Randomized Trial of Late Elective Angioplasty Versus Conservative Management for Patients With Residual Stenoses After Thrombolytic Treatment of Myocardial Infarction

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Background. After thrombolytic therapy for patients with acute myocardial infarction (MI), percutaneous transluminal coronary angioplasty (PTCA) is frequently performed because of the presence of a “significant” infarct vessel stenosis demonstrated at predischarge coronary angiography. Several studies have shown PTCA performed early after thrombolysis to be unnecessary or even harmful. However, PTCA in these trials was generally performed 1–3 days after MI, when the milieu in the infarct artery may be unsuitable for PTCA, and the incidence of major ischemic complications was high. To date, no trial has assessed whether delayed PTCA (4–14 days) should be performed in patients without evidence of ischemia on stress testing.

Methods and Results. To test the hypothesis that delayed PTCA might provide clinical benefit compared with medical therapy alone, 87 patients treated within 6 hours of chest pain onset with thrombolytic therapy and with negative functional test were randomized between PTCA to be performed 4–14 days after MI versus no PTCA. Both groups received medical therapy. Patients with postinfarct angina or prior Q wave infarction in the infarct distribution were excluded. The primary study end point was increase in left ventricular ejection fraction with exercise measured by radionuclide studies 6 weeks after MI, a parameter known from other studies to correlate inversely with future ischemic events. Clinical outcome was also monitored for 12 months. There were no differences between the study groups for any prereandomization variable recorded. Mean age was 57±10 years, 84% of patients were male, 21% had prior MI, 36% had anterior MI, 7% had multivessel disease, and the infarct stenosis measured 70±17% before randomization. PTCA was successful in 38 of 42 patients (88%) but resulted in non-Q wave MI due to acute closure of the treated site in three of 42 (9.5%). There was no difference in 6-week resting ejection fraction or increase in ejection fraction with exercise between the two groups (47±12% and 6±8%, respectively, in the PTCA group; 49±10% and 5±9% in the no-PTCA group; p=NS for both.) There were no deaths in either group. Actuarial 12-month infarct-free survival was 97.8% in the no-PTCA group and 90.5% in the PTCA group (p=0.07).

Conclusions. There was no functional or clinical benefit from routine late PTCA after MI treated with thrombolytic therapy in this relatively low-risk cohort of patients. These data strongly suggest that patients with an uncomplicated MI after thrombolytic therapy, even if they have a “significant” residual stenosis of the infarct vessel, should be treated medically if they are without evidence of ischemia on stress testing before hospital discharge. (Circulation 1992;86:1400–1406)

KEY WORDS • angioplasty • thrombolysis • myocardial infarction

Although several studies have found that percutaneous transluminal coronary angioplasty (PTCA) performed electively 1–3 days after thrombolytic treatment for acute myocardial infarc-

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Received April 16, 1992; revision accepted July 17, 1992.
with intravenous thrombolysis, with a negative or equivocal test for ischemia and a ≥50% infarct artery stenosis before hospital discharge.

Methods

Patient Population

All patients undergoing elective cardiac catheterization 4–14 days after acute myocardial infarction at each of the six investigational sites were screened to assess eligibility. Patients were eligible for inclusion if each of the following criteria were met: 1) they had received intravenous thrombolytic therapy (any accepted regimen?) within 6 hours of symptom onset of acute ST segment elevation myocardial infarction, 2) they had no evidence of prior Q wave infarction in the infarct territory, 3) they had a hospital course without postinfarction angina, 4) they had a stress test to a heart rate of ≥120 beats per minute or the equivalent that was negative or equivocal for ischemia ≥4 days after infarction, 5) they had an infarct-artery stenosis of ≥50%-diameter stenosis (visual assessment), and 6) they had anatomy suitable for PTCA (no left main narrowing ≥30% diameter stenosis or infarct-artery stenosis felt by the investigator to have an unsuitably high risk of complications). Patients were excluded if the infarct-artery could not be determined or if they had noncardiac illness that was judged likely to affect survival in the 2 years after study entry. During the study period, all patients meeting entry criteria 1–3 were encouraged but not required to undergo stress testing and cardiac catheterization before hospital discharge. All patients gave informed consent for participation in the study according to the institutional guidelines at each center. A registry of all eligible patients who were not randomized was kept at each participating institution.

