AngioJet Rheolytic Thrombectomy During Rescue PCI for Failed Thrombolysis: A Single-Center Experience

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ABSTRACT: Background. Previous studies have shown the efficacy of AngioJet Rheolytic Thrombectomy (RT) in reducing thrombus burden and improving coronary flow in acute myocardial infarction (MI). No study to date has specifically evaluated the use of AngioJet RT in patients undergoing rescue percutaneous coronary intervention (PCI) for failed thrombolysis, a setting that may be particularly beneficial given the extensive thrombus burden. The objective of this study was to evaluate the efficacy and safety of AngioJet RT during rescue PCI for failed thrombolysis. Methods. 214 consecutive patients were transferred to Good Samaritan Hospital to undergo rescue PCI for failed thrombolysis from January 2000 to October 2004. From this cohort, 32 patients (age 57 ± 9, 30% male) undergoing AngioJet RT for rescue PCI (RT group) were identified and matched by initial TIMI flow and infarct related artery (IRA) location to 32 patients (age 60 ± 12, 24% male) undergoing rescue PCI without AngioJet RT (Control group). TIMI frame count and TIMI thrombus grade were assessed at initial and final angiography. Angiographic success (TIMI 3 flow, < 50% residual stenosis) and in-hospital clinical events, including bleeding complications and major adverse cardiac events (MACE) such as death, recurrent MI, target vessel revascularization and emergent bypass surgery were evaluated. Clinical success was defined as angiographic success in the absence of MACE. Results. Baseline clinical characteristics were similar in both groups, except patients undergoing AngioJet RT were more likely to be males and less likely to be intubated on transfer. 30/32 (94%) patients achieved a TIMI thrombus grade of 0 in the RT group, compared to 22/32 (69%) in the Control group. Final IRA TIMI frame count was similar in the RT compared to the Control group (33 ± 21 vs. 38 ± 23, p = NS, respectively). The occurrence of no reflow was significantly lower in the RT compared to the Control group (13% vs. 55%, p < 0.001, respectively). There was a trend for higher angiographic success in the RT compared to the Control group (93% vs. 78%, p = 0.07, respectively). Clinical success was higher in the RT compared to the Control group (91% vs. 71%, p = 0.05, respectively). There were no differences in bleeding complications or MACE between the groups. Conclusion. AngioJet RT in high-risk patients undergoing rescue PCI for failed thrombolysis is safe and more effective in decreasing thrombus burden and preventing no reflow than conventional PCI.

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Percutaneous coronary intervention (PCI) for acute myocardial infarction (MI) in the setting of angiographic thrombus is associated with an increased risk of reocclusion and recurrent infarction. Distal embolization of thrombus during PCI is thought to be a major contributor to impaired tissue level perfusion. Previous studies have shown the efficacy of AngioJet Rheolytic Thrombectomy (Possis Medical, Minneapolis, Minnesota) in reducing thrombus burden and improving coronary flow. However, no study to date has specifically evaluated the use of AngioJet Rheolytic Thrombectomy (RT) in patients undergoing rescue PCI for failed thrombolysis. Given the high thrombus burden in this setting, AngioJet RT would be expected to be particularly useful and associated with marked improvements in thrombus burden and coronary flow. The objectives of this study were to characterize the safety and efficacy and to perform a detailed angiographic analysis of AngioJet RT in patients undergoing rescue PCI for failed thrombolysis.

Methods

Study population. Two hundred and fourteen consecutive patients were transferred to Good Samaritan Hospital in Los Angeles, California from January 2000 to October 2004 to undergo rescue PCI for failed thrombolysis. The definition of failed thrombolysis was established on clinical grounds and made by the referring physician. All patients had ongoing chest pain, continued ST-segment elevation, hemodynamic instability or malignant ventricular arrhythmias and required transfer for emergent coronary angiography. All patients underwent emergent coronary angiography within 6 hours of arrival. Thirty-two patients (15%) underwent AngioJet RT because of intracoronary thrombus per physician discretion (RT group, n=32). A group of 32 control patients were identified by matching patients based on infarct related artery (IRA) location and initial TIMI flow grade (control group, n=32).

Interventional procedures and definitions. Cardiogenic shock was defined as systolic blood pressure < 80 mmHg despite fluid boluses or dependence on vasopressor agents. All patients were treated with thrombolytic therapy prior to transfer (streptokinase 2%; tenecteplase 65%; tissue-type plasminogen activator 26%; retevase 7%). At the time of PCI, heparin was administered following arterial access to maintain an activated clotting time (ACT) of 200 to 250 if a glycoprotein (GP) IIb/IIIa inhibitor was used and 250 to 300 if a GP IIb/IIIa inhibitor was not used. Coronary angioplasty and stent placement were performed using standard techniques. AngioJet rheolytic thrombectomy was performed if significant thrombus was present at the discretion of the operator. Vascular access sheaths were removed 10 to 12 hours following the procedure if the fibrinogen level was greater than 200. After PCI, all patients received 325 mg aspirin and either ticlopidine 250 mg twice
daily or clopidogrel 75 mg once per day for 1 month if a bare metal stent was placed and for 6 months if a drug-eluting stent was placed.

