Comparison of AngioJet Rheolytic Thrombectomy Before Direct Infarct Artery Stenting With Direct Stenting Alone in Patients With Acute Myocardial Infarction

The JETSTENT Trial

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Objectives
The aim of this study was to determine whether rheolytic thrombectomy (RT) before direct infarct artery stenting as compared with direct stenting (DS) alone results in improved myocardial reperfusion and clinical outcome in patients with acute myocardial infarction.

Background
The routine removal of thrombus before infarct artery stenting is still a matter of debate.

Methods
This is a multicenter, international, randomized, 2-arm, prospective study. Eligible patients were patients with acute myocardial infarction, angiographic evidence of thrombus grade 3 to 5, and a reference vessel diameter ≥2.5 mm. Coprimary end points were early ST-segment resolution and 99mTc-sestamibi infarct size. An α value = 0.05 achieved by both coprimary surrogate end points or an α value = 0.025 for a single primary surrogate end point would be considered evidence of statistical significance. Other surrogate end points were Thrombolysis In Myocardial Infarction (TIMI) flow grade 3, corrected TIMI frame count, and TIMI grade 3 blush. Clinical end points were a composite of major adverse cardiovascular events at 1, 6, and 12 months.

Results
From December 2005 to September 2009, 501 patients were randomly allocated to RT before DS or to DS alone. The ST-segment resolution was more frequent in the RT arm as compared with the DS alone arm: 85.8% and 78.8%, respectively (p = 0.043), while no difference between groups were revealed in the other surrogate end points. The 6-month major adverse cardiovascular events rate was 11.2% in the thrombectomy arm and 19.4% in the DS alone arm (p = 0.011). The 1-year event-free survival rates were 85.2 ± 2.3% for the RT arm, and 75.0 ± 3.1% for the DS alone arm (p = 0.009).

Conclusions
Although the primary efficacy end points were not met, the results of this study support the use of RT before infarct artery stenting in patients with acute myocardial infarction and evidence of coronary thrombus. (AngioJet Rheolytic Thrombectomy Before Direct Infarct Artery Stenting in Patients Undergoing Primary PCI for Acute Myocardial Infarction [JETSTENT]; NCT00275990) (J Am Coll Cardiol 2010;56:1298–306) © 2010 by the American College of Cardiology Foundation

Occlusive thrombus complicating a ruptured or eroded atherosclerotic plaque is the most frequent pathologic substrate of acute myocardial infarction (AMI). Primary percutaneous intervention (PCI) for AMI may be complicated by distal atherothrombotic embolization, with resulting microvessel network disruption and failed myocardial reperfusion. Several primary PCI randomized studies assessing the efficacy of embolic protection devices or thrombectomy devices in improving myocardial reperfusion, and meta-
analyses derived from these studies have produced negative or conflicting results (1–5). Moreover, most studies did not show any clinical benefit of thrombectomy, and the indication for routine removal of thrombus before infarct artery stenting is still matter of debate.

Most of the concluded randomized trials used manual aspiration catheters, whereas only 2 studies used the rheolytic thrombectomy (RT) device, producing conflicting results (6,7).

The aim of this study was to determine whether RT before direct infarct artery stenting as compared with direct stenting (DS) alone results in improved myocardial reperfusion and clinical outcome in patients with AMI.

**Methods**

**Study design.** The comparison of the JETSTENT (AngioJet Rheolytic Thrombectomy Before Direct Infarct Artery Stenting With Direct Stenting Alone in Patients With Acute Myocardial Infarction) trial is a multicenter, international, randomized, 2-arm, prospective study (Online Appendix). The study is registered with ClinicalTrials.gov (NCT00275990). The trial was designed by the principal investigators and sponsored by Medrad Interventional/Possis (Minneapolis, Minnesota). Other than providing financial support and thrombectomy devices the sponsor was not involved in the management, collection, or analysis of data.