Stress Test Evaluation

To accommodate differences in institutional and clinical practice, several types of functional testing were allowed, although exercise thallium scintigraphy was preferred. For each exercise study, a minimum heart rate of ≥120 beats per minute was required to ensure adequate stress. Exercise ECG, thallium or gated bloodpool scintigraphy, dipyridamole or adenosine thallium, or pacing ECG stress testing was performed according to standard techniques.7-10

Definitions of an ischemic response for each test were as follows: 1) exercise ECG—≥1 mm flat or downsloping ST segment depression beyond baseline and ischemic cardiac pain with exercise; 2) thallium scintigraphy—redistribution of tracer either in a myocardial segment remote from the infarct or adjacent to the infarct involving more than just the immediate peri-infarct zone; 3) gated blood-pool scintigraphy—a decrease of ≥5 ejection fraction units from resting and ischemic cardiac pain with exercise; and 4) cardiac pacing—≥1 mm flat or downsloping ST segment depression beyond baseline persisting after termination of pacing or ischemic cardiac pain during pacing.

Coronary Angiography

Coronary angiography was performed in multiple angulated projections and visualized the infarct-related artery in at least two views using standard techniques. The infarct artery was determined by correlation of the presenting ECG pattern, left ventricular wall motion, and stenoses present at either immediate or delayed angiography.11

Randomization

After giving informed consent, patients were randomized equally to one of the two treatment strategies. The randomization was prospectively stratified by enrolling hospital and by the presence of a total (100% diameter stenosis) or less-severe infarct-artery stenosis. To achieve balance between treatment within each strata, permuted block randomization was used, and the investigators remained blinded to the block size. Randomization was accomplished using a closed-envelope system originating from the Coordinating Center at the University of Michigan.

Coronary Angioplasty

Coronary angioplasty was performed using standard techniques.12 In patients randomized to PTCA, an attempt at dilatation of the infarct artery was required. Treatment of other severe stenoses was left at the discretion of the investigator. However, if a staged procedure was intended, it must have been declared at the completion of the first PTCA and the second stage performed within 4 weeks, so as not to be counted as an adverse end point.

PTCA was considered successful if a final diameter stenosis <50% was obtained and there were no major ischemic complications (e.g., death, emergency bypass surgery, or myocardial infarction [creatine kinase, twice normal or greater with MB >4%]).

Medical Therapy After Randomization

All patients received aspirin 80–975 mg orally per day for a minimum of 6 months unless contraindicated. Patients treated with angioplasty received 10,000–20,000 units heparin i.v. during the procedure and were eligible to receive posttreatment heparin if considered indicated by the treating cardiologist. Treatment with other cardioactive agents, including nitrates, calcium channel blockers, other vasodilator agents, ß-blockers, and lipid-lowering agents, was left to the discretion of the treating cardiologist. Before end point stress testing at 5–7 weeks, however, it was strongly urged that patients be temporarily tapered off of ß-receptor-blocking agents.

After randomization, patient referral for cardiac catheterization or revascularization was at the discretion of the referring physician. Physicians were informed of the study and asked not to perform cardiac catheterization or coronary intervention in the absence of ischemic symptoms or functional tests suggesting ischemia.

Angiographic Core Laboratory Analysis

All entry and procedural angiograms were forwarded to the Angiographic Core Laboratory at the University of Michigan. Baseline infarct artery maximum percent diameter stenosis from the projection best demonstrating the severity of the stenosis in a nonforeshortened view was determined using a validated computer-assisted edge detection system.13 Other stenoses narrowed ≥50% also were measured. Percent diameter stenosis after treatment was similarly determined. Pretreatment lesion risk was assessed using a modification of the
American College of Cardiology/American Heart Association angioplasty lesion criteria. Left ventricular ejection fraction was determined from right anterior oblique injection using the area-length method. All analyses were performed by an experienced angiographer who was blinded to randomization status and clinical outcome.

Follow-up
All patients were contacted by mailed questionnaire or telephone at 3 months, 6 months, 1 year, and yearly thereafter to determine event rates and functional status.

Sample Size Determination and Primary End Points
The prespecified primary hypothesis of this study was that PTCA would increase the change from rest to exercise left ventricular ejection fraction as determined by gated blood-pool scintigraphy 5–7 weeks after infarction compared with medical therapy alone. Prespecified secondary end points were 12-month cardiac event-free survival (i.e., freedom from death, myocardial infarction, coronary artery bypass surgery, and coronary angioplasty) after randomization, 12-month infarction-free survival after randomization, worst Canadian Cardiovascular Society angina class in the 12 months after treatment, resting left ventricular ejection fraction 5–7 weeks after infarction, and peak heart rate achieved at supine exercise stress testing 5–7 weeks after infarction. A sample size estimate was made requiring a 95% likelihood of detecting an absolute 3% difference in change in left ventricular ejection fraction with exercise between groups, assuming a 6.5% SD in that parameter, 80% power, and normal distribution in both groups. These estimates were derived from prior studies. This calculation yields a sample size of 72 patients with completed and interpretable exercise studies. To allow for patient and data loss (a 20% margin of error), a target enrollment of 87 patients was set.

