Comparison of Rheolytic Thrombectomy Before Direct Infarct Artery Stenting Versus Direct Stenting Alone in Patients Undergoing Percutaneous Coronary Intervention for Acute Myocardial Infarction

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This randomized trial compared rheolytic thrombectomy before direct infarct artery stenting with direct infarct artery stenting alone in 100 patients with a first acute myocardial infarction (AMI). The primary end point of the study was early ST-segment elevation resolution, and the secondary end points were corrected Thrombolysis In Myocardial Infarction (TIMI) frame count, infarct size, and 1-month clinical outcome. The primary end point rates were 90% in the thrombectomy group and 72% in the placebo group (p = 0.022). Randomization to thrombectomy was independently related to the primary end point (odds ratio 3.56, p = 0.032). The corrected Thrombolysis In Myocaridal Infarctions (TIMI) frame count was lower in the thrombectomy group (18.2 ± 7.7 vs 22.5 ± 11.0, p = 0.032), and infarct size was smaller in the thrombectomy group (13.0 ± 11.6% vs 21.2 ± 18.0%, p = 0.010). At 1 month, there were no major adverse cardiac events. Rheolytic thrombectomy before routine direct infarct-related artery (IRA) stenting is highly feasible and provides more effective myocardial reperfusion in patients undergoing percutaneous coronary intervention for AMI.   ©2004 by Excerpta Medica, Inc.

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Macro- and microembolization during percutaneous coronary intervention (PCI) is frequent and may result in the obstruction of the microvessel coronary network.[1] In the setting of acute myocardial infarction (AMI), PCI-related embolization results in a decreased efficacy of mechanical reperfusion and myocardial salvage. Direct stenting without predilation may decrease embolization and the incidence of the no-reflow phenomenon.[2,3] More specific approaches to the problem of microvessel embolization during PCI include thrombectomy by different techniques and the use of anti-embolic protection devices. One randomized trial has reported rheolytic thrombectomy to be effective in decreasing embolization in patients who underwent PCI on venous grafts or native coronary vessel with massive thrombosis[4]; however, few data exist on the effectiveness of rheolytic thrombectomy in the setting of AMI.[5,6] This randomized trial assessed the efficacy of rheolytic thrombectomy before direct infarct artery stent implantation in patients who underwent PCI for AMI.

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Criteria for enrollment included chest pain persisting >30 minutes associated with an ST-segment elevation of ≥0.1 mV in ≥2 contiguous electrocardiographic leads. The exclusion criteria included (1) previous myocardial infarction, (2) administration of fibrinolytic therapy, (3) bundle branch block or ventricular pacing on the baseline electrocardiogram preventing analysis of the ST-segment changes, (4) infarct-related artery (IRA) diameter <2.5 mm on visual angiographic assessment, and (5) inability to obtain informed consent. Patients with cardiogenic shock due to predominant ventricular failure were included, as were patients with high-risk coronary anatomy. After coronary angiography, eligible patients were randomly assigned to direct IRA stenting alone or thrombectomy before stenting. Computer-generated sequences and assignments using a closed envelope system were used to perform randomization. Thrombectomy was accomplished with the second-generation rheolytic thrombectomy 4Fr catheter (AngioJet, Possis Medical, Minneapolis, Minnesota). Two types of stents were used: a tubular closed-cell carbon-coated stent (Techno, Sorin, Saluggia, Italy) and a tubular open-cell stent (Zeta, Guidant, Santa Clara, California). All patients received abciximab (ReoPro, Centocor, Malvern, Pennsylvania), if not contraindicated, immediately before the procedure as a bolus of 0.25 mg/kg of body weight followed by a 12-hour infusion at a rate of 0.125 μg/kg/min. Heparin was given as an initial bolus of 70 U/kg, and additional boluses were administered during the procedure to achieve an activated clotting time of 200 to 300 seconds. Patients were routinely treated with aspirin (325 mg/day indefinitely) and ticlopidine (500 mg/day for 1 month) or clopidogrel (75 mg/day for 1 month).

The primary end point of the study was the effectiveness of myocardial reperfusion as assessed by ST-segment elevation resolution analysis. The secondary end points were (1) corrected Thrombolysis In Myocardial Infarction (TIMI) frame count at the end of the procedure, (2) infarct size as assessed by technetium-99m sestamibi scintigraphy at 1 month, and (3) 1-month clinical outcome.

