

**Thrombectomy in AMI –
perspectives on a hot topic**

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Thrombectomy in AMI – The hot topic

1. Sardella et al
The EXPIRA prospective randomized trial
JACC 2009; 53: 309-315
2. Amin et al
J Interv Cardiol 2009; 22: 49-60
3. De Luca et al
Adjunctive manual Thrombectomy
improves myocardial perfusion and
mortality in STEMI: a meta analysis of
randomized trials
Euro Heart J 2008; 29: 3002-3010
4. Chao et al
Benefit of initial Thrombosuction on
myocardial perfusion
Int J Clin Pract 2008; 62: 555-561

Revascularization of Thrombus-Laden Lesions in AMI – The Burden on the Interventionalist

On Topaz, MD

Throughout revascularization of coronary arteries and saphenous vein grafts in acute myocardial infarction (AMI) and acute coronary syndromes, the burden of a thrombus can be "felt" by interventionalists. You know that ominous "feeling" when angiography demonstrates a large size thrombus — a notorious marker of procedural complications. And, extensive literature clearly supports your concern,¹⁻⁵ because visible thrombus possesses imminent risk of flow impairment, distal embolization, "no reflow" phenomenon with microcircular obstruction and infarct expansion. If treated inadequately, thrombus turns into an active, "angry" component causing further flow cessation and at times accounting for development of cardiogenic shock and even death. Can interventionalists discern the presence, quantify the size of a thrombus and proceed accordingly with a dedicated treatment strategy? The answer is controversial. Traditionally, it has been shown that angiography has a low sensitivity for detection of intracoronary thrombus, and it is likely that the true incidence of thrombus is underestimated.^{6,7} However, with recent improved imaging in the cath lab and heightened awareness to visible thrombus and its deleterious effects on outcome, interventionalists seem to have developed a more accurate appraisal of thrombus. When the accuracy of visual assessment of thrombus was validated by independent core lab QCA analysis, it has been convincingly demonstrated that interventionalists can precisely identify and differentiate between each level of TIMI thrombus grade and treat accordingly.⁸

The best method for the percutaneous undertaking of a large size thrombus in AMI is yet unknown and management strategies vary considerably. Limited treatment with only heparin is still in use due to severe underestimation of the thrombus hazard. In contrast, attempts at complete thrombus burden removal with mechanical devices appear to gain momentum. Unfortunately, many in the field still attempt to handle visible large size thrombus with balloon only, perhaps due to a lingering influence of early days ("When I face a large coronary thrombus I just beat it to death with the balloon," was frequently heard from one of the field's founders). Some continue to treat angiographic thrombus with the quite ineffective glycoprotein IIb/IIIa receptor antagonists,^{9,10} while others manage visible thrombus with unsubstantiated use of filter protection.¹¹ Many then naively deploy a stent for thrombus displacement hoping that it will somehow end up squeezing the thrombus and associated debris selectively onto the vessel's wall. In several high volume centers, mechanical thrombectomy devices are first in line, frequently in combination with direct coronary injections of low-dose thrombolytics.¹² Regardless, the burden of the thrombi continues to be high and costly.

In this issue of the journal, Burzotta et al¹³ describe early experience of treating thrombus-laden lesions in AMI by applying an aspiration catheter and a distal protection device. The authors are to be commended for the concept and especially for avoiding the temptation to routinely use a thrombus removal device for *all* AMI lesions. They correctly centered their efforts on lesions with *significant* thrombus load. In contrast, a Rescue aspiration catheter was unjustifiably applied in a recent AMI study to *all* lesions *regardless* of visible thrombus.¹⁴ A similar mistaken strategy took place in the rheolytic thrombectomy AIMI study.

The revascularization technique of Burzotta et al incorporated aspiration first, then distal protection followed by stent implantation. The aspiration was done with a Diver CE catheter that was slowly advanced in aspiration mode along the culprit lesion. Once the syringe was full, the device was retracted and reintroduced up to six times. The aim was creation of a tunnel within the thrombus which would enable crossing for deployment of a distal protection filter. While utilization of aspiration devices is simple technically, in our experience they do not provide adequate removal of large size thrombus, especially multilayered, resistant clot. The frequent need to recross the target several times certainly adds to the risk of distal embolization. Moreover, from a technological standpoint, to ensure maximal efficiency, an aspiration catheter needs to provide multiple large-sized holes that drain into a large extraction lumen. This is required to accommodate large thrombus content and its debris. Intriguingly, the present generation of aspiration catheters are designed to "forcefully" fit into a 6 Fr guiding catheter. Such small lumen diameter probably compromises the efficiency of the abovementioned holes. As for filter protection devices, the concept is attractive but their performance is questionable"; the receiving vessel requires a landing zone of no less than 3-4 cm, and deployment can be cumbersome. Cont.

Journal of Invasive Cardiology August 2007: Vol. 19; No. 8, pp. 324-325

Editorial Comment

On the Hostile Massive Thrombus and the Means to Eradicate It

On Topaz, MD

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Medical College of Virginia,
Virginia Commonwealth University,
Richmond, Virginia
CCI 2005; 65: 280-281.