Recurrent ischemia was defined as anginal chest pain and electrocardiogram (ECG) changes (ST-segment depression or T-wave changes) occurring after the index PCI procedure and not accompanied by elevated cardiac enzymes. Recurrent MI was defined as anginal chest pain and ST-segment re-elevation on ECG occurring after the index PCI procedure associated with elevated cardiac enzymes. No reflow was defined as transient or permanent reduction of TIMI flow grade to 0 or 1 from a higher flow grade, at any point during the procedure. Bleeding events were classified as severe or moderate according to the definitions of the Global Use of Strategies to Open Occluded Coronary Arteries (GUSTO 2b) Trial. Severe bleeding was defined as intracranial bleeding or bleeding resulting in hemodynamic compromise. Moderate bleeding was defined as bleeding that required blood transfusion but that did not lead to hemodynamic compromise. Major adverse cardiac events (MACE) were defined as the composite of death, recurrent MI or ischemia, emergent coronary artery bypass grafting (CABG) or repeat target vessel revascularization (TVR). Emergent CABG was defined as CABG within 24 hours of an unsuccessful PCI. Angiographic success was defined as restoration of TIMI 3 flow in the IRA with < 50% residual stenosis. Clinical success was defined as angiographic success with freedom from MACE.

Angiographic analysis. Angiograms were reviewed by two investigators blinded to clinical information and outcome. The initial injection of the IRA was used to determine initial TIMI flow grade and final TIMI flow grade was assessed following guidewire removal. Thrombus grade was evaluated by the methods of the TIMI study group. TIMI frame count (TFC) was measured at the initial and final angiogram by the methods of Gibson et al. The culprit coronary lesion was classified by American College of Cardiology (ACC)/American Heart Association (AHA) criteria.

Statistical analysis. Analyses were performed using SAS® Statistical Software (SAS Institute Inc, Cary, North Carolina). Continuous variables are presented as means ± standard deviations and were compared using student’s t-test and frequencies were compared using the chi-square test. A p-value of < 0.05 was considered significant.

Results

Baseline characteristics. Characteristics of the study groups are shown in Table 1. In general, the groups were similar, except the RT group had a higher prevalence of males and the Control group had a higher prevalence of patients intubated prior to transfer. Time from thrombolytic therapy to angiography and the use of GP IIb/IIIa inhibitors, percutaneous transluminal coronary angioplasty and coronary stents also were similar between the groups. Length of implanted stent was similar among the two groups.

Angiographic findings. The prevalence of ACC/AHA type C lesion and initial percent stenosis were similar among the 2 groups (Table 2). Final angiography showed a trend for a higher prevalence of TIMI grade 3 flow in the RT compared to the Control group (94% vs. 78%, p = 0.07, respectively) (Figure 1). At initial angiography, there was a higher prevalence of combined TIMI thrombus grade 4 and 5 in the RT compared to the Control group (84% vs. 59%, p = 0.03, respectively), indicating a higher thrombus burden in the RT compared to the Control group prior to PCI. At final angiography, more patients in the RT group achieved TIMI thrombus grade 0 compared to those in the Control group (94% vs. 69%, p = 0.01, respectively) (Figure 1). Distal embolization and coronary perforation occurred equally in both groups (Table 2). No reflow was significantly reduced in the RT compared to the Control group (13% vs. 56%, p = 0.0002, respectively). TIMI frame count was similar between both groups at initial and at final angiography (Table 2). The improvement in TIMI frame count from initial to final angiography was similar between both groups: 48 ± 33 for the RT group and 46 ± 32 for the Control group (Figure 1).

Clinical outcome. Major bleeding events, stroke, need for emergent bypass surgery, recurrent MI, emergent TVR and death occurred equally in both groups (Table 3). More patients in the Control group developed renal failure compared to the RT group (19% vs. 3%, p = 0.05, respectively).

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<tr>
<th>Table 1. Baseline clinical characteristics of AngioJet Rheolytic Thrombectomy and Control groups.</th>
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<tr>
<td><strong>RT Group (n=32)</strong></td>
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<tr>
<td>Age, years</td>
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<tr>
<td>Male, n (%)</td>
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<tr>
<td>Body Mass Index</td>
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<tr>
<td>Diabetes Mellitus, n (%)</td>
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<td>Hypertension, n (%)</td>
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<tr>
<td>Prior MI, n (%)</td>
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<td>Prior coronary bypass, n (%)</td>
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<td>Multi-vessel CAD, n (%)</td>
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<td>Prior cardiac arrest, n (%)</td>
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<td>Intubated on transfer, n (%)</td>
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<tr>
<td>Cardiogenic shock, n (%)</td>
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<tr>
<td>Infarct Related Artery</td>
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<tr>
<td>LAD</td>
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<tr>
<td>Left Circumflex</td>
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<td>RCA</td>
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<td>Left Main</td>
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<td>Vein Graft</td>
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<td>Time from thrombolytic to angiography, hours</td>
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<tr>
<td>Glycoprotein IIb/IIIa Inhibitor, n (%)</td>
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<tr>
<td>PTCA</td>
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<tr>
<td>Stent</td>
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<td>Stent length (mm)</td>
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<td>Intraaortic balloon pump</td>
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1 mean ± standard deviation; PTCA = percutaneous transluminal coronary angioplasty; MI = myocardial infarction; CAD = coronary artery disease; LAD = left anterior descending artery; RCA = right coronary artery.

