Rheolytic thrombectomy during percutaneous revascularization for acute myocardial infarction: Experience with the AngioJet catheter

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Background Although balloon angioplasty and stenting are effective in the treatment of acute myocardial infarction (MI), reduced coronary flow and distal embolization frequently complicate interventions when thrombus is present. Adjunctive treatment with mechanical thrombectomy devices may reduce these complications.

Methods and Results We evaluated the angiographic and clinical outcomes of 70 patients with acute MI (16% with cardiogenic shock) and with angiographically evident thrombus who were treated with AngioJet rheolytic thrombectomy followed by immediate definitive treatment. Procedure success (residual diameter stenosis <50% and Thrombolysis in Myocardial Infarction [TIMI] flow ≥2 after final treatment) was achieved in 93.8%. Clinical success (procedure success without major in-hospital cardiac events) was achieved in 87.5%, with an in-hospital mortality rate of 7.1%. Final TIMI 3 flow was achieved in 87.7%. AngioJet treatment resulted in a mean thrombus area reduction from 73.2 ± 64.6 mm² at baseline to 15.5 ± 30.1 post-thrombectomy (P < .001). Subsequent definitive treatment included stenting in 67% and balloon angioplasty alone in 26% of patients. Procedural complications included distal embolization in six patients and perforation in two patients. There were no further major adverse events during 30-day follow-up.

Conclusion Rheolytic thrombectomy can be performed safely and effectively in patients with acute MI, allowing for immediate definitive treatment in thrombus-containing lesions. (Am Heart J 2001;141:353-9.)

Sudden thrombotic occlusion is responsible for acute myocardial infarction (MI) in the majority of patients, and rapid restoration of normal coronary flow preserves myocardial function and improves long-term prognosis. Early reperfusion can be accomplished with pharmacologic thrombolysis or primary percutaneous angioplasty. Primary angioplasty has been shown to provide higher rates of Thrombolysis in Myocardial Infarction (TIMI) 3 coronary flow and preservation of left ventricular function compared with pharmacologic thrombolysis but is limited by higher rates of reocclusion, recurrent infarction, and restenosis compared with elective angioplasty. The presence of thrombus in acute MI may be a major factor responsible for the development of these complications.

Although thrombus removal before definitive catheter-based intervention in acute MI may be desirable, antecedent or adjunctive pharmacologic thrombolysis has not been shown to improve the clinical outcomes of coronary intervention. Strategies using combined reduced-dose thrombolysis and subsequent intervention, however, show promise. The use of glycoprotein IIb/IIIa receptor antagonists as an adjunctive pharmacologic regimen to direct angioplasty has been shown to reduce the need for urgent repeat interventions. Mechanical removal of thrombus with transluminal extraction atherectomy (TEC catheter, Interventional Technologies, San Diego, Calif) may obviate the problems of systemic thrombolysis, but treatment is associated with suboptimal outcomes in thrombus-containing lesions.

AngioJet rheolytic thrombectomy (Possis Medical, Minneapolis, Minn) is a catheter-based method for thrombus removal. High-velocity saline solution jets are used to create a localized low-pressure zone at the distal catheter tip (Bernoulli effect), which results in the maceration and removal of thrombus through an exhaust.
lumen. The use of rheolytic thrombectomy in the treatment of non-MI thrombus-containing coronary lesions has been previously reported. The purpose of the current study was to assess the safety and clinical efficacy of adjunctive rheolytic thrombectomy during percutaneous revascularization for acute MI.

**Methods**

**Patient population**

The study population included 70 consecutive patients who had a transmural acute MI within 8 hours of symptom onset and who were enrolled in the Food and Drug Administration (FDA)-approved Vein Graft AngioJet Study-1 (VeGAS 1) or VeGAS 2 acute MI Registry. The protocols were approved by the Institutional Review Boards at each site. Sixteen patients were drawn from VeGAS 1, a 90-patient pilot registry of AngioJet thrombectomy in thrombus-containing saphenous vein bypass grafts and native coronary arteries. The remaining 54 patients were drawn from the VeGAS 2 Acute MI Registry, which included 90 patients with angiographic thrombus, treated with AngioJet during an acute MI, and who were seen within 24 hours of symptom onset. Only those patients who were seen within 8 hours of symptom onset were included in the current analysis.

