Effectiveness of Rheolytic Coronary Thrombectomy With the AngioJet Catheter

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Thrombus-filled lesions are associated with a higher rate of acute complications and long-term restenosis following conventional coronary or saphenous vein graft (SVG) intervention. To evaluate the clinical effectiveness of rheolytic thrombectomy in a nonselected population in the glycoprotein IIb/IIIa blockade era, we reviewed clinical, angiographic, and procedural data on 119 patients who underwent 126 consecutive coronary AngioJet procedures (29% in SVGs, and 71% in native coronary arteries) from July 1998 to August 2000. Glycoprotein IIb/IIIa blockers were used in 88%. Most vessels (68% of SVGs, 74% of native coronary arteries) were occluded initially. Complete or substantial removal of filling defects was achieved in 76% of SVGs and 66% of native coronary cases. The AngioJet rheolytic thrombectomy device led to significant improvement in lumen diameter and Thrombolysis In Myocardial

Infarction (TIMI) flow, with reduction in the thrombotic lesion length (p < 0.05). Angiographic success (<30% residual stenosis, TIMI-3) was attained in 73% of SVGs and 87% of native coronary procedures. Distal embolization occurred in 13 cases, and was less likely to occur in patients treated with abciximab (0%) compared with patients treated with other glycoprotein IIb/IIIa blockers or heparin alone (17%, p = 0.02). A favorable response to the AngioJet (odds ratio 3.9) and freedom from embolization (odds ratio 14.6) were associated with a higher procedural success rate. In-hospital and long-term clinical outcomes were favorable. Thus, rheolytic thrombectomy resulted in significant reduction of the thrombus burden in most patients, restored TIMI-3 flow, and led to favorable short- and long-term outcomes. © 2002 by Excerpta Medica, Inc.

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iven the high complication rates with conventional angioplasty techniques, 1–3 mechanical reduction of thrombus burden may result in better outcomes following percutaneous coronary interventions (PCIs). Rheolytic thrombectomy using the AngioJet catheter (Possis, Minneapolis, Minnesota) results in effective thrombus removal; it has been shown to be safer, more efficacious, and to reduce overall medical care costs compared with coronary infusion of urokinase for vein graft and native coronary interventions.4,5 It has also been reported to be effective for treating acute myocardial infarction (AMI).6,7 However, rheolytic thrombectomy effectiveness has not been adequately studied in nonselected saphenous vein graft (SVG) and native coronary interventions, or stent thrombosis, using adjunctive glycoprotein IIb/ IIIa blockade. Therefore, we present a large singlecenter experience with the AngioJet device, in an

unselected population who underwent PCI for SVG, native coronary, and stent thrombosis.

METHODS

Study population: Between July 1998 and August 2000, 4,965 PCIs were performed at the Beth Israel Deaconess Medical Center in Boston, and case-related information was entered prospectively into a database. This included 119 consecutive patients who underwent 126 AngioJet rheolytic thrombectomy procedures. Patients were selected for this procedure if they had angiographic evidence of a substantial thrombus in a culprit native coronary or SVG >2.0 mm in diameter that was targeted for percutaneous intervention. Clinical, angiographic, and procedure related information was also obtained from online medical records, and cine angiograms on all but 7 cases were retrieved.

Procedure description: The LF 140 Possis AngioJet is a 140-cm-long 5Fr stainless steel catheter that tapers to 3.5Fr in the distal 5 cm. The catheter is attached to a driving unit with a piston pump that generates highpressure pulsed flow (10,000 lbs/in² at 50 ml/min) pushed into a hypotube lumen. This lumen ends up in a loop at the catheter tip containing 6 high-velocity jets that are directed retrograde into the collecting lumen of the catheter across a 1-mm gap. Saline, which exits the loop at a speed of about 450 km/hour, creates a vortex (Venturi effect) that fragments and aspirates thrombus material.8

Following angiography with findings suspicious

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for thrombus, weight-based heparin (70 μm/kg) was administered, aiming at achieving an activated clotting time of 300 seconds. A temporary right ventricular pacing lead was placed in patients who underwent right coronary or dominant circumflex native or graft treatment to prevent symptomatic bradyarrhythmias. Most procedures were performed through an 8Fr guiding catheter, but 6Fr and 7Fr large lumen catheters (Zuma 2, Medtronic, California) were occasionally used (4 cases). After crossing the lesion with a 0.014-in guidewire, distal angiography was often performed using a sidehole injection catheter or the lumen of an over-the-wire balloon to evaluate the quality of the distal bed, and the presence and length of the thrombus. The AngioJet catheter was positioned distal to the suspected thrombus. The pump unit was then activated and thrombectomy was performed by slow (0.5 mm/s) withdrawal of the catheter. Multiple passes were performed until no improvement in angiographic appearance was noted. Following thrombectomy, balloon angioplasty and/or stenting was performed. Coronary "slow flow" was treated with intracoronary diltiazem (250 to 500 µg) and/or nitroglycerin (100 to $200 \mu g$).