Statistical Analysis
Comparisons of continuous variables between groups was performed using either unpaired t tests or Wilcoxon's rank-sum tests if the data were found to be nonnormally distributed. Comparisons of discrete variables were performed with Fisher's exact test. Logrank analyses were used to assess differences in outcome over time. In the event of an intergroup imbalance (p≤0.10) in baseline variables associated with outcome, adjustment for those effects was made using covariate analyses. Twelve-month event-free survival was estimated using Kaplan-Meier techniques. Data were analyzed according to the intention to treat method.

Results
Baseline Characteristics
Randomized patients. The two groups were remarkably similar for all baseline characteristics assessed (Table 1). Most patients were middle-aged men who presented for thrombolytic therapy <4 hours after symptom onset with Killip class 1 characteristics. Twenty-one percent of patients had had a previous infarction. The location of the index infarction was anterior in 31 patients (36%) and inferior in 56 patients (64%). Ninety-three percent of patients had one-vessel disease, and infarct-related stenoses measured 70±17%.

Registry patients. Thirty patients were eligible for randomization but were not randomized. They differed from patients randomized only by having a lower incidence of prior myocardial infarction (0% versus 21%, p=0.02). There was no difference in the age (58±11 versus 57±10 years), sex (78% versus 84% male), time to thrombolytic therapy (2.7±1.3 versus 2.9±2.7 hours), incidence of anterior infarction (37% versus 35%), or incidence of total coronary occlusion (7% versus 11%) between registry and randomized patients. The reasons for failure to randomize were physician refusal (53%), patient refusal (37%), and patient not approached for randomization (10%).

Prehospital Discharge Functional Testing
There were no differences between groups for functional testing-related variables. Of the patients randomized to PTCA, 43% had exercise ECG tests, 26% had exercise thallium tests, 9% had dipyridamole thallium tests, and 5% had pacing tests in the catheterization laboratory. Testing was performed on day 7±3. Of those with exercise tests, the mean heart rate was 128±15 beats per minute. Of the patients randomized to conservative therapy, 31% had exercise ECG tests, 49% had exercise thallium tests, 11% had dipyridamole thallium tests, and 7% had exercise gated pool blood scanning. Testing was performed on day 7±2. Of those with exercise tests, mean heart rate was 128±13 beats per minute.

<table>
<thead>
<tr>
<th>TABLE 1. Baseline Characteristics of the Percutaneous Transluminal Coronary Angioplasty and Conservatively Managed Groups</th>
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<tbody>
<tr>
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<tr>
<td>Age (mean±SD)†</td>
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<tr>
<td>Male sex (%)</td>
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<tr>
<td>Diabetes mellitus (%)</td>
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<tr>
<td>Hypercholesterolemia (%)</td>
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<tr>
<td>Hypertension (%)</td>
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<tr>
<td>Current smoker (%)</td>
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<tr>
<td>Prior myocardial infarction (%)</td>
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<tr>
<td>Killip class</td>
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<tr>
<td>Anterior/inferior infarction (%)</td>
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<tr>
<td>Time symptoms to thrombolytic therapy (hours)</td>
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<tr>
<td>Thrombolytic agent</td>
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<tr>
<td>Streptokinase (%)</td>
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<tr>
<td>t-PA (%)</td>
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<tr>
<td>Other (%)</td>
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<tr>
<td>Infarct artery %DS pretreatment</td>
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<tr>
<td>Infarct artery totally occluded (%)</td>
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<td>Left ventricular ejection fraction (%)</td>
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†Continuous variables presented as mean±1 SD.
*No p≤0.10.
TABLE 2. Effect of Percutaneous Transluminal Coronary Angioplasty on Clinical Outcomes

<table>
<thead>
<tr>
<th></th>
<th>Angioplasty (n=42)</th>
<th>Conservatively managed (n=45)</th>
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<tr>
<td>PTCA success (%)</td>
<td>88</td>
<td>...</td>
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<tr>
<td>PTCA major ischemic complications (%)</td>
<td>9.5</td>
<td>...</td>
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<tr>
<td>6-Week resting LVEF (%)</td>
<td>47±12</td>
<td>49±10</td>
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<tr>
<td>6-Week peak exercise heart rate (bpm)</td>
<td>125±26</td>
<td>123±20</td>
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<tr>
<td>6-Week rest to exercise LVEF (%)</td>
<td>6±8</td>
<td>5±9</td>
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<tr>
<td>12-Month infarct-free survival (%)</td>
<td>88.7*</td>
<td>100.0*</td>
</tr>
<tr>
<td>12-Month event-free survival (%)</td>
<td>77.1</td>
<td>79.1</td>
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<tr>
<td>Angina class</td>
<td>0.2±0.4†</td>
<td>0.5±0.7†</td>
</tr>
<tr>
<td>NYHA heart failure class</td>
<td>1.1±0.3</td>
<td>1.1±0.3</td>
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PTCA, percutaneous transluminal coronary angioplasty; LVEF, left ventricular ejection fraction; bpm, beats per minute; NYHA, New York Heart Association.