Patients analyzed in the current study were identified by a Clinical Events Committee, blinded to the goals of the study, on the basis of evidence of acute MI and symptom onset within 8 hours of intervention. Acute MI was defined as the presence of at least two of the following three criteria: ongoing ischemic pain, ≥0.1 mm ST elevation in two contiguous electrocardiogram (ECG) leads, and elevation of cardiac enzymes to at least two times the upper limit of normal. Patients were also required to meet all the following angiographic inclusion criteria: target lesion reference diameter of at least 2.0 mm; angiographically evident thrombus, defined as a mobile or fixed intraluminal filling defect outlined or stained by contrast dye; and target lesion with at least 70% diameter stenosis. Patients were excluded if they had received thrombolytic therapy within 24 hours of the intended AngioJet procedure.

**Patient treatment**

On arrival to the emergency department, patients received a chewable aspirin (325 mg) along with standard medical treatment for acute MI (intravenous β-blockers, nitrates, etc), at the emergency physician’s discretion. After the diagnosis of acute MI was confirmed and informed consent was obtained, the patient was taken to the cardiac catheterization laboratory for emergency mechanical intervention. Intravenous heparin was given to maintain an activated clotting time of >250 seconds. Platelet IIb/IIIa antagonists were used in 26.2% of patients.

The AngioJet LF140 rheolytic catheter is a 5F, dual-lumen, over-the-wire design, as described previously. Multiple high-velocity saline solution jets create a localized low-pressure zone at the catheter distal tip (Bernoulli effect), which results in the maceration and removal of thrombus through the effluent lumen (Figure 1). An external piston pump console provides the pressurized pulsatile flow that supplies the jets.

After angiographic confirmation of the presence of thrombus, an 8F or 9F guiding catheter was placed in the target vessel, followed by advancement of a 0.014- or 0.018-inch guide wire into the distal vessel. Because transient bradycardiac rhythm may occur during rheolytic thrombectomy, a temporary pacing wire was generally placed before treatment. The thrombectomy catheter was then connected to the pump console, flushed, and advanced through the guiding catheter over the guide wire. The pump console was activated by depressing a foot switch, and the catheter was passed slowly across the thrombosed segment in either a distal-to-proximal or proximal-to-distal direction, at a rate of 1 to 2 mm per second. Angiography was obtained after each pass, and additional
passes were performed until all filling defects had been removed or there was no further improvement between passes. In most cases, adjunctive balloon angioplasty or stenting was performed after thrombectomy, with use of standard techniques. Stent sizing was based on a balloon-to-artery ratio of 1.1:1 and inflation pressures of 10 to 20 atmospheres to attain <10% residual stenosis by visual estimate. After final balloon angioplasty or stenting, anticoagulant and antiplatelet therapy included various combinations of aspirin (325 mg daily), ticlopidine (250 mg twice daily for 4 weeks), coumadin (titrated to international normalized ratio of 2.0-2.5), and intravenous heparin for 24 to 48 hours.

Data collection
Clinical data were obtained by study coordinators using standardized case report forms, were independently monitored, and were submitted to the data coordinating center (CDAC, Harvard Medical School, Boston, Mass). ECGs were reviewed by the Electrocardiographic Core Laboratory (CDAC, Boston, Mass) blinded to clinical events. Procedural angiograms were submitted to the Angiographic Core Laboratory (Washington Hospital Center, Washington, DC) and analyzed with the CAAS2 system (Phil Medical, Maastricht, The Netherlands). Clinical follow-up was obtained at hospital discharge and at 4 weeks after the index procedure. All events were adjudicated by an independent Clinical Events Committee.

Angiography
Cineangiograms of the target lesion were acquired in two angiographic projections before and after thrombectomy treatment and after final treatment. Intracoronary nitroglycerin (50-200 µg) was recommended before angiography, unless contraindicated. The mean reference vessel diameter, minimal lumen diameter (MLD), percent diameter stenosis, and thrombus area were calculated from an average of the two angiographic projections with use of an automated edge detection algorithm (CAAS2). Thrombus area was determined before and after thrombectomy and after final treatment by dividing the vessel in multiple equal segments and calculating the axial length and width of radiolucency in each segment.