Angiographic evaluation: Angiographic analysis was performed in 119 cases; those who analyzed the data were blinded to clinical data and clinical and angiographic outcomes. Modified American College of Cardiology/American Heart Association criteria were used to classify the target lesion. Initial anterograde flow was assessed before guidewire placement according to the Thrombolysis In Myocardial Infarction (TIMI) criteria, 10 including frame counts. 11 Successful delivery of the device was confirmed by careful review of the angioplasty report and was defined as positioning of the catheter beyond the presumed distal edge of the thrombotic lesion. The angiographic probability of thrombus was evaluated as previously described⁸ (3 points for definite [mobile, globular, or rattail filling defect], 2 for probable [sessile filling defect, mid-vessel total occlusion in a SVG], 1 for possible [small filling defect, haziness, ostial total occlusion with convexity or extended beak], and 0 point for unlikely thrombus [luminal surface irregularity, flush ostial total occlusion in a vein graft]). Response to rheolytic thrombectomy was graded as complete (3 points) removal of filling defects, substantial (2 points) removal (<50% of original filling defect remaining), partial (1 point) removal (>50% of original filling defect remaining), and minimal or no change (0 point).8 Post-AngioJet TIMI flow and frame count were evaluated, as well as the occurrence of distal embolization at any point during the procedure (defined as a new distal cut-off compatible with embolus, residual but displaced filling defects, or TIMI 0 to 1 flow in a distal branch unresponsive to intracoronary nitroglycerin or diltiazem). Slow flow was considered when a reduction in flow was noted without evidence of distal cut-off or dissection. Off-line quantitative coronary angiography was performed using visual calipers referenced to the diameter of the guiding catheter on projected images as previously described. 12 Lesion

length was measured shoulder-to-shoulder or to the end of the filling defect. Angiographic success was defined as residual stenosis of <30% by quantitative coronary angiography, with TIMI 3 flow.

Clinical evaluation and long-term follow-up: A clinical estimate of the age of the thrombus was performed using the following scoring system: 2 points for fresh (<24 hours, e.g., AMI), 1 point for recent (>24 hours but <2 weeks, e.g., unstable angina, post-AMI), and 0 for long term. A preintervention combined clinical and angiographic thrombus score was computed by adding the estimated age of thrombus and the angiographic probability of thrombus.⁸ Information on hospital outcomes was collected prospectively for the database, including death, stroke, myocardial infarction (creatine kinase and creatine kinase-MB levels were routinely monitored for 24 hours after the procedure and a creatine kinase >2 times upper limit of normal with creatine kinase-MB >5% was considered diagnostic for AMI), repeat revascularization, recurrent ischemia, and vascular complications. Clinical outcomes during follow-up were evaluated by careful review of the online medical record and by direct telephone contact.

Statistical analysis: Discrete data are reported as percentages, and continuous data as mean \pm SD. Continuous variables were compared by Student's t test and categorical variables were compared using the Fisher's exact test. Non-normally distributed continuous data were compared using the Wilcoxon rank-sum test. One-sample Wilcoxon sign-rank tests were performed for comparison of pre- and postprocedure angiographic variables. The Mantel-Haenszel trend test was used to evaluate the ability of the combined clinical and angiographic thrombus score to predict a favorable response to the AngioJet. Logistic regression models were then used to determine predictors of angiographic success. Backwards elimination algorithms were used to generate the final model. Kaplan-Meier methods were used to estimate the event-free survival of the whole cohort, and the log-rank test was used to compare patients treated for graft thrombosis with those treated for native coronary thrombosis. All p values were 2-tailed and a p value <0.05 was considered statistically significant. All statistical analyses were performed with SAS for Windows (version 8, SAS Institute, Cary, North Carolina).

