Group	p Value
1-mo follow-up			
No. of pts eligible	72	75	
Coronary angio done	71 (99%)	72 (96%)	0.331
Early restenosis or reocclusion	12 (17%)	2 (3%)	0.004
MLD (mm)	2.58 ± 1.08	3.06 ± 0.71	0.002
6-mo follow-up			
No. of pts eligible	59	72	
Coronary angio done	56 (95%)	68 (94%)	0.905
Late restenosis or reocclusion	17 (30%)	10 (15%)	0.036
MLD (mm)	2.00 ± 1.05	2.36 ± 0.88	0.040
Cumulative follow-up			
No. of pts eligible	71	74	
Coronary angio done	68 (96%)	70 (95%)	0.740
All restenoses and reocclusions	29 (43%)	12 (17%)	0.001

Data presented are mean value ± SD or number (%) of patients (pts). angio = angiography; other abbreviations as in Tables 1 and 2.

Clinical and angiographic outcomes of the nonrandomized patient group. Clinical and angiographic outcomes of the nonrandomized patient group are summarized in Table 5. Early recurrent ischemia occurred in three patients (4%). Five patients with severe multivessel disease were discharged with the indication to complete myocardial revascularization by elective CABG. Between 1 and 6 months, recurrent ischemia occurred in five patients (9%). The cumulative in-hospital and late recurrent ischemia rate was 11% for the entire group and 12% for patients with a stented IRA. For patients with a stented IRA, the rate of recurrent ischemia was similar to that of the randomized stent patient group (12% vs. 9%, p = 0.610) and lower than that of the randomized nonstent patient group (12% vs. 28%, p = 0.025). Overall, the 6-month cardiac mortality rate in this group was 10% and was higher than the 3% rate of the combined randomized groups (p = 0.020). The excess mortality in this group was mostly due to excess cardiac deaths for refractory cardiogenic shock.

Table 5. Clinical and Angiographic Outcomes of Nonrandomized Patient Group

	Early Events (0–30 d)	Late Events (31–180 d)	All Events (0–180 d)
No of pts with clinical follow-up	70	57	70
Recurrent ischemia	3 (4%)	5 (9%)	8 (11%)*
Death	1 (1%)	0	1 (1%)
Reinfarction	0	0	0
Target vessel revasc	2 (3%)	5 (9%)	7 (10%)
PTCA	1	2	3
CABG	1 (1%)	3 (5%)	4 (6%)
Other causes of cardiac death	5 (7%)	1 (2%)	6 (9%)
Noncardiac death	0	2 (4%)	2 (3%)
Nontarget CABG	5 (7%)	0	5 (7%)
Bleeding and vascular complications	5 (7%)	0	5 (7%)
Overall cardiac mortality	6 (9%)	1 (2%)	7 (10%)
No. of pts eligible for angio follow-up	59	54	56
Coronary angio done	55 (93%)	44 (81%)	46 (82%)
Restenosis or reocclusion	2 (4%)	12 (27%)	14 (30%)

*Seven patients underwent stenting of the infarct-related vessel at the first procedure; one patient had standard coronary angioplasty only. Data presented are number (%) of patients. Abbreviations as in Tables 1, 3 and 4.

Angiography was repeated at 6 months in 44 (81%) of 54 patients eligible for the follow-up. The late restenosis and reocclusion rate was 27%. At 6 months, the mean MLD of the IRA was 2.18 ± 1.11 mm. Cumulative early and late restenosis and reocclusion rate was 30%.

Discussion

We performed a randomized trial comparing primary IRA stenting with optimal standard PTCA with respect to major adverse events related to recurrent ischemia. The study design included some unique features: 1) Unlike other ongoing trials that randomize patients to stent or nonstent treatment before primary PTCA (12–16), FRESCO trial patients were randomized only after an optimal angiographic result had been achieved with standard PTCA, because the potential benefit of elective coronary stenting as a primary modality treatment in AMI is unknown. We considered patients with a nonoptimal angiographic result to be inelegibile for randomization because several observational studies (6–9) strongly suggest a benefit of IRA stenting for dissection or a suboptimal angiographic result after PTCA. 2) To correctly assess the feasibility of stenting and to avoid the potential bias due to subjective selection of patients suitable for stenting, the study protocol did not include any exclusion criterion, except for a reference vessel diameter <2.5 mm. 3) Clinical, angiographic and procedural data were also collected for patients with a nonoptimal angiographic result to assess differences in clinical and angiographic outcomes compared with those of the randomized patient groups.

The results of the study confirm the primary study hypothesis. Elective stenting of the IRA resulted in a lower incidence of aggregate clinical events related to early and late recurrent ischemia. The cumulative 6-month recurrent ischemia rate was 9% in the stent group and 28% in the PTCA group (p = 0.003). Consistent with the clinical outcome, angiographic follow-up showed a significantly lower rate of cumulative 6-month restenosis and reocclusion of the IRA in the stent group than in the PTCA group (17% vs. 43%, p = 0.001). The benefit of coronary stenting in lowering the incidence of restenosis or reocclusion is evident early, within the first 30 days, and late, from 1 to 6 months after the procedure because early and late restenosis rates were both significantly lower in the stent group. In the acute phase, coronary stenting prevents significant recoil and may correct latent dissection. The latter mechanism seems to be relevant because in nearly all patients in the PTCA group with in-hospital recurrent ischemia, emergency coronary angiography revealed occlusive or subocclusive dissection. In the late phase, the larger postprocedural lumenal

diameter provided by stenting (17) and the effect on vascular remodeling (18) may explain the benefit of stenting in lowering late restenosis and reocclusion rates.