End points
Procedure success was defined as attainment of TIMI grade 2 or 3 coronary flow and residual diameter stenosis <50% by use of any percutaneous method. The primary end point in this study was clinical success, defined as procedural success without death, major disabling stroke, or emergency bypass surgery during the index hospital stay. Device success was defined as the restoration of TIMI 3 coronary flow and attainment of <50% diameter stenosis after thrombectomy treatment only. Secondary end points included 30-day major adverse cardiovascular events (death, reinfarction, target vessel revascularization) and procedural complications, including perforation, sustained slow flow, distal embolization, bleeding complications, and vascular complications.

Sustained slow flow was defined as the occurrence of sudden reduced coronary flow to <TIMI 2 after there had previously been a patent segment with normal antegrade flow. Distal embolization was defined as the migration of a filling defect or thrombus to distally occlude the target vessel or one of its branches or a new abrupt cutoff of distal vessels and branches (by Angiographic Core Lab assessment). Bleeding complications consisted of procedure-related blood transfusions. Vascular complications were defined as the occurrence of hematoma >4 cm, retroperitoneal bleed, false aneurysm, atrioventricular fistula, peripheral ischemia/nerve injury, hemolysis, or hemolytic anemia. Major disabling stroke was defined as a major neurologic event resulting in a permanent disabling neurologic deficit. Repeat target vessel revascularization was defined as the adjudicated need for a surgical or percutaneous revascularization procedure after the index procedure and within the follow-up period on the basis of recurrence of symptoms or objective evidence of ischemia and confirmed angiographically as renarrowing of the target lesion to >50%.

Statistical analysis
Continuous end points were expressed as mean ± SD. Chi-square tests were used to compare count data, and continuous end points were compared with 2-sided unpaired Student t tests. All statistical analyses were performed with SAS software (version 6.12, SAS Institute, Cary, NC).

Results
Baseline characteristics
Baseline demographic and clinical characteristics are summarized in Table I. The study sample consisted of 70 patients (70 lesions) with a mean age of 60 ± 11 years. Eleven patients (16%) came to the hospital with cardiogenic shock, defined as hypotension requiring pressor or inotropic support. The culprit lesion was located in the left anterior descending (25%), right (45%), left circumflex (9%), and left main (1%) coronary arteries, or saphenous vein graft (20%).

Procedure results and in-hospital outcomes
The AngioJet catheter was successfully delivered in all 70 patients (Figure 2). Further mechanical treatment...
after thrombectomy was performed in 95% of the patients: coronary stenting in 67%, balloon angioplasty alone in 26%, rotational atherectomy in 1%, and directional atherectomy in 1%. Four patients required additional intracoronary thrombolytic therapy (urokinase) to further decrease the thrombus burden. Bradycardia induced by operation of the AngioJet catheter occurred in 51.9% of patients, and this was managed with atropine in 3.8%, temporary pacemaker in 17.3%, and combination atropine/pacemaker in 30.7%. Procedural success was achieved in 93.8% and clinical success in 87.5% of patients. Device success was achieved in 78.0%. The in-hospital mortality rate was 7.1% (5 deaths), and no patients required emergency bypass surgery or had a stroke. Procedural complications included distal embolization in 6 patients (8.6%), transient no reflow in 11 patients (15.7%), sustained slow flow in 2 patients (2.9%), and perforation in 2 patients (2.9%, both successfully sealed by prolonged balloon inflation, without tamponade). Bleeding complications
Angiographic results
TIMI grade 3 flow was present in 79.4% of the patients after thrombectomy and in 87.7% after final treatment ($P < .001$ for both postthrombectomy and final vs baseline) (Table II). Final TIMI 2 or 3 flow was achieved in 96.9%. There were four instances in which TIMI 3 flow after thrombectomy was reduced to TIMI 2 flow after final treatment (7.4%). The final treatment in these cases was stenting in three and balloon angioplasty in one.

The MLD increased from 0.42 ± 0.56 mm before the procedure to 1.31 ± 0.76 mm after thrombectomy and to 2.4 ± 0.75 mm after final treatment. Thrombus burden was reduced from 73.2 ± 64.6 mm² at baseline to 15.5 ± 30.1 mm² after thrombectomy and to 3.2 ± 12.8 mm² after final treatment ($P < .001$ for both postthrombectomy and final vs baseline).

30-Day clinical outcome
After discharge from the hospital, there were no additional deaths, strokes, recurrent MIs, or need for repeat percutaneous or surgical target vessel revascularization by 30-day follow-up. The overall 30-day freedom from major adverse cardiac event rate was 92.9% (65 of 70 patients).