A 12-lead electrocardiogram was recorded continuously 30 minutes after infarct artery recanalization. The ST-segment changes were evaluated in the single lead, with the most prominent ST-segment elevation

TABLE 1 Baseline Characteristics and Procedural Data

Variable	Thrombectomy (n = 50)	Placebo (n = 50)	p Value
Age (yrs) (mean ± SD)	63 ± 13	66 ± 12	0.251
Men	41 (82%)	39 (78%)	0.617
Current smoker	19 (38%)	14 (28%)	0.288
Hypertension	18 (36%)	19 (38%)	0.836
Cholesterolemia >200 mg/dl	23 (46%)	24 (48%)	0.841
Diabetes mellitus	9 (18%)	8 (16%)	0.790
Angina pectoris	10 (20%)	4 (8%)	0.084
Anterior wall acute myocardial infarction	17 (34%)	23 (46%)	0.221
Cardiogenic shock	3 (6%)	6 (12%)	0.295
Infarct coronary artery			0.470
Left anterior descending	17 (34%)	23 (46%)	
Right	26 (52%)	21 (42%)	
Circumflex	7 (14%)	6 (12%)	
Multivessel coronary disease	15 (30%)	20 (40%)	0.295
Preprocedural TIMI grade flow 0–1	38 (76%)	40 (80%)	0.629
Time-to-treatment (h) (mean ± SD)	3.9 ± 2.0	4.4 ± 2.8	0.295
Infarct artery stenting	49 (98%)	49 (98%)	1.000
Direct stenting	47 (94%)	41 (82%)	0.065
Multiple stents	12 (24%)	13 (26%)	0.817
Stent length (mm)	20.7 ± 9.2	21.1 ± 20.1	0.848
Rheolytic thrombectomy	48 (96%)	4 (8%)	<0.001
Abciximab administration	49 (98%)	49 (98%)	1.000
Intra-aortic balloon counterpulsation	3 (6%)	5 (10%)	0.461

TABLE 2 End Points

Variable	Thrombectomy (n = 50)	Placebo (n = 50)	p Value
Early ST-segment elevation resolution	45 (90%)	36 (72%)	0.022
Corrected TIMI frame count (mean ± SD)	18.2 ± 7.7	22.5 ± 11.0	0.032
Technetium-99m sestamibi infarct size (%) (mean ± SD)	13.0 ± 11.6	21.2 ± 18.0	0.010
Death	0	0	
Reinfarction	0	0	
Target vessel revascularization	0	0	
Major bleeding requiring blood transfusion	0	1 (2%)	0.315
Disabling stroke	1 (2%)	0	0.315

*Mean ± SD.

type I error (α) of 0.05, 50 patients per group were required. Discrete data are summarized as frequencies, and continuous data are summarized as mean ± SD. Chi-square test analysis was used for comparison of categorical variables. Student's t test was used to test differences among continuous variables. Forward stepwise multivariate logistic regression analysis was performed to identify independent correlates of the primary end point. All analyses were conducted according to the intention-to-treat principle. A p value <0.05 was considered statistically significant. Analyses were performed with SPSS 8.0 (SPSS Inc., Chicago, Illinois).

Between November 2002 and June 2003, 137 patients with AMI underwent PCI, and 100 were randomized to direct infarct artery stenting alone or thrombectomy before direct infarct artery stenting. The reasons for excluding 37 patients from randomization were previous myocardial infarction (n = 18), infarct artery diameter <2.5 mm (n = 8), bundle branch block or ventricular pacing (n = 3), and inability to obtain informed consent (n = 8).

Table 1 lists the baseline patient characteristics and the procedural data. Patients treated with direct stenting alone had a greater incidences of a history of angina, anterior AMI, and cardiogenic shock, but these differences did not reach statistical significance. There were no primary PCI failures. Overall, 98% of patients had direct IRA stenting. The thrombectomy device directly crossed the occlusion in 48 patients (96%), but the device crossed the target lesion only after predilation with a 2.0-mm angioplasty balloon in 2 patients. Thrombectomy increased TIMI infarct artery flow from 0.60 ± 1.09 to 2.82 ± 0.56 (p <0.001). Four patients treated with the stent alone were then treated with thrombectomy because of residual angiographic evidence of massive thrombosis after direct stenting. Nearly all patients in the 2 groups were treated with abciximab.