**Patients.** All patients with ST-segment elevation AMI were considered eligible for the study without restriction based on age or clinical status on presentation. Thus, patients with cardiogenic shock were eligible for the study. The diagnosis of AMI: 1) chest pain persisting >30 min and <12 h; and 2) ST-segment elevation >1 mm in at least 2 contiguous leads or presumably new left bundle branch block. Clinical exclusion criteria were: 1) thrombolysis for current AMI; 2) major surgery <6 weeks; 3) stroke <30 days or any history of hemorrhagic stroke; 4) comorbidities with expected survival <1 year; and 5) participation in another study.

The study was approved by the institutional ethics committee at each participating center, and patients signed written informed consent.

**Randomization.** Randomization to RT before DS or DS alone was performed after coronary angiography and wiring of the infarct artery (Fig. 1). The TIMI (Thrombolysis In Myocardial Infarction) study thrombus score was used for the assessment of thrombus dimensions (8). Patients with angiographic evidence of TIMI thrombus grades 3 to 5 after infarct artery wiring could be randomized if the reference diameter of the infarct artery was ≥2.5 mm on visual assessment. Angiographic criteria for exclusion from randomization included: 1) TIMI thrombus grade <3; 2) infarct artery reference diameter <2.5 mm on visual assessment; 3) previous stenting of the infarct artery; and 4) inability to identify the infarct artery. Evidence of massive coronary thrombus, diffuse disease, a major branch involved in the culprit lesion, calcification, left

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**Figure 1 Randomization Flow**

- **501 Patients Randomized**
  - **256 Patients Assigned to Thrombectomy Before Stenting**
    - **Primary End Points**
      - 246 Included in Analysis of ST-Segment Resolution
      - 217 Included in Analysis of Infarct Size
    - **Angiographic End Points**
      - 252 Included in Analysis of Final TIMI Flow
      - 228 Included in Analysis of Final cTFC
      - 215 Included in Analysis of Final TIMI Blush
    - **Clinical End Points**
      - 256 Included in Analysis of 1-Month MACE
      - 251 Included in Analysis of 6-Month MACE
  - **245 Patients Assigned to Direct Stenting Alone**
    - **Primary End Points**
      - 240 Included in Analysis of ST-Segment Resolution
      - 208 Included in Analysis of Infarct Size
    - **Angiographic End Points**
      - 241 Included in Analysis of Final TIMI Flow
      - 216 Included in Analysis of Final cTFC
      - 211 Included in Analysis of Final TIMI Blush
    - **Clinical End Points**
      - 245 Included in Analysis of 1-Month MACE
      - 242 Included in Analysis of 6-Month MACE

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**Abbreviations and Acronyms**

- **AMI = acute myocardial infarction**
- **IQR = interquartile range**
- **MACE = major adverse cardiovascular events**
- **PCI = percutaneous coronary intervention**
- **STR = ST-segment elevation resolution**
- **TIMI = Thrombolysis In Myocardial Infarction**
main disease, or severe vessel tortuosity were not angiographic exclusion criteria. Randomization was carried out by computer-generated sequence, and assignments were provided by a centralized telephone system.

**Rheolytic thrombectomy.** The AngioJet rheolytic thrombectomy system (Medrad Interventional/Possis, Minneapolis, Minnesota) consists of a drive unit console, a disposable pump set, and a 4-F disposable catheter. Thrombectomy is accomplished with high-velocity saline jets contained within the distal catheter tip. These jets create a strong negative pressure (Bernoulli effect) that entrains the thrombus to the catheter inflow windows, where it is captured, fragmented, and evacuated from the body through the catheter and associated tubing. The single-pass anterograde thrombectomy technique was used. This technique includes: 1) catheter activation at least 1 cm proximal to the thrombus, to create a suction vortex before advancing the device; 2) advancing the thrombectomy catheter slowly (1 to 3 mm/s) to and through the thrombosed segment; and 3) restarting the thrombectomy at the end of the proximal-to-distal pass, with a distal-to-proximal pullback. After the first pass, the device was retrieved into the guide catheter, and an angiographic check was performed to assess restoration of TIMI flow. If a TIMI flow grade 2 or 3 was restored and there was no more evidence of residual thrombus, thrombectomy treatment was stopped, whereas a second or third pass could be made if there was evidence of residual thrombus or a TIMI flow grade <2.