Editorial Comment

Focus on the Infarct-Related Artery: A Thrombus Runs Through It

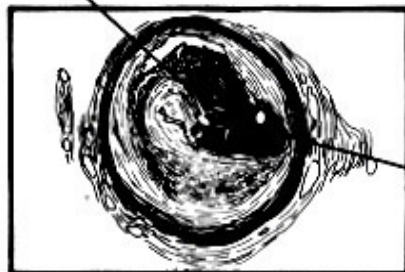
On Topaz, MD

Cardiac Catheterization Laboratories,
Medical College of Virginia Hospitals,
McGuire Veterans Administration Medical Center,
Virginia Commonwealth University,
Richmond, Virginia

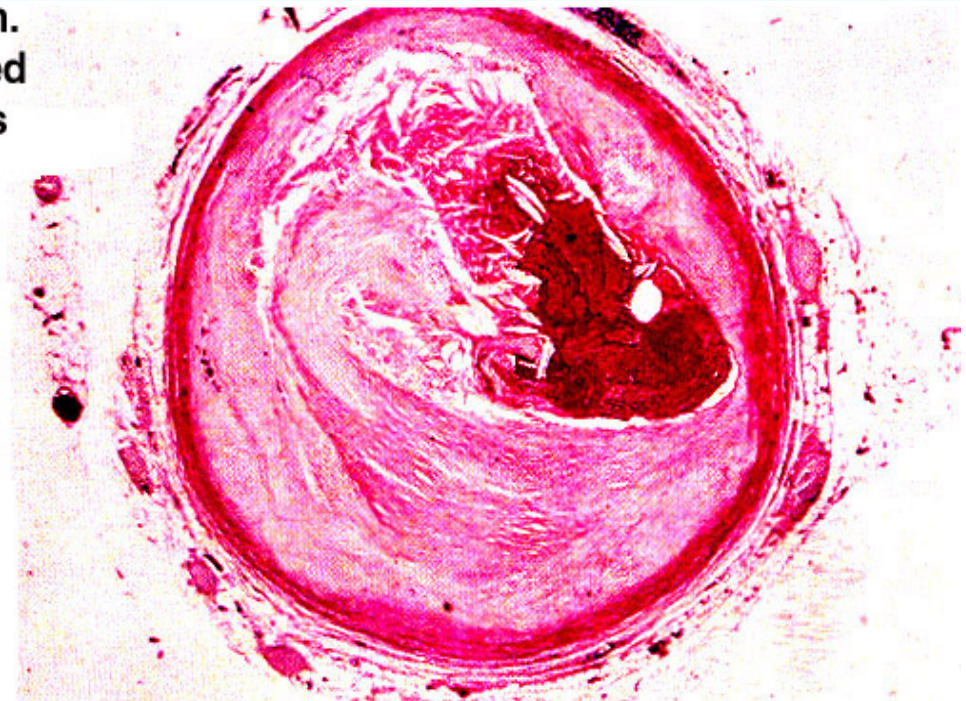
CCI 2002; 57: 340-341

Thrombosed coronary artery in transverse section. The lumen is completely occluded by a mass of red thrombus. Above and to the left of the thrombus is a plaque of athroma which contains lipid.

Lipid in Athermatous Plaque



Thrombus



Many major STEMI studies do not measure or grade thrombus burden¹, this despite recognition of the structural complexity of thrombus² and its significant effect on PCI outcomes³.

1. Conti CR Editorial. STEMI: thrombus formation and prognosis. Clin Cardiol 2008; 31: 3-5
2. Furie B, Furie BC Mechanisms of thrombus formation. NEJM 2008; 359: 938-949.
3. Topaz O Editorial. Revascularization of thrombus-laden lesions in AMI – the burden on the interventionalist.
J Invas Cardiol 2007; 19: 324-325

Angiographic Stent Thrombosis After Routine Use of Drug-Eluting Stents in ST-Segment Elevation Myocardial Infarction

The Importance of Thrombus Burden

Georgios Sianos, MD, PHD, Michail I. Papafaklis, MD, Joost Daemen, MD, Sofia Vaina, MD, Carlos A. van Mieghem, MD, Ron T. van Domburg, PHD, Lampros K. Michalis, MD, MRCP, Patrick W. Serruys, MD, PHD,

Objectives This study sought to investigate the **impact of thrombus burden** on the clinical outcome and **angiographic infarct-related artery stent thrombosis (IRA-ST)** in patients routinely treated with drug-eluting stent (DES) implantation for ST-segment elevation myocardial infarction

Background There are limited data for the safety and effectiveness of DES in STEMI.

Methods We retrospectively analyzed 812 consecutive patients treated with DES implantation for STEMI. Intracoronary thrombus burden was angiographically estimated and categorized as large thrombus burden (LTB), defined as thrombus burden >2 vessel diameters, and small thrombus burden (STB) to predict clinical outcomes. Major adverse cardiac events (MACE) were defined as death, repeat myocardial infarction, and IRA reintervention.