The end point rates and outcomes are listed in Table 2. The early ST-segment resolution rate was higher in the thrombectomy group than in the stenting-only group, and TIMI frame count was lower in the thrombectomy group. The 1-month technetium-99m sestamibi scintigrams showed smaller infarcts in the thrombectomy group than in the stenting-only group. At 1 month, there were no major adverse cardiac events. In patients without anterior AMI, early ST-segment resolution was more frequent (94% vs 70%; p = 0.015) and the infarct size was smaller (13.6 ± 10.4 vs 19.6 ± 14.1; p = 0.063) in the thrombectomy group than in the stenting-only group.

before mechanical intervention. The ST-segment elevation was measured to the nearest 0.5 mm at 60 ms after the J point with the aid of hand-held calipers. A previous study[7] defined early ST-segment elevation resolution as a ≥50% decrease in ST-segment elevation at 30 minutes after IRA recanalization.

Quantitative coronary angiography included the assessment of TIMI grade flow, TIMI frame count, reference infarct artery diameter, and minimum lumen diameter. These quantitative angiographic parameters were assessed as previously described.[8–10]

The 1-month technetium-99m sestamibi scintigraphy and determination of infarct size at 1 month were performed as previously described.[11]

Investigators unaware of patients' treatment assignments and clinical outcomes performed independent analyses of the electrocardiograms, scintigrams, and angiograms.

The sample size was calculated on the following assumption: early ST-segment resolution would occur in 68% of patients randomized to direct stenting alone and in 90% of patients randomized to thrombectomy before stenting. To detect a difference with 80% power and a

By multivariate analysis, the only variables related to the primary end point were randomization to thrombectomy (odds ratio 3.56, 95% confidence interval 1.11 to 11.42, p = 0.032), and diabetes mellitus (odds ratio 0.24, 95% confidence interval 0.07 to 0.86, p = 0.029).

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This study assessed the efficacy of rheolytic thrombectomy as adjunctive management before routine direct stenting and avoided the confounding effects of procedural variables other than direct stenting, such as conventional balloon angioplasty, conventional stenting before or after dilation, and use or nonuse of abciximab. This feature allowed a correct assessment of the potential of rheolytic thrombectomy for prevention of atheroembolism during PCI. The principal finding from the present trial was that rheolytic thrombectomy before routine direct infarct artery stenting is highly feasible and provides more effective myocardial reperfusion as shown by the more frequent early ST-segment resolution, the lower TIMI frame count values, and smaller infarcts in patients randomized to thrombectomy versus patients randomized to stenting only. After adjustment for differences in clinical, angiographic, and procedural characteristics by multivariate analysis, rheolytic thrombectomy remained independently related to the primary end point. Thus, it is unlikely that the nonsignificant baseline characteristic imbalance between groups affected the primary end point.

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Effect of Hypnotic Sedation During Percutaneous Transluminal Coronary Angioplasty on Myocardial Ischemia and Cardiac Sympathetic Drive

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Forty-six patients were randomized to receive drug (group 1) or hypnotic sedation (group 2) during percutaneous transluminal coronary angioplasty of the left anterior descending coronary artery. Intracoronary and standard electrocardiograms were continuously registered, and heart rate spectral variability was studied. Normalized units of low- and high-frequency components and the ratio of low to high frequency were measured during balloon inflations. The ST segment shifted at the first balloon inflation from 0.02 ± 0.01 to 0.09 ± 0.6 mm in group 1 and from 0.02 ± 0.08 to 0.1 ± 0.6 in group 2 mm (p <0.05). In group 1, the low-frequency band and the ratio of low to high frequency increased significantly during the first balloon inflation (from 59 ± 10 to 75 ± 10 normalized units and from 2.4 ± 1.4 to 7.3 ± 4.7, respectively; p <0.001). The increase of the ratio of low to high frequency was significantly related to ST shift (r = 0.706; p <0.01). In contrast, no significant variation of spectral parameters was found in group 2. The increase in cardiac sympathetic activity associated with balloon inflation and myocardial ischemia during percutaneous transluminal coronary angioplasty of the left anterior descending coronary artery was selectively eliminated by hypnosis but not by drug sedation. ©2004 by Excerpta Medica, Inc.

Percutaneous transluminal coronary angioplasty (PTCA) is used widely in patients with coronary artery disease. During balloon inflation, brief periods of myocardial ischemia are followed by immediate reperfusion, but few and inconclusive data are available about the influence of these short periods of myocardial ischemia and reperfusion on the cardiac