*p=0.07; †p=0.04.

Results of Coronary Angioplasty

Randomized patients. Angioplasty was successful in 38 of 42 patients (88%) (Table 2). One distal right coronary artery occlusion could not be crossed with a guidewire. Three patients (9.5%) had apparent thrombus-mediated arterial closure and suffered non-Q wave infarcts despite immediate treatment with intracoronary thrombolitics. Their peak creatine kinase level after PTCA was 455±390 IU. Mean stenosis severity after successful PTCA was 35±10%.

Registry patients. Six of 30 nonrandomized patients had attempted PTCA. There were four successful results (67%), one unsuccessful uncomplicated result (16%), and one failed PTCA with subsequent death (16%). Thus, the overall results of PTCA were success, 88%; procedure-related myocardial infarction, 6.3%; procedure-related death, 2.1%; and emergency bypass surgery, 0%. Each of the four patients with major complications had a subtotal infarct artery stenosis, complex morphology (modified American College of Cardiology/American Heart Association Task Force lesion type B1, B2, or C4), p=0.09 versus type A), and apparent thrombus-mediated closure at the treated site, and three had complications despite repeat administration of thrombolytic therapy.

Treatment After Hospital Discharge

Medications received through the initial 6-week period did not differ between the two groups. Thirty-seven percent of patients received β-blockers, 68% received calcium blockers, 43% received nitrates, and 7% received other vasodilators. Thirty-one of the 32 patients (97%) discharged on β-blockers had them withdrawn before 6-week exercise testing.

Clinical follow-up was obtained in all randomized patients. In the PTCA group, three patients (7%) had late PTCA, and one patient (2%) had late bypass surgery. In the conservatively managed group, four patients (9%) had late PTCA, and one patient (2%) had late bypass surgery. All late revascularizations were performed after the 6-week stress test.

Six-Week Functional Testing

There was no difference between mean duration of exercise, maximum heart rate, resting ejection fraction, or response to exercise between the two groups (Table 2). If one considers an increase from rest to exercise of ≥5 units to be normal in the convalescent phase of myocardial infarction, then only 23 of 38 PTCA patients (60%) and 21 of 40 conservatively managed patients (53%) had a normal response (p=NS), yet the vast majority were angina free. Even with exclusion of the PTCA patients with angioplasty-induced myocardial infarction, there was no difference in ejection fraction response to exercise (5±7% in PTCA patients, 5±9% in conservatively managed patients).

Late Clinical Outcome

Late revascularization treatments are described above. No cardiac deaths occurred in either randomized group, and one patient in the conservatively treated group died of a malignancy. There were no infarctions during the 12 months of follow-up. There was no difference between groups in 12-month event-free survival (PTCA, 83%; medical, 80%; p=NS), but there was a trend toward worsened infarct-free survival with PTCA (90% versus 98%, p=0.07). In a post-hoc analysis evaluating outcome in all patients (n=117), infarct-free survival in patients not having prehospital discharge PTCA was superior to that in patients having PTCA (97.8% versus 90.0%, p=0.03). Moderate or severe heart failure (New York Heart Association functional class, ≥II) was uncommon, occurring in two in 42 PTCA patients (5%) and three of 45 no-PTCA patients (7%) (p=NS). Angina at latest follow-up occurred more frequently in the conservatively managed group, but it generally was very mild.

Discussion

Despite its modest size, due to its randomized nature and conclusive results, this trial adds important information regarding the merits of what has come in many centers to be routine postthrombolytic patient management—delayed elective dilatation of residual high-grade stenoses in patients with negative or equivocal stress test results.
Differences From Other Postinfarction Intervention Trials

Two large-scale trials, the Thrombolysis in Myocardial Infarction (TIMI) II and the Should We Intervene After Thrombolysis? (SWIFT) studies, have conclusively demonstrated that early PTCA should not be routinely performed after successful thrombolysis. However, the excessive incidence of PTCA-related complications noted in these studies, in which PTCA was performed at a time (1–3 days after infarction) when the infarct artery probably has residual thrombus and a generally unfavorable milieu for PTCA, may have limited extrapolation of the results to clinical care at many centers. It is not certain if angioplasty performed at a somewhat later date might carry the same risk. Only the relatively small-scale trial of Barbash et al., in which PTCA was performed 5 days after thrombolysis, is analogous in the timing of intervention to this study. Furthermore, in none of these studies was the functional severity of the stenosis assessed before coronary angioplasty.