RESULTS

Patient characteristics: The study cohort consisted of 119 patients who underwent 126 rheolytic thrombectomy procedures (29% in SVG and 71% in native coronary arteries, including 17 cases of stent thrombosis). Baseline characteristics are listed in Table 1. Patients treated for native coronary thrombosis were younger, had a lower prevalence of prior AMI and prior PCI, and were more likely to present with AMI compared with patients treated for thrombosed grafts.

Baseline angiographic data are listed in Table 2. Right coronary artery SVGs or native segments were the more frequent sites for thrombus removal with this device. Lesions were all type B or C lesions, with a higher

TABLE 1 Baseline Characteristics of Patients Treated with Rheolytic Thrombectomy					
	SVG	Native			
	(n = 37)	(n = 89)	p Value		
Age (yrs)	66 ± 12	60 ± 14	0.03		
Men	28 (76%)	59 (66%)	0.40		
Systemic hypertension	29/34 (85%)	57/83 (69%)	0.07		
Diabetes mellitus	14/36 (39%)	21/83 (25%)	0.19		
Smoking (prior or current)	23/33 (70%)	54/74 (73%)	0.82		
Hypercholesterolemia (>200 mg/dl)	30/34 (88%)	56/75 (75%)	0.13		
Prior AMI (before current admission)	23/29 (79%)	12/67 (18%)	< 0.01		
Prior PCI	27/36 (75%)	20/85 (24%)	< 0.01		
Indication for catheterization			< 0.01		
AMI	12 (32%)	61 (68%)			
Post-MI	8 (22%)	21 (24%)			
Unstable angina	15 (41%)	7 (8%)			
Other	2 (5%)	0 (0%)			
Stent thrombosis	2 (5%)	15 (1 <i>7</i> %)	0.15		
Emergency procedure (%)	15 (41%)	66 (74%)	< 0.01		
Cardiogenic shock (%)	2 (5%)	8 (9%)	0.72		
3-Vessel disease (%)	33 (92%)	21 (24%)	< 0.01		
Age of the treated SVG (years)	8.7 ± 4.5	<u>.</u> .	_		
LV ejection fraction (%)	48 ± 13	44 ± 11	0.09		
Glycoprotein Ilb/Illa antagonist (%)	31/34 (91%)	69/79 (87%)	0.25		
Tirofiban	21/34 (62%)	35/79 (44%)			
Eptifibatide	1/34 (3%)	10/79 (13%)			

9/34 (26%)

23/79 (29%)

TABLE 2 Baseline Angiographic Findings					
	SVG (n = 37)*	Native (n = 89)*	p Value		
Vessel or graft target vessel			0.01		
Left anterior descending	8 (22%)	19 (21%)			
Circumflex	13 (35%)	12 (13%)			
Right	16 (43%)	58 (65%)			
Lesion type			< 0.01		
B1	1 (3%)	3 (3%)			
B2	10 (27%)	58 (65%)			
C	26 (70%)	28 (32%)			
Angiographic probability of thrombus [†]			0.72		
Definite	25/34 (74%)	67/85 (79%)			
Probable	7/34 (20%)	10/85 (12%)			
Possible	1/34 (3%)	8/85 (9%)			
Unlikely	1/34 (3%)	0/85 (0%)			
Initial TIMI grade flow			0.47		
0	25 (68%)	66 (74%)			
1	2 (5%)	7 (8%)			
2 3	4 (11%)	6 (7%)			
3	6 (16%)	10 (11%)			
Pre-AngioJet					
Reference diameter (mm)	3.6 ± 1.3	3.1 ± 0.8	0.08		
Minimal lumen diameter (mm)	0.7 ± 0.7	0.7 ± 0.6	0.63		
Diameter stenosis (%)	79 ± 20	78 ± 19	0.85		
Lesion length-including thrombus (mm)	28 ± 21	21 ± 13	0.10		
TIMI grade 0	8/31 (26%)		0.16		
TIMI frame count (if TIMI > 0)	49 ± 42	66 ± 47	0.14		

Data are displayed as mean ± SD or percentage.

proportion of type C lesions in the graft group. Most vessels (68% of SVGs and 74% of native coronary) were occluded (TIMI 0) at the time of the initial angiography. A prophylactic temporary pacemaker was placed in 93%

of right coronary, 50% of left anterior descending, and 78% of left circumflex graft or native coronary cases.