A comparison of outcomes of patients undergoing saphenous vein graft intervention with those undergoing native coronary artery intervention is shown in Table III. The procedure success rate and TIMI 3 flow rate were higher in native coronary arteries. There were no significant differences in outcomes of patients who received IIb/IIIa antagonists compared with those who did not receive this treatment (Table IV).

Discussion
The current study showed that AngioJet treatment successfully removed angiographically evident intracoronary/graft thrombus (net thrombus area reduction of 57.7 mm²), resulting in final TIMI 3 flow in the majority of patients (87.8%). Our series of 70 patients represents a severely ill, high-risk subset of patients with acute MI: 16% had cardiogenic shock, the mean baseline ejection fraction was 44%, 37% had prior MI, and the culprit thrombus lesion was located in a saphenous vein graft or the left main coronary artery in 21%. An acceptable overall 1-month mortality rate of 7.1% (5 in-hospital deaths) was achieved, and rates of distal embolization (8.6%) and sustained slow flow (2.9%) were also relatively low, despite intervention in the setting of extensive angiographically evident thrombus. The incidence of perforation was 2.9%. The perforation rate was 1.1% in the VeGAS 1 pilot study (n = 90 patients) and 1.7% in the VeGAS pivotal randomized trial (n = 350 patients). In each of these cases, we were not able to determine the specific role of the AngioJet catheter in the mechanism of perforation because the perforation was evident only after the final definitive stenting procedure. However, the potential for final treatment to cause perforation in these patients was underscored by the 1.2% perforation rate seen in the control arm of the VeGAS 2 trial. To avoid possible injury, it is recommended that the AngioJet catheter not be used in vessels less than 2.0 mm, and we have found that no other lesion or vessel characteristics were predictive of complications (using all available data from the trials).

Because prior studies have not explicitly addressed the treatment of acute MI patients with overt intracoronary thrombus, direct comparison with our results is difficult. Our study, however, demonstrated a final TIMI 3 grade flow in 87.7% of patients, which is higher than the 73% rate seen in the Global Use of Strategies To Open Occluded Coronary Arteries in Acute Coronary Syndromes (GUSTO IIb) study² but lower than the 96% rate achieved in the Primary Angioplasty in Myocardial Infarction (PAMI) Stent Trial. We observed no incidence of recurrent ischemia, infarction, or repeat revascularization at 30 days, which compares favorably with the 9% to 15% recurrent ischemia rate seen in the other studies and the 3.8% reinfarction rate

### Table III. Outcomes by vessel type: saphenous vein grafts and native coronary arteries

<table>
<thead>
<tr>
<th>Outcome</th>
<th>Saphenous vein graft (n = 14 lesions)</th>
<th>Native coronary artery (n = 56 lesions)</th>
<th>Statistical significance</th>
</tr>
</thead>
<tbody>
<tr>
<td>TIMI 3 flow (%)</td>
<td>71.4</td>
<td>92.2</td>
<td>$P = .059$</td>
</tr>
<tr>
<td>Procedure success (%)</td>
<td>78.6</td>
<td>98.0</td>
<td>$P = .029$</td>
</tr>
<tr>
<td>Clinical success (%)</td>
<td>78.6</td>
<td>90.0</td>
<td>$P = .357$</td>
</tr>
<tr>
<td>Postprocedure distal embolization (%)</td>
<td>7.1</td>
<td>9.8</td>
<td>$P = .99$</td>
</tr>
<tr>
<td>30-Day mortality (%)</td>
<td>7.1</td>
<td>7.1</td>
<td>$P = .99$</td>
</tr>
</tbody>
</table>

### Table IV. Outcomes by use of glycoprotein IIb/IIIa antagonists*

<table>
<thead>
<tr>
<th>Outcome</th>
<th>+IIb/IIIa use (17 patients, 26.2%)</th>
<th>–IIb/IIIa use (48 patients, 73.8%)</th>
<th>Statistical significance</th>
</tr>
</thead>
<tbody>
<tr>
<td>TIMI 3 flow (%)</td>
<td>88.2</td>
<td>87.5</td>
<td>$P = .99$</td>
</tr>
<tr>
<td>Procedure success (%)</td>
<td>88.2</td>
<td>95.8</td>
<td>$P = .28$</td>
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<tr>
<td>Clinical success (%)</td>
<td>81.3</td>
<td>89.6</td>
<td>$P = .40$</td>
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<tr>
<td>Postprocedure distal embolization (%)</td>
<td>0</td>
<td>12.5</td>
<td>$P = .33$</td>
</tr>
<tr>
<td>30-Day mortality (%)</td>
<td>11.8</td>
<td>5.7</td>
<td>$P = .59$</td>
</tr>
</tbody>
</table>