**Infarct artery stenting.** In both arms, DS was attempted in all cases using bare-metal stents. The stent type choice was at the operator’s discretion. If the stent failed to directly cross the lesion, pre-dilation was performed using an undersized balloon to decrease the risk of embolism before stent implantation. Pressure deployment and expansion were at the discretion of the operator according to the characteristics of the stent and lesion.

**Adjunctive treatments.** Patients received 325 mg of aspirin orally, or 250 mg intravenously at the emergency room, and a loading dose of 600 mg of clopidogrel before or immediately after the procedure. All patients received abciximab (ReoPro, Centocor, Malvern, Pennsylvania) unless contraindicated. Abciximab was administered immediately before or during the procedure as a bolus of 0.25 mg/kg body weight followed by a 12-h infusion at a rate of 0.125 \( \mu \)g/kg/min. Heparin was given as an initial bolus of 70 U/kg, and additional boluses were administered during the procedure to achieve an activated clotting time of 200 to 250 s. After the procedure, patients were treated with aspirin (100 to 325 mg daily indefinitely) and clopidogrel (75 mg daily for 6 months). Other drugs such as beta-blockers, angiotensin-converting enzyme inhibitors, and statins were used in accordance with standard and recommended practice.

**Multivessel intervention.** Multivessel intervention was allowed only in patients with cardiogenic shock; otherwise, procedures in noninfarct arteries were performed after the 1-month scintigraphy.

**Follow-up.** All patients were scheduled for clinical follow-up at 1, 6, and 12 months. All other possible information derived from hospital readmission or from the referring physician, relatives, or municipality live registries were entered into the prospective database. The treatment protocol did not include angiographic follow-up. Unscheduled angiography was allowed on the basis of clinical indication.

**End points.** The study was designed to test the hypothesis that RT before DS will result in improved myocardial reperfusion, increased myocardial salvage, decreased infarct size, and better clinical outcome. Moreover, the removal of thrombus allowing a better estimate of the diameter and length of the target lesion may result in the use of stents with the most appropriate size.

Surrogate coprimary end points of the study are ST-segment elevation resolution (STR) at 30 min after PCI, and infarct size as assessed by \(^{99m}\text{Tc}\) sestamibi scintigraphy at 1 month.

Baseline and 30-min post-procedure, a 12-lead electrocardiogram was recorded using the same electrocardiograph. The ST-segment changes were evaluated in the single lead with the most prominent ST-segment elevation before mechanical intervention. The ST-segment elevation was measured to the nearest 0.5 mm at 60 ms after the J point with the aid of hand-held calipers. The STR was defined as a reduction in ST-segment elevation \( \geq 50\% \) at 30 min after infarct artery recanalization (9). The STR was assessed by physicians blinded to treatment assignment at a central core laboratory.

All eligible patients underwent electrocardiography-gated single positron emission computed tomography imaging with \(^{99m}\text{Tc}\) sestamibi at 1 month (30 ± 10 days) after the index procedure. Raw patient data were processed by a physician blinded to treatment assignment at a central core laboratory. Infarct size was expressed as percentage involvement of the left ventricle (10). Patients who died before the scheduled scintigraphy had an imputed infarct size equal to the 75th percentile for the treatment arm.

Other surrogate secondary end points include: 1) post-PCI TIMI flow grade 3; 2) corrected TIMI frame count; and 3) TIMI blush grade 3 (11–13). All angiographic markers of reperfusion and quantitative coronary angiography analysis were performed at central core laboratory by physicians not involved in the study.