Acute procedural outcomes: Procedural data and angiographic outcomes are listed in Table 3. The delivery of the 5Fr AngioJet device was successful in 97% of SVGs and 91% of native coronary procedures. The AngioJet was highly effective in both subsets. After thrombectomy, TIMI grade 3 flow was achieved in 83% of SVGs and 68% of native arteries (71% overall) (Figure 1). Complete or substantial removal of filling defects was observed in 76% of SVGs and 66% of native coronary thrombectomy procedures (Figure 2). Distal embolization was more likely to occur in smaller vessels (reference diameter 2.7 ± 0.6 vs 3.3 \pm 1.0 mm, p = 0.03). Other risk factors for distal embolization were diabetes mellitus (21% vs 6%, p = 0.04), lower left ventricular ejection fraction (31 \pm 9% vs 46 \pm 12%), emergency procedures (13% vs 0%, p = 0.01), and treatment with heparin alone or with a small molecule glycoprotein IIb/IIIa agent (eptifibatide or tirofiban) rather than with abciximab (17% vs 0%, p = 0.02). Although not reported systematically, temporary pacing was required for transient heart block or other severe bradyarrhythmia in 60% of right coronary or graft rheolytic thrombectomies, but only in 2 left anterior descending and 4 left circumflex coronary or graft cases.

In-hospital clinical outcomes: A total of 5 patients, all of whom had AMI, died in-hospital. Three patients were in cardiogenic shock, and 1 died of a major hemorrhagic stroke after receiving thrombolytics. In 2 of these 5 deaths, the intervention was unsuccessful. In-hospital outcomes were favorable for the remainder of the cohort. None of the 119 patients required urgent repeat PCI or urgent bypass surgery. The incidence of post-PCI creatine kinase elevation (>2 times the upper limit of normal) was 4% in patients who underwent the interventional procedure after AMI or for an unstable angina syn-

Predictors of angiographic success: We sought to evaluate the ability to predict success with the Angio-Jet according to the combined clinical and angiographic scoring system (Figure 3). Higher pre-Angio-

Abciximab

^{*}Cine angiograms were missing on 4 native cases and 3 graft cases, and quanitative coronary angiography could not be performed. For these 7 cases, data were collected from online medical records, the institution prospective database, and careful review of the procedural reports.

[†]Definite = mobile, globular or rat-tail filling defect; Probable = sessile filling defect, mid-vessel total occlusion in a SVG; Possible = small filling defect, haziness, ostial total occlusion with convexity or extended beak; Unlikely = luminal surface irregularity, flush ostial total occlusion in a vein graft.

TABLE 3 Procedures and Angiographic Outcomes

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	Graft (n = 37)*	Native (n = 89)*	p Value		
Successful delivery of device	36 (97%)	81 (91%)	0.28		
Post-AJ					
Reference diameter (mm)	3.4 ± 1.1	3.1 ± 0.7	0.18		
Minimal lumen diameter (mm)	1.4 ± 0.8	1.4 ± 0.8	0.79		
DS	57 ± 26	55 ± 26	0.73		
Lesion length-including thrombus (mm)	16 ± 17	15 ± 14	0.10		
TIMI grade 0	1/29 (3%)	4/77 (5%)	1.0		
TIMI frame count (if post-AJ TIMI >0)	28 ± 34	32 ± 30	0.77		
Change from pre-AJ					
Reference diameter (mm)	-0.3 ± 1.2	$+0.0 \pm 0.3$	0.24		
Minimal lumen diameter (mm)	$+0.7 \pm 0.6^{\dagger}$	$+0.7\pm0.8^{\dagger}$	0.92		
DS	$-21 \pm 22^{\dagger}$	$-23\pm28^{\dagger}$	0.74		
Lesion length-including thrombus (mm)	$-13 \pm 18^{\dagger}$	$-7 \pm 13^{\dagger}$	0.12		
TIMI frame count	-11 ± 37	$-26 \pm 4^{\dagger}$	0.17		
Stent implantation	31 (84%)	69 (78%)	0.63		
Without balloon predilation	15/31 (48%)	29/69 (42%)	0.65		
Stent length (mm)	49 ± 30	27 ± 15	< 0.01		
Stent length before AJ lesion length	16 ± 29	4 ± 16	0.03		
Implanted stent shorter than original lesion	4/23 (1 <i>7</i> %)	23/55 (42%)	0.07		
Complete/substantial removal of FD [‡]	21/32 (76%)	59/77 (66%)	0.25		
Distal embolization	2/32 (6%)	11/85 (13%)	0.51		
Coronary dissection	0 (0%)	0 (0%)	1.0		
Acute closure	0 (0%)	3/77 (4%)	0.56		
Transient slow flow	12/28 (43%)	37/73 (51%)	0.51		
Final minimal lumen diameter (mm)	2.9 ± 1.0	3.1 ± 0.8	0.20		
Final TIMI flow 0–2	6/34 (18%)	10/87 (11%)	0.38		
Angiographic success (<30% DS and TIMI 3)	27 (73%)	77 (87%)	0.08		

^{*}Cineangiograms were missing on 4 native cases and 3 graft cases, and quanitative coronary angiography could not be performed. For these 7 cases, data were collected from online medical records, the institution prospective database, and careful review of the procedural reports.