A substantial minority (33%) of patients eligible for primary PTCA were not eligible for randomization to elective stent treatment. Nearly all these patients underwent nonelective coronary stenting. Although stenting was frequently accomplished as a rescue procedure, and multiple stent implantation was needed in many patients, the rate of recurrent ischemia was only slightly higher than that of the stent group and lower than that of the PTCA group. Thus, nonelective stenting, as well as primary elective stenting, may lower the incidence of early and late major adverse events related to recurrent ischemia.

IRA stenting may be considered highly feasible because there were no stent deployment failures. This high procedural success rate was achieved with the use of the Gianturco-Roubin stent as the first-choice device, whose trackability allows successful placement even in unfavorable anatomic settings. Preliminary results of other trials (12,13,15,16) suggest that the feasibility of primary stenting of the IRA may be high, even when other types of stents are used. However, in those studies, stenting was not attempted in a substantial minority of patients who were considered unsuitable for stenting because of unfavorable anatomic characteristics.

Conclusions. The results of the present trial suggest that primary stenting of the IRA results in improved 6-month outcome as a consequence of a lower incidence of major cardiac events related to recurrent ischemia. Thus, stenting might be considered a primary treatment modality for patients with an AMI.

References

1. O'Neill WW, Brodie BR, Ivanhoe R, et al. Primary coronary angioplasty for acute myocardial infarction (the Primary Angioplasty Registry). Am J Cardiol 1994;73:627–34.
2. Brodie BR, Grines CL, Ivanhoe R, et al. Six-month clinical and angiographic follow-up after direct angioplasty for acute myocardial infarction: final results from the Primary Angioplasty Registry. Circulation 1994;25:156–62.
3. Nakagawa Y, Iwasaki Y, Kimura T, et al. Serial angiographic follow-up after successful direct angioplasty for acute myocardial infarction. Am J Cardiol 1996;78:980–4.
4. O'Murchu B, Gersh BJ, Reeder GS, Bailey KR, Holmes DR. Late outcome after percutaneous transluminal coronary angioplasty during acute myocardial infarction. Am J Cardiol 1993;72:634–9.
5. Zijlstra F, de Boer J, Ottervanger JP, Liem AL, Hoorntje JCA, Suryapranata H. Primary coronary angioplasty versus intravenous streptokinase in acute myocardial infarction: differences in outcome during a mean follow-up of 18 months. Coronary Artery Dis 1994;5:707–12.
6. Garcia-Cantu E, Spaulding C, Corcos T, et al. Stent implantation in acute myocardial infarction. Am J Cardiol 1996;77:451–4.
7. Rodriguez AE, Fernandez M, Santaera O, et al. Coronary stenting in patients undergoing percutaneous transluminal coronary angioplasty during acute myocardial infarction. Am J Cardiol 1996;77:685–9.
8. Antoniucci D, Valenti R, Buonamici P, et al. Direct angioplasty and stenting of the infarct-related artery in acute myocardial infarction. Am J Cardiol 1996;78:568–71.
9. Saito S, Hosokawa G, Kunikane K, Tanaka S, Miyake S. Primary stent implantation without coumadin in acute myocardial infarction. J Am Coll Cardiol 1996;28:74–81.
10. The TIMI Study Group. The Thrombolysis in Myocardial Infarction (TIMI) Trial: phase 1 findings. New Engl J Med 1985;312:932–6.
11. Rentrop KP, Cohen M, Blank EH, Phillips RA. Changes in collateral filling immediately after controlled coronary artery occlusion by an angioplasty balloon in human subjects. J Am Coll Cardiol 1985;5:587–92.
12. Hoorntje JC, Suryapranata H, de Boer MJ, Zijlstra F, van't Hof AW, van den Brink L. ESCOBAR: primary stenting for acute myocardial infarction: preliminary results of a randomized trial [abstract]. Circulation 1996;94: Suppl I:I-570.
13. Saito S, Hosokawa G, Suzuki S, Nakamura S, for the Japanese PASTA Trial Study Group. Primary stent implantation is superior to balloon angioplasty in acute myocardial infarction: the result of the Japanese PASTA (Primary Angioplasty versus Stent Implantation in Acute Myocardial Infarction) Trial [abstract]. J Am Coll Cardiol 1997;29:Suppl A:390A.
14. Rodriguez A, Fernandez M, Bernardi V, et al. Coronary stents improved hospital results during coronary angioplasty in acute myocardial infarction: preliminary results of a randomized controlled study (GRAMI trial). J Am Coll Cardiol 1997;29:Suppl A:221A.
15. Benzuly KH, O'Neill WW, Gangaddharan V, et al. Stenting in acute myocardial infarction (STAMI): six-month follow-up [abstract]. J Am Coll Cardiol 1997;29:Suppl A:456A.
16. Stone GW, Brodie BR, Griffin JJ, et al. Prospective, multicenter study of the safety and feasibility of primary stenting in acute myocardial infarction: in-hospital and 30-day results of the PAMI stent pilot trial. J Am Coll Cardiol 1998;31:23–30.
17. Fischman DL, Leon MB, Baim DS, et al. A randomized comparison of coronary-stent placement and balloon angioplasty in the treatment of coronary artery disease. N Engl J Med 1994;331:496–501.
18. Mintz GS, Popma JJ, Hong MK, et al. Intravascular ultrasound to discern device-specific effects and mechanisms of restenosis. Am J Cardiol 1996;78 Suppl 3A:18–22.