Key secondary clinical end points are the 1-, 6-, and 12-month composite of major adverse cardiovascular events (MACE) including death, myocardial infarction, target vessel revascularization, and stroke.

Reinfarction was defined as recurrent chest pain with ST-segment or T-wave changes and recurrent elevation of cardiac enzymes. Target vessel revascularization was defined as coronary angioplasty or coronary surgery performed because of restenosis or reocclusion of the infarct artery.
Stroke was defined as an acute neurological defect lasting >24 h. Major bleeding was defined according to the TIMI criteria (14).

All clinical events were adjudicated by an independent clinical event committee blinded to treatment allocation after review of original source documentation.

### Statistical methods.

Based on the results of a previous study (6), the study was powered to demonstrate an increase in STR from an expected 70% in the DS alone group to 90% in the RT arm, and a 30% relative reduction in infarct size with RT, assuming a 16% infarct size with standard deviation of 14% in the control arm. An $\alpha$ value = 0.05 achieved by both coprimary surrogate end points or an $\alpha$ value = 0.025 for a single primary surrogate end point would be considered evidence of statistical significance. The statistical power is 95%, based on a maximum sample size of 500 patients (with 450 evaluable patients) randomized in a 1:1 allocation ratio, considering an undeterminable primary end point in 10% of patients and an overall experimental type I error of 0.05 using a 2-sided hypothesis test. Discrete data are summarized as frequencies, whereas continuous data are summarized as mean ± SD or median and interquartile range (IQR) as appropriate. The chi-square test or Fisher exact test was used for comparison of categorical variables, and the unpaired 2-tailed Student $t$ test or Mann-Whitney rank-sum test was used to test differences among continuous variables. Survival curves were generated using the Kaplan-Meier method, and the difference between groups was assessed by log-rank test. The multivariable analysis to evaluate the independent contribution of clinical, angiographic, and procedural variables to the surrogate and clinical end points were performed by forward stepwise logistic regression analysis or the Cox proportional hazards model. For logistic regression analyses, model discrimination was assessed with $c$-statistic, and goodness of fit with the Hosmer-Lemeshow test. All tests were 2-sided, and a $p < 0.05$ was considered significant. All analyses were performed using the software package SPSS version 11.5 (SPSS, Inc., Chicago, Illinois).

### Results

Study enrollment began in December 2005 and ended in September 2009, and 501 patients from 8 sites were randomly assigned to RT before DS or DS alone. The mean age of the entire patient cohort was 63.7 ± 11.9 years, 38% of patients had anterior AMI, and 4% of patients were in cardiogenic shock due to left ventricular failure on admission. Thrombus grade 5 rate after coronary wiring was 28.4% in the RT arm and 24.3% in the direct stenting arm. The 2 study arms were well matched in all baseline characteristics (Tables 1 and 2).

Table 3 summarizes the procedural characteristics. The median delay from hospital admission to artery puncture...
was similar in the 2 arms: 34 min (IQR 15 to 67 min) in the RT arm and 31 min (IQR 18 to 60 min) in the DS arm. Compliance with assigned treatments was high in both arms: 88% of patients had DS, and 97% of patients received abciximab. Nearly all patients (94%) in the thrombectomy arm received the treatment without the need for target lesion pre-dilation, whereas only 2% of patients randomized to DS alone crossed over to thrombectomy. Patients in the DS alone arm received more stents, with a resulting higher total stent length. The total procedural time (time from arterial puncture to the completion of the final angiogram) was longer in the RT arm (additional median procedural time 13.5 min).

No major procedural complications occurred in the RT arm, whereas 1 patient in the DS alone arm had a coronary perforation that was treated with a covered stent. Overall, major bleeding complication rate was 2.8%, and was similar between the 2 groups.