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The contrast volume and fluoroscopy times were similar among both groups (Table 2). Angiographic success showed a trend to be higher in the RT compared to the Control group (91% vs. 78%, p = 0.07, respectively). Clinical success was higher in the RT compared to the Control group (91% vs. 72%, p = 0.05, respectively).

**Discussion**

The treatment of thrombus-containing lesions during PCI remains problematic. A variety of devices have been reported to remove angiographically apparent coronary thrombus. The Pronto catheter (Vascular Solutions Inc, Minneapolis, Minnesota) allows manual aspiration of clot, but lacks a safety and/or efficacy trial of significant size in the coronary circulation. The X-sizer catheter system (EndiCOR Medical Inc., San Clemente, California) employs a mechanical clot removal mechanism and has been studied in the coronary circulation, but lacks FDA approval for coronary use. The AngioJet RT system performs a mechanical thrombectomy and has been validated as an effective method to remove thrombus in the setting of acute MI. In the current study, these observations were extended by characterizing the use of AngioJet RT in a consecutive series of patients undergoing rescue PCI for failed thrombolysis. Patients undergoing AngioJet RT achieved more effective thrombus removal as indicated by a higher prevalence of TIMI 0 thrombus grade at final angiography. This thrombus removal superiority occurred despite the unfair bias of more extensive thrombus burden in the AngioJet RT group at initial angiography as demonstrated by a higher prevalence of TIMI thrombus grade 4 and 5, compared to the Control group.

GP IIb/IIIa inhibitors have also been advocated as a treatment for thrombus containing lesions. However, GP IIb/IIIa inhibitors have not been specifically studied in the setting of rescue PCI for failed thrombolysis and their use may be associated with increased bleeding complications.

The use of AngioJet RT was associated with a significantly lower incidence of the no-reflow phenomenon, higher clinical success and a trend toward higher angiographic success. Reducing the occurrence of no-reflow is clearly beneficial during rescue PCI for failed thrombolysis, given the critical nature of these patients and the detrimental effects of no-reflow on clinical outcome. In addition, there were no cases of coronary perforation and major bleeding events were similar compared to the control group, indicating the safety of AngioJet RT during rescue PCI.

Two recently reported randomized trials have sought to validate rescue PCI as a viable clinical strategy following failed thrombolysis. Both the Middlesbrough Early Revascularization to Limit Infarction (MERLIN) Trial and the Rescue Angiography after Failed Thrombolysis (REACT) Trial were randomized studies which found a benefit for rescue PCI compared to conservative therapy. The findings of the REACT Trial were more compelling as both recurrent
MI and the combined endpoint for rescue PCI were reduced. In contrast, the MERLIN Trial only found a benefit of rescue PCI for the combined endpoint that was driven primarily by a reduction in revascularization rates. Differences in trial design may partially explain these findings as the use of streptokinase as the thrombolytic agent was significantly lower in REACT compared to the MERLIN Trial (59% vs. 96%). In addition, there was a significantly higher use of coronary stents and GP IIb/IIIa agents in the REACT Trial. Our study attempts to gain additional insight into whether further technical refinement during rescue PCI, with mechanical thrombus removal using AngioJet RT, might yield further improvements in clinical outcome. It was found that AngioJet RT achieved more effective thrombus removal with the achievement of TIMI thrombus grade 0 in 94% of patients (compared to 69% in the Control group) and markedly reduced the incidence of no-reflow to 13% (compared to 59% in the Control group). While the results using AngioJet RT during rescue PCI are encouraging, the current study is limited by a relatively small subgroup and larger trials will be required to verify these results.

**Study limitations**

This report represents a single-center, observational, prospective study of consecutive patients undergoing rescue PCI for failed thrombolysis treated at 1 institution by a single group of interventional cardiologists. The use of AngioJet RT was not pre-specified, but was done at operator discretion for thrombus-containing lesions.

**Conclusions**

AngioJet RT with rescue PCI for failed thrombolysis in this study was safe and effectively removed thrombus, reduced the occurrence of no-reflow and tended to improve procedural outcomes. Physicians should consider AngioJet RT in the setting of angiographic thrombus during rescue PCI.

**References**


**Figure 1. Improvement in TIMI frame count.**