Relevance of the Primary End Point

In several large-scale long-term follow-up analyses of patients treated with reperfusion therapy for acute infarction, left ventricular ejection fraction, high-grade residual infarct artery stenoses, a history of prior infarction, multivessel disease, and age best predicted 2–5-year event-free survival. Other studies have stressed the importance of left ventricular end-systolic dimension. Although not specifically evaluated in large numbers of patients in this setting, exercise capacity by radionuclide testing has been shown to have considerable prognostic value after infarction and, hence, was selected for the primary end point of a study the size of this study.

Implications of a Negative or Equivocal Stress Test in This Setting

Sutton and Topol have recently shown that the most common explanation for a fixed or peri-infarct redistribution defect on thallium scintigraphy performed early after myocardial infarction in patients treated with thrombolytic therapy is a completed or nearly complete infarct, not a total coronary occlusion of the infarct artery. Others also have emphasized the difficulties in identifying infarct artery patency and noninfarct artery stenoses in this setting. Thus, it is not surprising that left ventricular function can be only at best marginally improved by successful treatment of high-grade stenoses supplying the infarcted area in these patients. The results of this study for ejection fraction at rest and with exercise and for long-term heart failure class are concordant with this impression.

Other potential beneficial effects of PTCA in this setting might be prevention of later closure of the artery with infarction and/or elimination of a potential conduit for collateral formation, regardless of the early effect on ventricular function. However, angioplasty has not been shown to reduce the risk of infarction in this or other settings, and the follow-up of patients in this and other studies would suggest that patients without inducible ischemia after infarction have a generally excellent intermediate-term prognosis.

Risk of Coronary Angioplasty Early After Myocardial Infarction

The clinical and anatomic risk factors for PTCA-induced ischemic complications have been reasonably well described and include unstable angina, visible thrombus, and other morphological features of the stenosis. Thus, the 11–13% incidence of angioplasty-mediated infarction reported by the TIMI and SWIFT trial investigators after early postthrombolytic PTCA should not be unexpected. Analyses from large PTCA registries suggest that the period of heightened risk may extend for at least 2 weeks after presentation with unstable angina and perhaps also that long after infarction. The 9.5% incidence of infarction after PTCA in this study of delayed PTCA extends these observations. Although the number of adverse events in this study was too few to make widespread generalizations, each procedural infarction was associated with angiographic features suggestive of thrombus. It is uncertain if more powerful antiplatelet agents currently under investigation might decrease this risk. At present, angioplasty in the stable postinfarction patient, even when indicated by virtue of demonstrated reversible ischemia, might be best deferred for several weeks.

Study Limitations

Interpretation of the results of this study must take into consideration its several limitations. First, the relatively small number of randomized patients places constraints on justifiable conclusions. Although the statistical power to detect or exclude benefit in terms of meaningful improvement in left ventricular ejection fraction response to exercise is considerable, the power to detect differences in clinical outcome is limited. The treatment differences in long-term infarct-free survival composed a secondary end point and must be considered with data from other similar small-scale studies evaluating late PTCA after infarction. Second, the patients studied were in general of expected low risk due to infrequent severe ventricular dysfunction or multivessel disease; hence, the results should not be extended beyond that group. In fact, an unknown number of patients with “high-risk” anatomy probably were referred directly for PTCA without stress testing and so were ineligible for both randomization and registry analysis. Third, few patients (11%) had a totally occluded infarct artery, so the “open vessel hypothesis” was not tested.
Implications

The results of this study substantially extend those of other randomized trials1-3 to suggest that 1) patients without moderate-severe left ventricular dysfunction in this setting should undergo routine functional testing before hospital discharge because in the absence of ischemic result, 1-year prognosis is excellent and, therefore, 2) routine PTCA of postinfarct stenoses in patients with well-preserved left ventricular function and without reversible ischemia should not be performed in the prehospital discharge setting to avoid the 8-10% risk of procedure-related death.

Appendix

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Treatment of Post-Thrombolytic Stenoses (TOPS) Study Group.
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Circulation. 1992;86:1400-1406
doi: 10.1161/01.CIR.86.5.1400

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