Table 4 summarizes the surrogate end point results. Of 501 patients, 486 (97%) had paired electrocardiograms available for ST-segment analysis. ST-segment elevation resolution occurred in 85.8% of patients randomly assigned to thrombectomy and in 78.8% of patients randomly allocated to DS alone (p = 0.043).

Of 501 patients, 415 (83%) had scintigraphy available for measurement of infarct size. Infarct size was smaller in the thrombectomy arm, but this difference did not reach statistical significance: the median infarct size was 11.8% (IQR

Table 5 Clinical End Points

<table>
<thead>
<tr>
<th></th>
<th>Rheolytic Thrombectomy (n = 256)</th>
<th>Direct Stenting (n = 245)</th>
<th>p Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>1 month</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>MACE</td>
<td>8 (3.1)</td>
<td>17 (6.9)</td>
<td>0.050</td>
</tr>
<tr>
<td>Death</td>
<td>4 (1.6)</td>
<td>7 (2.9)</td>
<td></td>
</tr>
<tr>
<td>Myocardial infarction</td>
<td>2 (0.8)</td>
<td>3 (1.2)</td>
<td></td>
</tr>
<tr>
<td>TVR</td>
<td>2 (0.8)</td>
<td>6 (2.5)</td>
<td></td>
</tr>
<tr>
<td>Stroke</td>
<td>0 (0)</td>
<td>1 (0.4)</td>
<td></td>
</tr>
<tr>
<td>Major bleeding</td>
<td>10 (3.9)</td>
<td>4 (1.6)</td>
<td>0.123</td>
</tr>
<tr>
<td>Stent thrombosis</td>
<td>3 (1.2)</td>
<td>4 (1.6)</td>
<td>0.660</td>
</tr>
<tr>
<td>6 months</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>MACE</td>
<td>28 (11.2)</td>
<td>47 (19.4)</td>
<td>0.011</td>
</tr>
<tr>
<td>Death</td>
<td>7 (2.8)</td>
<td>11 (4.5)</td>
<td></td>
</tr>
<tr>
<td>Myocardial infarction</td>
<td>2 (0.8)</td>
<td>3 (1.2)</td>
<td></td>
</tr>
<tr>
<td>TVR</td>
<td>18 (7.2)</td>
<td>32 (13.2)</td>
<td></td>
</tr>
<tr>
<td>Stroke</td>
<td>1 (0.4)</td>
<td>1 (0.4)</td>
<td></td>
</tr>
<tr>
<td>1 year*</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>MACE</td>
<td>33 (14.9)</td>
<td>50 (22.7)</td>
<td>0.036</td>
</tr>
<tr>
<td>Death</td>
<td>7 (3.2)</td>
<td>14 (6.4)</td>
<td></td>
</tr>
<tr>
<td>Myocardial infarction</td>
<td>2 (0.9)</td>
<td>3 (1.4)</td>
<td></td>
</tr>
<tr>
<td>TVR</td>
<td>22 (9.9)</td>
<td>32 (14.5)</td>
<td></td>
</tr>
<tr>
<td>Stroke</td>
<td>2 (0.9)</td>
<td>1 (0.4)</td>
<td></td>
</tr>
</tbody>
</table>

Values are n (%). *Eligible patients, n = 452.

MACE = major adverse cardiovascular events; TVR = target vessel revascularization.