AJ = AngioJet; DS = diameter stenosis; FD = filling defects.

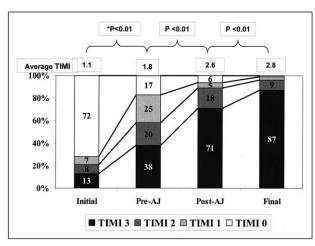


FIGURE 1. Coronary flow on initial angiography, before and after AngioJet (AJ) thrombectomy and at the time of final angiography. *Wilcoxon sign-rank test.

Jet combined clinical and angiographic scores (angiographic probability of thrombus + estimated age of the thrombus) were associated with better response to the AngioJet (p value for trend = 0.002).

From univariate predictors of procedure success (odds ratio [OR] > 1) or failure (OR < 1), 3 independent predictors were identified using multiple logistic regression analyses: (1) quantitative response to the AngioJet thrombectomy (OR 3.9, for every increase of 1 point on a 0- to 3-point scale); (2) the original lesion length including thrombus (OR 0.9, per millimeter); and (3) freedom from distal embolization throughout the procedure (OR 14.6). After adjusting for the other confounding predictors, the type of vessel treated (SVG vs native coronary) was not predictive of the acute outcome.

Long-term follow-up: Long-term clinical follow-up was carried out in 87 of 104 patients (84%) who had angiographic success. Initial procedure failure was considered an event. Follow-up averaged 8 ± 6 months. Event-free survival, defined as freedom from initial procedural failure, death, recurrent myocardial infarction, target vessel revascularization, or documented restenosis or ischemia, was 57% at 6-month follow-up and stabilized between 50% and 60% beyond that time point, and was similar for patients treated for SVG or native coronary thrombosis (p = 0.7) (Figure 4). Excluding initial procedure failures, 69% of patients remained free from death, myocardial infarction, target vessel restenosis or revascularization, or ischemia 6

months following a successful thrombectomy procedure.

DISCUSSION

Clinical effectiveness of the AngioJet thrombectomy: This study is the largest single-center experience with detailed clinical and angiographic analysis of the use of AngioJet thrombectomy in a nonselected population. Despite high-risk findings, such as a high rate of total occlusion, long lesions with thrombus, and a high estimated angiographic probability of thrombus in >90% of patients, the AngioJet thrombectomy procedure was successful in 104 patients (83%), resulting in a complete or substantial removal of filling defects in 73%. This process was accompanied with significant minimal lumen diameter enlargement, flow improvement, and reduction in thrombus length, all surrogates for thrombus burden reduction. Because the length of the implanted stent has been clearly identified as a predictor for in-stent restenosis, ^{13,14} efforts to reduce the total length of stent have gained impetus. As a result of thrombectomy, up to 42% of native coronary arteries received a stent shorter than the original lesion. Transient slow-flow phenomenon was frequently observed, but was successfully reversed in most cases with intracoronary vasodilators, with no adverse impact on final outcomes. Thrombus embolization and

 $^{^{\}dagger}$ One-sample Wilcoxon sign-rank test p <0.05.

 $^{^{\}ddagger}$ Complete removal = no residual filling defects; substantial removal = <50% of original filling defect

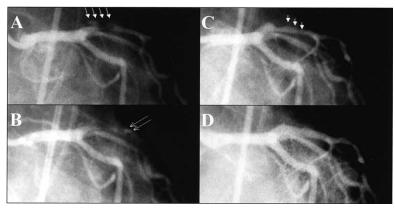


FIGURE 2. Coronary angiographic illustration of AngioJet thrombectomy in a patient with AMI. (A) The right anterior oblique caudal angiographic view shows a subtotally occluded left anterior descending artery with visible thrombus (arrows). (B) The right anterior oblique caudal projection shows the AngioJet catheter (arrows) distal to thrombus. (C) Angiography following AngioJet thrombectomy shows significant removal of thrombus with restoration of TIMI 3 flow. (D) Final angiography after stenting reveals no residual stenosis and TIMI 3 flow.