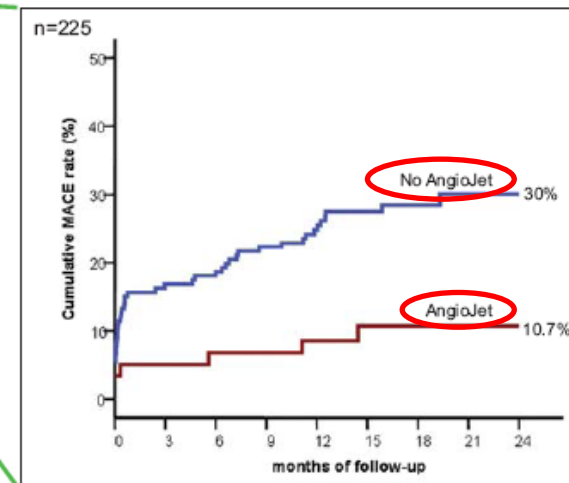
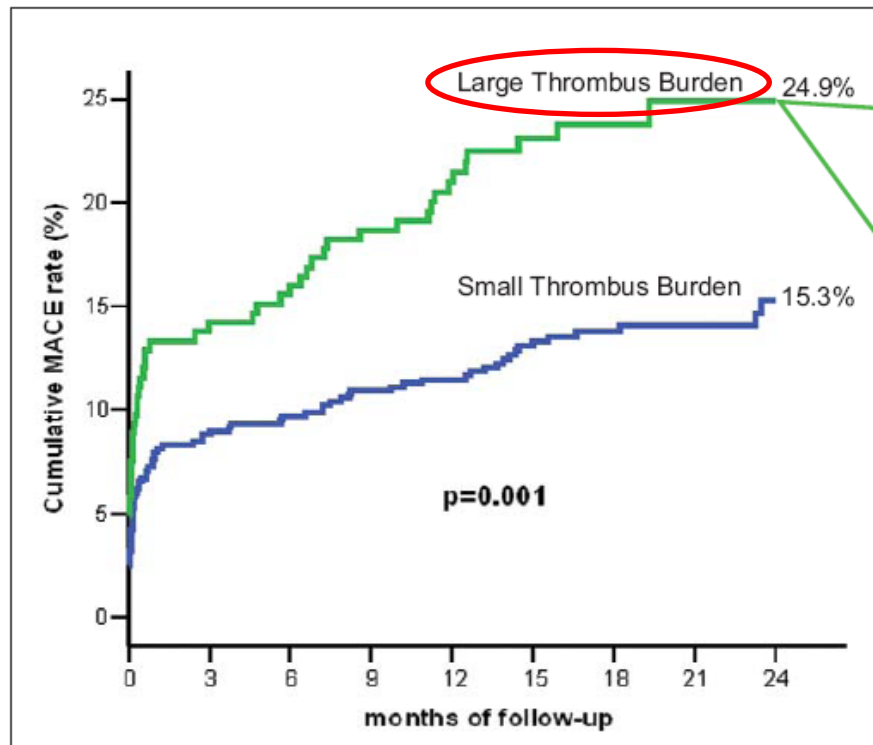
Results Mean duration of follow-up was 18.2 ± 7.8 months. Large thrombus burden was an independent predictor of mortality (hazard ratio [HR] 1.76, $p = 0.023$) and MACE (HR 1.88, $p = 0.001$). The cumulative angiographic IRA-ST was 1.1% at 30 days and 3.2% at 2 years, and continued to augment beyond 2 years. It was significantly higher in the LTB compared with the STB group (8.2% vs. 1.3% at 2 years, respectively, $p < 0.001$). Significant independent predictors for IRA-ST were LTB (HR 8.73, $p < 0.001$), stent thrombosis at presentation (HR 6.24, $p = 0.001$), bifurcation stenting (HR 4.06, $p = 0.002$), age (HR 0.55, $p = 0.003$), and rheolytic thrombectomy (HR 0.11, $p = 0.03$).

Conclusions **Large thrombus burden is an independent predictor of MACE and IRA-Stent Thrombosis in patients treated with DES for STEMI.**

(J Am Coll Cardiol 2007;50:573-83)