Table 3 Procedural Characteristics

<table>
<thead>
<tr>
<th></th>
<th>Rheolytic Thrombectomy (n = 256)</th>
<th>Direct Stenting (n = 245)</th>
<th>p Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Emergency room to PCI, min*</td>
<td>34 (15-67)</td>
<td>31 (18-60)</td>
<td>0.727</td>
</tr>
<tr>
<td>Procedural time, min</td>
<td>59.5 (44.7–70)</td>
<td>46 (35-60)</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>Temporary pacemaker before RT</td>
<td>2 (0.7)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Pre-dilation before RT</td>
<td>5/241 (2.1)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>TIMI flow grade 3 after RT</td>
<td>159/222 (72)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Stent per patient</td>
<td>1.26 ± 0.54</td>
<td>1.40 ± 0.73</td>
<td>0.022</td>
</tr>
<tr>
<td>Mean stent length, mm</td>
<td>23.7 ± 10.9</td>
<td>25.9 ± 14.1</td>
<td>0.050</td>
</tr>
<tr>
<td>Multiple stenting</td>
<td>58 (23)</td>
<td>72 (30)</td>
<td>0.079</td>
</tr>
<tr>
<td>Abciximab</td>
<td>249 (97)</td>
<td>239 (98)</td>
<td>0.841</td>
</tr>
<tr>
<td>Intra-aortic balloon pump</td>
<td>8 (3.1)</td>
<td>9 (3.7)</td>
<td>0.735</td>
</tr>
<tr>
<td>Procedural success†</td>
<td>237 (92.6)</td>
<td>229 (93.5)</td>
<td>0.696</td>
</tr>
</tbody>
</table>

Values are median (interquartile range), n (%), or mean ± SD. *Time from admission to arterial puncture. †Residual stenosis <30% and TIMI flow grade 3 by operator’s assessment.

DS = direct stenting; RT = rheolytic thrombectomy; other abbreviations as in Tables 1 and 2.
3.15% to 23.70%) in the thrombectomy arm and 12.7% (IQR 4.75% to 23.30%) in the DS alone arm (p = 0.398).

With regard to the secondary angiographic surrogate end points, the number of patients who could be assessed by the core laboratory for post-procedure TIMI flow grade 3, corrected TIMI frame count, and TIMI myocardial blush were 493 (98%), 444 (87%), and 426 (85%), respectively. None of these 3 angiographic end points was different between treatment arms. A myocardial blush grade 3 was revealed in >70% of patients in both arms.

Table 5 and Figure 2 summarize the clinical outcome. The 1-month MACE rate was 3.1% in the thrombectomy arm and 6.9% in the DS alone arm (p = 0.05). The difference between arms in MACE rate was increased at

**Figure 2** Clinical Outcome

Clinical outcome at (A) 1 month, (B) 6 months, and (C) 1 year rheolytic thrombectomy (RT [green bars]) versus direct stenting (DS [red bars]).

MACE = major adverse cardiovascular events; MI = myocardial infarction; TVR = target vessel revascularization.
6-month follow-up (11.2% and 19.4%, respectively; p = 0.011), and maintained at 1-year follow-up (14.9% and 22.7%, respectively; p = 0.036). By Kaplan–Meier analysis, the 1-year estimated freedom from MACE was 85.2 ± 2.3% for the thrombectomy arm, and 75.0 ± 3.1% for the DS alone arm (p = 0.009) (Fig. 3). The STR was inversely related to the occurrence of 1- and 6-month MACE and death (Table 6).

The 2 main findings of the present study can be summarized as follows: 1) randomization to RT was associated with more frequent STR than was DS alone, whereas no difference was found in the other surrogate markers of myocardial reperfusion; and 2) RT plus DS as compared with DS alone resulted in a significant decrease in MACE at 1 month, and this difference was increased at 6 and 12 months.

The difference in STR between the 2 arms did not reach the pre-defined a value of 0.025, which is the standard value for a study including 2 coprimary end points. However, the significance of the difference observed in this trial is supported by the results of the multivariable analysis that shows randomization to RT to be an independent predictor both of STR and MACE. Moreover, STR was strongly associated with the occurrence of death and MACE. These finding confirms STR, as defined in our study, as a valid surrogate end point, and further supports the significance of the observed difference between arms.