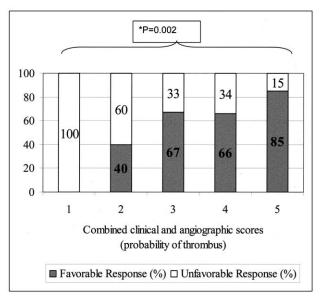


FIGURE 3. Response to the AngioJet according to prethrombectomy angiographic and clinical probability of thrombus, with better response with higher probability of thrombus. *Mantel-Haenszel trend test.

release of vasoactive substances may explain the response to vasodilators, whereas irreversible "no-reflow" resulting from atheroembolization may be less common in the presence of thrombotic lesions. 15,16 Despite thrombus burden reduction at the lesion site, visible distal embolization still occurred in 6% of graft cases and 13% of native coronary cases, and was associated with higher procedural failure. However, incidence of distal embolization was strikingly reduced in patients treated with abciximab compared with patients who received other glycoprotein IIb/IIIa antagonists or heparin alone. Although thrombus might be associated with a higher restenosis rate, 17 we observed favorable overall event-free survival in patients who underwent a successful thrombectomy pro-

cedure. This tends to confirm the lack of significant vessel trauma from the retrograde-directed high-velocity saline jets. 18 Finally, we report the feasibility of the AngioJet thrombectomy for acute stent thrombosis.

Predictors of angiographic success and favorable response to the AngioJet: Despite a low sensitivity of angiography (compared with angioscopy) for detection of thrombus, its specificity is high.¹⁹ Using a multivariate analysis approach, we identified 3 angiographic predictors adversely related to the acute outcome: (1) longer thrombotic lesion; (2) unfavorable response to AngioJet thrombectomy; and (3) occurrence of visible distal embolization during the procedure. The use of abciximab was not a predictor of acute success, likely because of a high co-linear association with distal embolization.

Using a simple combined clinical estimate of the age of thrombus and the angiographic probability of a thrombotic lesion as previously described, we observed a significant linear relation between higher pre-AngioJet scores and better responses to the device. This suggests that with a better selection of patients, we may increase the proportion of patients with substantial or complete removal of defects, an angiographic outcome that has been associated with a higher overall acute procedural success.

Long-term follow-up: Long-term clinical follow-up was achieved in most patients, with an average of >6months. As a reflection of this very high-risk population, the 6-month event-free survival was only 57% when considering the high proportion of procedure failure in patients with SVG thrombosis. However, when analyzing only patients who underwent a successful thrombectomy procedure, 69% of this selected cohort remained event-free. Most events were attributable to presumed or documented target vessel reste-

Comparison with previous reports on AngioJet coronary thrombectomy: Aside from the Vein Graft Angio-Jet Study (VeGAS-2) trial, which showed a higher procedural success with the AngioJet, in association with a significant reduction in bleeding and vascular complications compared with a local infusion of urokinase,⁴ 2 case series have been published to date. Nakagama et al⁶ reported their experience with native coronary rheolytic thrombectomy in 31 patients who had an acute or recent myocardial infarction. With the exception of 2 failures in patients in whom the device was used as a bailout for no-reflow, the procedure was successful in all other patients. They did not observe any no-reflow phenomenon, and distal embolization occurred in 10% of cases. No patient received glycoprotein IIb/IIIa inhibitors. More recently, Silva et al⁷ reported outcomes with AngioJet thrombectomy performed for AMI in patients enrolled in VeGAS-1 and VeGAS-2 AMI registries. Ninety patients underwent

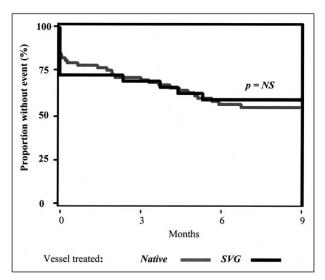


FIGURE 4. Event-free survival (initial procedure failure, death, AMI, target vessel revascularization, restenosis, or ischemia) in patients treated for graft or native coronary thrombosis with the AngioJet.

AngioJet thrombectomy without pretreatment with a glycoprotein IIb/IIIa blocker, with a procedural success of 93.8%. Use of the AngioJet resulted in a significant net thrombus area reduction, which was associated with distal embolization in 8.9% and sustained slow flow in 2.9% of patients.