Large Unresolved Thrombus Impacts MACE

Large Thrombus Increases MACE¹

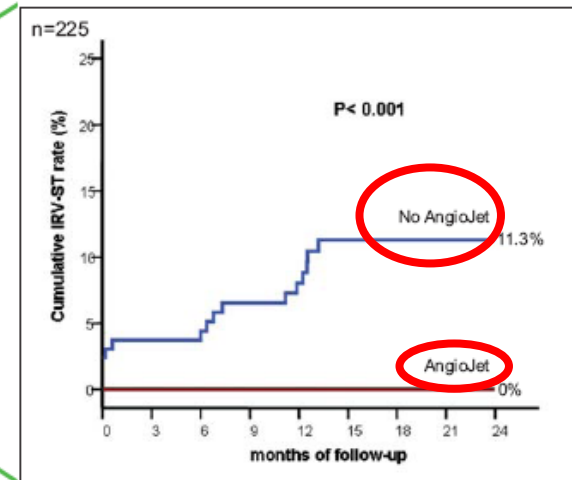
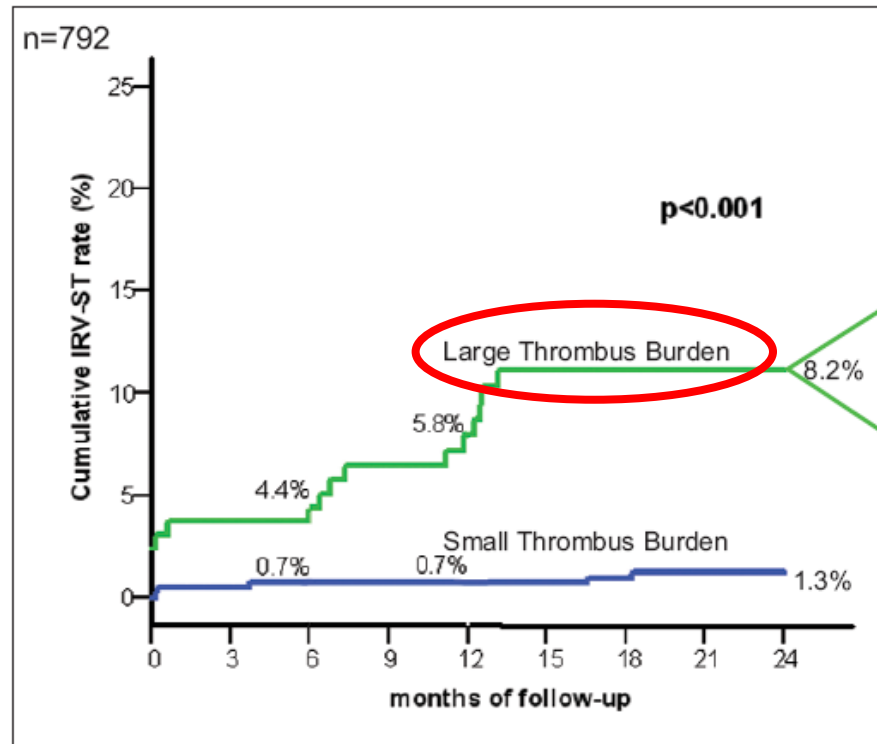


Adapted from data presented in the JACC article:

¹Sianos G, Papafaklis M, Daemen J, Vaina S, van Mieghem C, van Domberg R, Michalis L, Serruys P. Angiographic Stent Thrombosis After Routine Use of Drug-Eluting Stents in ST-Segment Elevation Myocardial Infarction: The Importance of Thrombus Burden. J Am Coll Cardiol, 2007;50:572-583