Several explanations may be proposed as to why the study did not show difference between arms in the other surrogate end points. Regarding infarct size, the most likely explanation is the poor spatial resolution of 99mTc sestamibi scintigraphy, about 10 mm full width half maximum. Thus, it will miss differences smaller than this size especially in the extent of subendocardial infarction (15). With regard to the angiographic surrogate end points, it should be noted that their assessment derives from a single time point sampling of a dynamic phenomenon and that these snapshot measurements cannot fully explore the integrity of the microvessel network (16). Finally, it should be noted that in contrast to other trials of thrombectomy in AMI, the study assessed the potential additive value of adjunctive thrombectomy in patients receiving routine DS without pre- or post-dilation and abciximab with an associated risk of embolization and microvessel disruption lower than conventional balloon angioplasty followed by stenting or nonuse of abciximab (17–20). As a result, in the control arm, myocardial perfusion as assessed by electrocardio-
graphic, nuclear imaging, and angiographic markers was better than expected. The most important finding of the study is the better clinical outcome of patients randomized to RT plus DS as compared with DS alone. The RT was inversely related to the risk of adverse events and was associated with a nearly 50% relative reduction in MACE. The difference between arms was driven mainly by death and TVR, suggesting that the benefit of thrombectomy is related both to better myocardial reperfusion and to decreased recurrent ischemia. The latter could be related to increased stent length and incomplete apposition in the control arm due to the presence of unresolved thrombus. This hypothesis is supported by a nonrandomized study on RT on primary PCI performed by Sianos et al. (21) that has shown that a baseline large thrombus is a strong predictor of early and late stent thrombosis, and that patients treated with RT before stenting had a lower stent thrombosis and MACE rates than patients treated with conventional PCI.

The safety profile of RT, as revealed in this study, is high, considering that no major procedural complications related to the device were encountered, and that <1% of patients needed a temporary pacemaker to prevent or treat severe bradycardia.

The results of the JETSTENT trial are not consistent with the results of the AIMI (Angiojet Rheolytic Thrombectomy In Patients Undergoing Primary Angioplasty for Acute Myocardial Infarction) trial (7). The AIMI trial, which enrolled 480 patients, did not show difference in STR between the thrombectomy arm and control, while infarct size as assessed by 99mTc sestamibi scintigraphy was larger and 1-month MACE rate was higher in the thrombectomy arm. The difference in MACE rate was attributable to a higher mortality in the thrombectomy arm as compared with control (4.6% and 0.8%, respectively; \( p = 0.02 \)). Whereas the JETSTENT trial included only patients with angiographic evidence of thrombus, the AIMI trial excluded patients with large amounts of thrombus, and only a minority of patients (21%) had evidence of moderate or large thrombus. Moreover, some procedural findings may explain the worse outcome in the AIMI trial, such as the use of a retrograde technique in the majority of thrombectomy patients that includes first crossing the lesion without the device activated, with the associated increased risk of embolism, the high delay from admission to randomization (>2.5 h), and the high major procedural complication rate (>10%). All these procedural findings with their negative impact on outcome may have overcome any benefit of thrombectomy.

Two other studies have demonstrated a clinical benefit of removal of thrombus using manual aspiration catheters, the TAPAS (Thrombus Aspiration During Percutaneous Coronary Intervention in Acute Myocardial Infarction Study) trial and the EXPIRA (Thrombectomy With Export Catheter in Infarct-Related Artery During Primary Percutaneous Coronary Intervention) trial (22,23). Major differences in study design and procedural characteristics prevent the comparison of these studies to the JETSTENT trial. However, all 3 studies contribute to a growing body of evidence confirming the benefit of thrombus removal before infarct artery stenting.

Conclusions

Although the primary efficacy end points were not met, the results of this study support the use of RT before infarct artery stenting in patients with AMI and evidence of coronary thrombus. However, the routine use of RT in AMI should be confirmed by future larger trials.

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Key Words: coronary stenting • infarct artery • thrombectomy.

**APPENDIX**

For a complete list of investigators and participating sites, please see the online version of this article.