Comparison with previous studies with thrombotic lesions treated without thrombectomy: The absence of a control arm leads to historical comparisons to evaluate the incremental benefit of AngioJet thrombectomy. In a substudy of the Evaluation of IIb/IIIa Platelet Receptor Antagonist 7E3 in Preventing Ischemic Complications (EPIC) trial, a standard approach with initial balloon angioplasty in the presence of angiographic thrombus yielded a much higher incidence of abrupt closure (13%) than the one observed in our study.²⁰ In 21 patients who underwent acute infarct angioplasty and/or stenting in SVGs, the distal embolization rate was high (57%) with poor overall angiographic success (48%).²¹ However, investigators from the Mayo Clinic reported high angiographic success (97%), low rates of hospital death (2%), and favorable long-term outcomes after standard angioplasty and stenting using abciximab, with incidences of acute closure (4%) or distal embolization (9%) that were similar to those reported in the present study.

Study limitations: No angiographic follow-up was available for most of our patients.

We did not measure thrombus area but rather the thrombotic lesion length and the minimal lumen diameter pre- and postintervention as indicators of efficacy. Because fragments of thrombus may lie against the vessel wall, causing some irregularity beside the main thrombus area, we believed a simple measurement of the lesion length pre- and post-thrombectomy would be a simpler but still accurate estimate of the thrombus burden. Any reduction in lesion length from

pre- to post-AngioJet would likely represent thrombus removal.

In conclusion, rheolytic thrombectomy with the AngioJet catheter in an unselected population resulted in significant reduction of the thrombus burden in most patients, particularly in those with high clinical and angiographic probabilities of thrombus. A favorable response to AngioJet thrombectomy is associated with a higher procedural success rate. Patients treated with abciximab appeared to be more protected from distal embolization compared with those treated with other glycoprotein IIb/IIIa agents or heparin alone. The overall long-term follow-up was favorable in patients successfully treated for vein graft and coronary thrombosis. Further investigations are needed to evaluate the incremental benefits of adjunctive rheolytic thrombectomy over a less expensive strategy with initial balloon angioplasty without thrombus removal in patients treated with glycoprotein IIb/IIIa blockers.

- 1. Ellis SG, Roubin GS, King SB, Douglas JS Jr., Weintraub WS, Thomas RG, Cox WR. Angiographic and clinical predictors of acute closure after native vessel coronary angioplasty. *Circulation* 1988;77:372–379.
- **2.** Ellis SG, Guetta V, Miller D, Whitlow PL, Topol EJ. Relation between lesion characteristics and risk with percutaneous intervention in the stent and glycoprotein IIb/IIIa era: an analysis of results from 10,907 lesions and proposal for new classification scheme. *Circulation* 1999;100:1971–1976.
- **3.** Singh M, Berger PB, Ting HH, Rihal CS, Wilson SH, Lennon RJ, Reeder GS, Bresnahan JF, Holmes DR. Influence of coronary thrombus on outcome of percutaneous coronary angioplasty in the current era (the Mayo Clinic experience). *Am J Cardiol* 2001;88:1091–1096.
- **4.** Kuntz RE, Baim DS, Cohen DJ, Popma JJ, Carrozza JP, Sharma S, McCormick DJ, Schmidt DA, Lansky AJ, Ho KK, et al. A trial comparing rheolytic thrombectomy with intracoronary urokinase for coronary and vein graft thrombus (the Vein Graft AngioJet Study [VeGAS 2]). *Am J Cardiol* 2002;89:326–330.
- **5.** Cohen DJ, Ramee S, Baim DS, Sharma S, Carrozza JP, Cosgrove R, Jones N, Berezin RH, Cutlip DE, Ho KK, Kuntz RE. Economic assessment of rheolytic thrombectomy versus intracoronary urokinase for treatment of extensive intracoronary thrombus: results from a randomized clinical trial. *Am Heart J* 2001; 142-648-656
- 6. Nakagawa Y, Matsuo S, Kimura T, Yokoi H, Tamura T, Hamasaki N, Nosaka H, Nobuyoshi M. Thrombectomy with AngioJet catheter in native coronary arteries for patients with acute or recent myocardial infarction. Am J Cardiol 1999;83:994–999.
- **7.** Silva JA, Ramee SR, Cohen DJ, Carrozza JP, Popma JJ, Lansky AA, Dandreo K, Baim DS, George BS, McCormick DJ, Setum CM, Kuntz RE. Rheolytic thrombectomy during percutaneous revascularization for acute myocardial infarction: experience with the AngioJet catheter. *Am Heart J* 2001;141:353–359.
- **8.** Whisenant BK, Baim DS, Kuntz RE, Garcia LA, Ramee SR, Carrozza JP. Rheolytic thrombectomy with the Possis AngioJet? Technical considerations and initial clinical experience. *J Invasive Cardiol* 1999;11:421–426.
- **9.** Ryan TJ, Bauman WB, Kennedy JW, Kereiakes DJ King SB I III, McCallister BD, Smith SC Jr., Ullyot DJ. Guidelines for percutaneous transluminal coronary angioplasty. A report of the American Heart Association/American College of Cardiology Task Force on assessment of diagnostic and therapeutic cardiovascular procedures (committee on percutaneous transluminal coronary angioplasty). *Circulation* 1993;88:2987–3007.
- 10. Sheehan FH, Braunwald E, Canner P, Dodge HT, Gore J, Van Natta P, Passamani ER, Williams DO, Zaret B. The effect of intravenous thrombolytic therapy on left ventricular function: a report on tissue-type plasminogen activator and streptokinase from the Thrombolysis in Myocardial Infarction (TIMI Phase I) trial. *Circulation* 1987;75:817–829.
- 11. Gibson CM, Cannon CP, Daley WL, Dodge JT, Alexander B, Marble SJ, McCabe CH, Raymond L, Fortin T, Poole WK, Braunwald E. TIMI frame count: a quantitative method of assessing coronary artery flow. *Circulation* 1996;93: 879–888.
- **12.** Kuntz RE, Safian RD, Carrozza JP, Fishman RF, Mansour M, Baim DS. The importance of acute luminal diameter in determining restenosis after coronary atherectomy or stenting. *Circulation* 1992;86:1827–1835.
- 13. Kereiakes D, Linnemeier TJ, Baim DS, Kuntz R, O'Shaughnessy C, Hermiller J, Fink S, Lansky A, Nishimura N, Broderick TM, Popma J. Usefulness of stent length in predicting in-stent restenosis (the MULTI-LINK stent trials). *Am J Cardiol* 2000;86:336–341
- **14.** Goldberg SL, Loussararian A, De Gregorio J, Di Mario C, Albiero R, Colombo A. Predictors of diffuse and aggressive intra-stent restenosis. *J Am Coll Cardiol* 2001;37:1019–1025.