DES Stent Thrombosis More Prevalent with Large Unresolved Thrombus

Large Thrombus Increases Stent Thrombosis¹

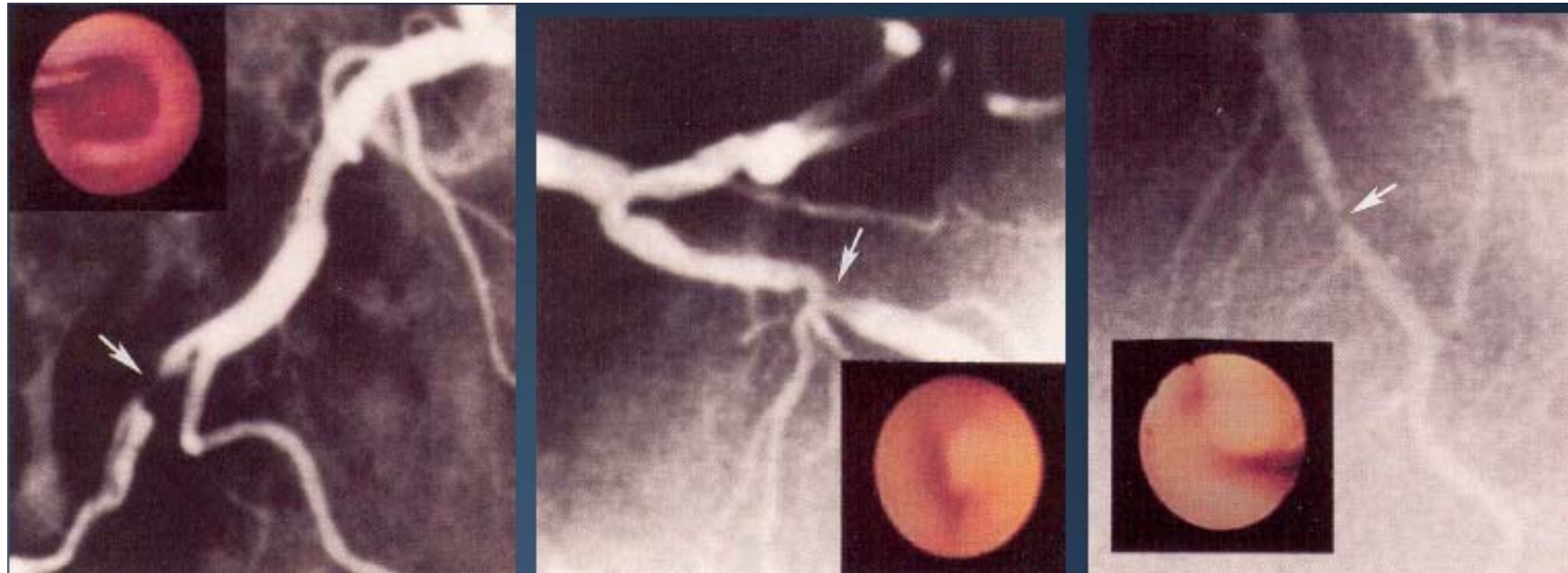


Adapted from data presented in the JACC article

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¹Sianos G, Papafaklis M, Daemen J, Vaina S, van Mieghem C, van Domberg R, Michalis L, Serruys P. Angiographic Stent Thrombosis After Routine Use of Drug-Eluting Stents in ST-Segment Elevation Myocardial Infarction: The Importance of Thrombus Burden. J Am Coll Cardiol, 2007;50:572-583