*Data available for 65 of 70 patients.
and 3% two-vessel revascularization rate seen in the PAMI Stent Trial.2,21-24 An important distinction between our study and these prospective primary percutaneous transluminal coronary angioplasty (PTCA)/stent trials is that cardiogenic shock, prior stroke, and culprit lesions located in the left main artery or a vein graft were excluded in the other trials. Compared with patients who were enrolled in the primary PTCA trials, the mortality rate is up to five times greater for patients who have clinical factors that exclude them from these trials.25 In a recent series of stenting in patients with acute MI complicated by cardiogenic shock, the 6-month mortality rate was 27%, with all deaths occurring in the initial 30 days.26 Results from the randomized Should We Emergently Revascularize Occluded Coronaries for Cardiogenic Shock (SHOCK) trial (to evaluate early revascularization in acute MI complicated by cardiogenic shock) showed a 30-day mortality rate of 46.7% and a 6-month mortality rate of 50.3%, which was significantly lower compared with rates observed for patients treated with medical stabilization only.27

Other percutaneous strategies for the treatment of thrombus-containing lesions in acute MI include mechanical compression by balloon angioplasty or stenting and catheter-based interventions using transluminal extraction atherectomy (TEC) or intravascular ultrasonographic thrombolysis. The TEC device macerates atherosclerotic plaque and coronary thrombi by the interaction of a rotating cutter and a continuous vacuum suction.17 TEC has been shown to be effective in the treatment of native coronary artery and saphenous vein graft disease complicated by thrombus, although distal embolization occasionally occurs. In a prospective evaluation of 100 patients with acute MI undergoing TEC treatment, procedure success was achieved in 94%, TIMI 3 flow was achieved in 65%, but thrombus removal was not quantified.28 Intravascular ultrasonic thrombolysis (Acology System, Angiosonics, Morrisville, NC) applies low-frequency ultrasound for rapid mechanical thrombolysis. The initial results of ultrasonic thrombolysis in 15 patients with acute anterior MI showed successful TIMI 3 reperfusion in 87%, with a low in-hospital complication rate.29

Primary stenting in acute MI has been shown to reduce the need for repeat interventions.24,30 Restorations of high coronary flow rates usually suffices to overcome the prothrombotic tendencies of the freshly placed stent exposed to the intravascular pool of activated platelets seen with acute MI. However, when stents are placed in emergency situations or as bail-out devices after nonstent procedures, the rate of stent thrombosis may be substantial, especially in the presence of a large thrombus burden.31 AngioJet has also been used successfully in the treatment of acute/subacute coronary stent thrombosis.32 In the setting of acute MI, stenting may result in a decline in coronary flow, and the incidence of reduced TIMI flow by stenting or balloon angioplasty was 7.4% in our study. These results are consistent with those observed in the PAMI stent trial and we therefore provide no evidence that AngioJet thrombectomy reduces the problem of occasional reduced flow after stenting.33

The use of IIb/IIIa antagonists has been shown to decrease procedural complication rates in patients with acute coronary ischemia undergoing balloon angioplasty or stenting; however, the incremental benefit that these agents add to stenting has not been established.15,16,33 IIb/IIIa antagonists were used in a minority of patients in our study, and no significant additional benefit was demonstrated (Table IV); however, our study was not designed to evaluate combined treatment of IIb/IIIa antagonists with AngioJet thrombectomy.

Limitations

Because of the exploratory nature of our study, we did not attempt to demonstrate the incremental benefit of AngioJet thrombectomy in the MI setting, by comparison with alternative methods of revascularization. Therefore we cannot determine the true clinical utility of this device compared with other strategies for the treatment of acute MI complicated by angiographically evident thrombus. Nevertheless, the degree of thrombus resolution in the current study was impressive, and the relatively low incidence of complications suggests that direct thrombus removal may play an important role in the treatment of acute MI in select patients.

References