- 15. Piana RN, Paik GY, Moscucci M, Cohen DJ, Gibson CM, Kugelmass AD, Carrozza JP, Kuntz RE, Baim DS. Incidence and treatment of 'no-reflow' after percutaneous coronary intervention. Circulation 1994;89:2514-2518.
- 16. Rawitscher D, Levin TN, Cohen I, Feldman T. Rapid reversal of no-reflow using abciximab after coronary device intervention. Cathet Cardiovasc Diagn 1997;42:187-190.
- 17. Violaris AG, Melkert R, Herrman JP, Serruys PW. Role of angiographically identifiable thrombus on long-term luminal renarrowing after coronary angioplasty: a quantitative angiographic analysis. Circulation 1996;93:889-997.
- 18. Henry TD, Setum CM, Wilson GJ, Morris JE, Johnston RB, Jenson ML. Preclinical evaluation of a rheolytic catheter for percutaneous coronary artery/ saphenous vein graft thrombectomy. J Invasive Cardiol 1999;11:475-484.
- 19. White CJ, Ramee SR, Collins TJ, Escobar AE, Karsan A, Shaw D, Jain SP, Bass TA, Heuser RR, Teirstein PS, et al. Coronary thrombi increase PTCA risk. Angioscopy as a clinical tool. Circulation 1996;93:253-258.
- 20. Khan MM, Ellis SG, Aguirre FV, Weisman HF, Wildermann NM, Califf RM, Topol EJ, Kleiman NS. Does intracoronary thrombus influence the outcome of high risk percutaneous transluminal coronary angioplasty? Clinical and angiographic outcomes in a large multicenter trial. EPIC Investigators. Evaluation of IIb/IIIa Platelet Receptor Antagonist 7E3 in Preventing Ischemic Complications. J Am Coll Cardiol 1998;31:31-36.
- 21. Watson PS, Hadjipetrou P, Cox SV, Pyne CT, Gossman DE, Piemonte TC, Eisenhauer AC. Angiographic and clinical outcomes following acute infarct angioplasty on saphenous vein grafts. Am J Cardiol 1999;83:1018-1021.