Thrombus by Angioscopy

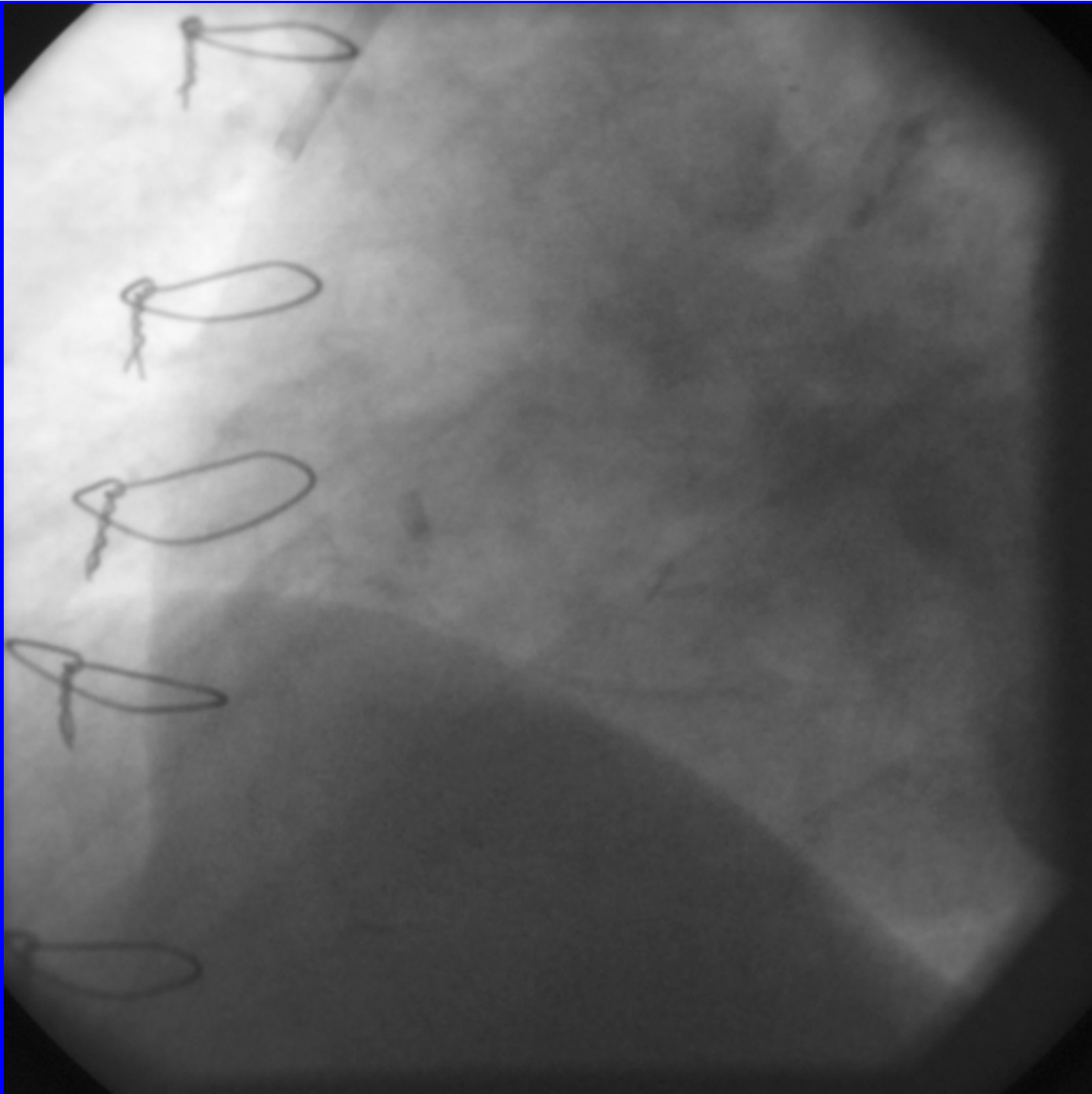


Red Thrombus

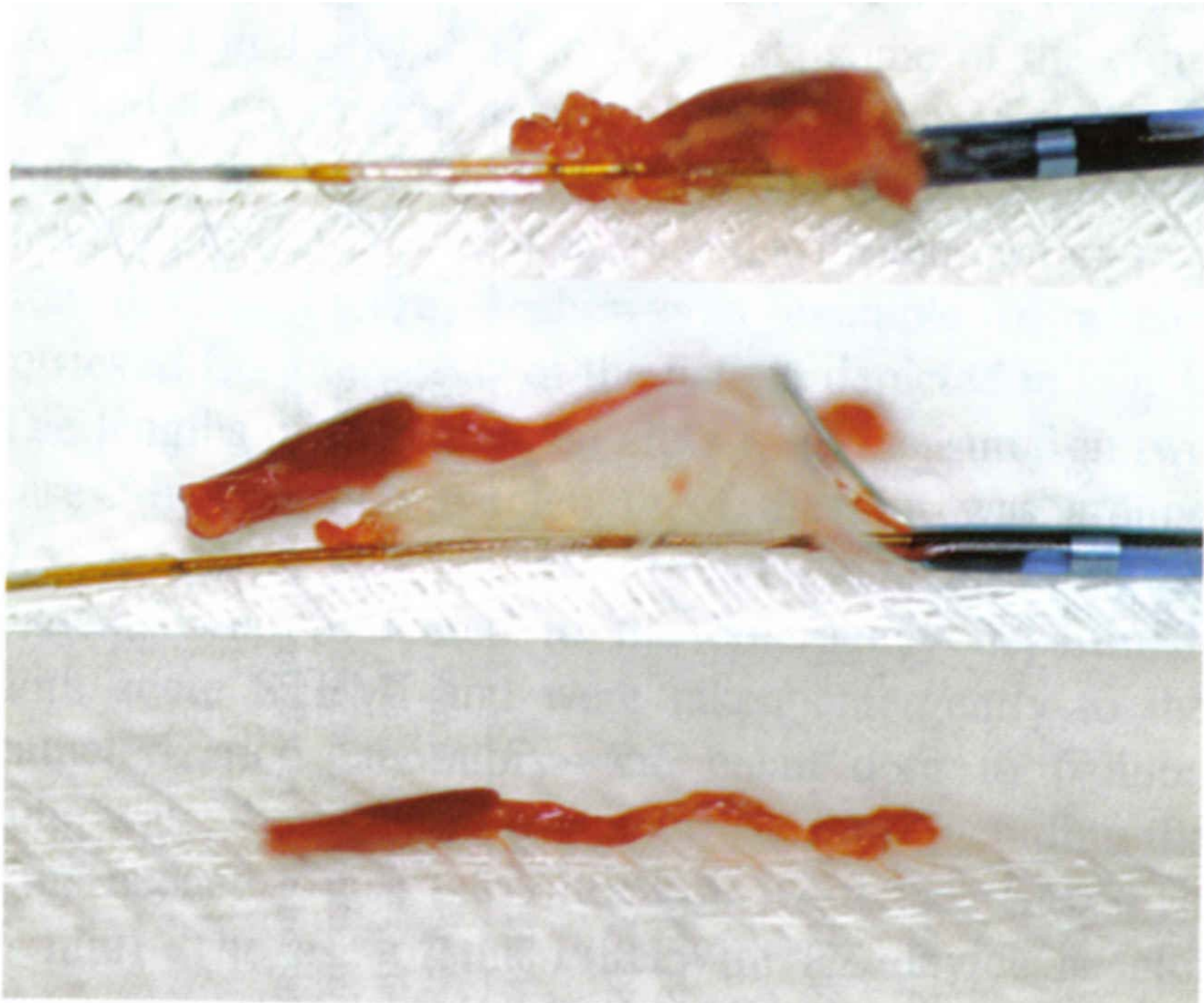
White Thrombus

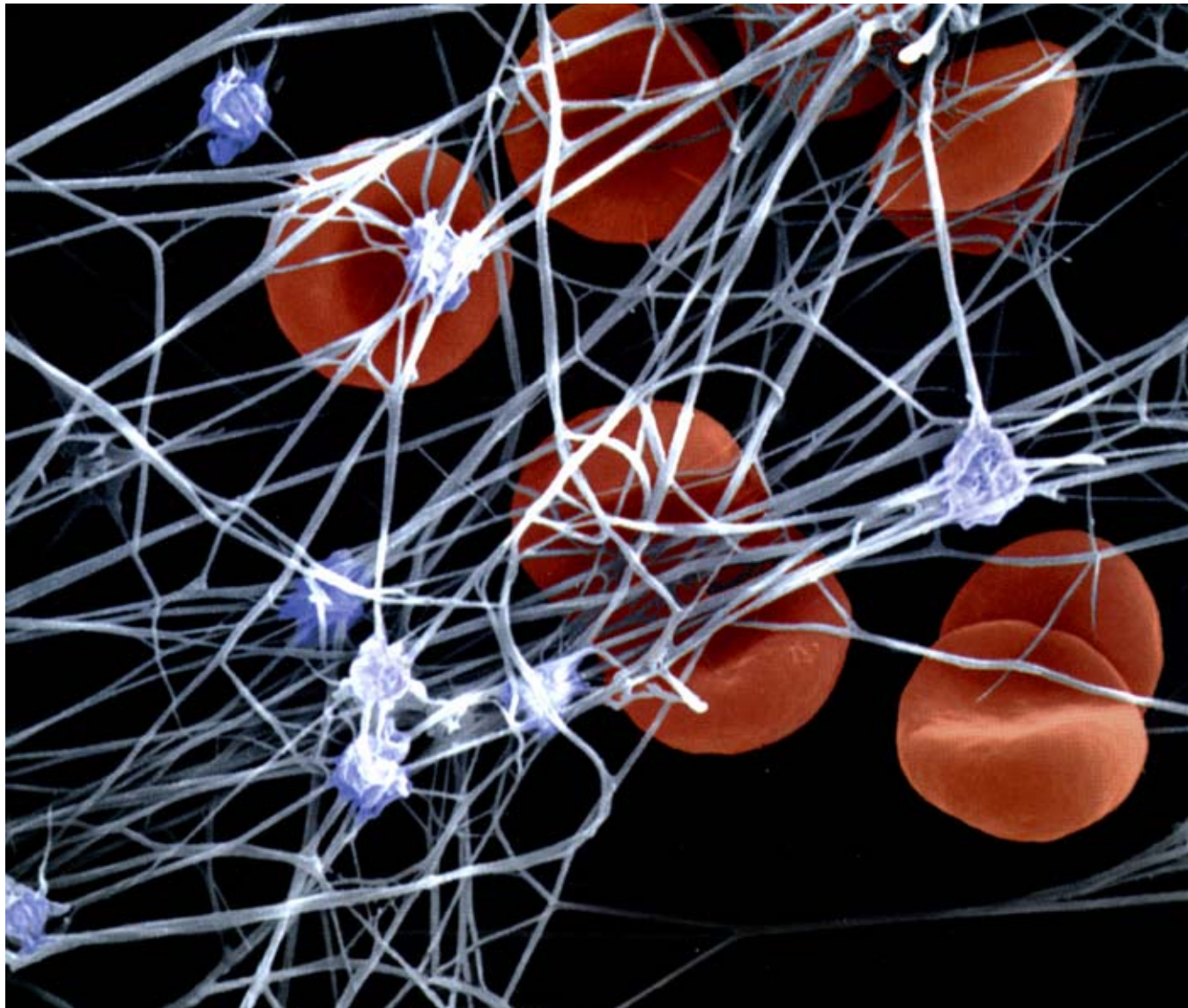
Fibrous Plaque

Abela GS, et al. Am J Cardiol 1999; 83: 94-97



The massive hostile thrombus





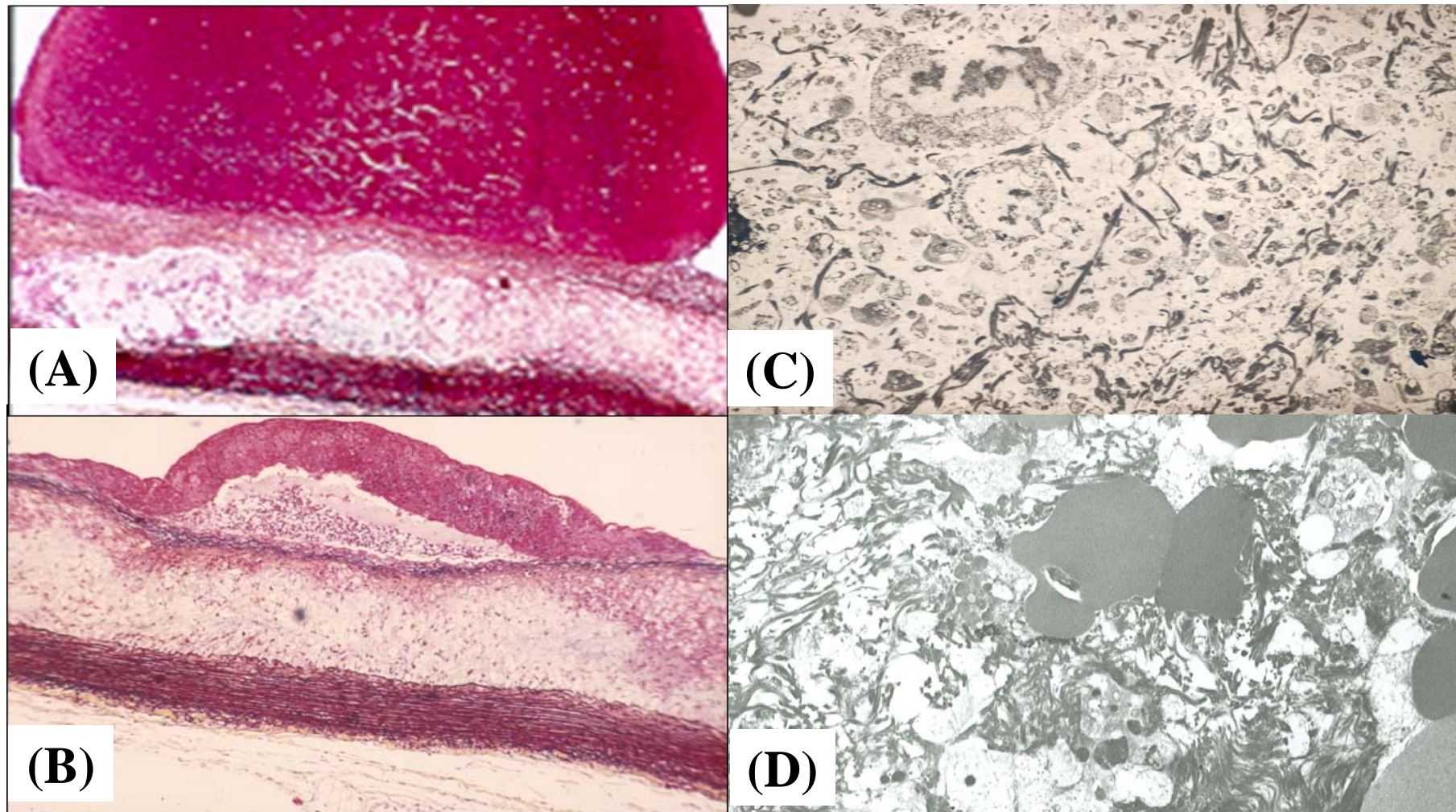
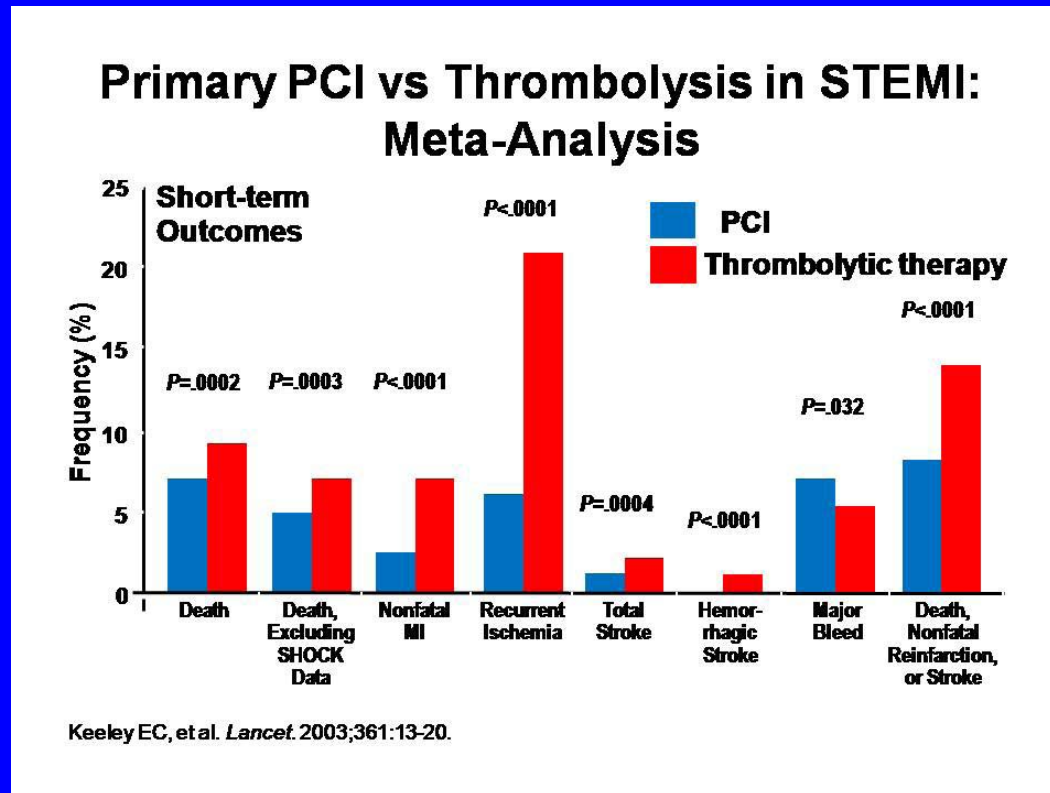


Fig. 6 (A) Light micrograph of a **white thrombus** overlying a plaque on the intimal surface of the rabbit aorta (Movat's pentachrome stain, platelets stain red, magnification x 160). This demonstrates a dense thrombus with no loose inner spaces. **(B)** Light micrograph of a **red thrombus** overlying a plaque on the intimal surface of the aorta (Movat's pentachrome stain, magnification x 180). This demonstrates a dense surface thrombus layer with loose inner core. **(C)** Transmission electron micrograph of a **white thrombus** demonstrating a high concentration of platelets with fibrin and few red blood cells (Magnification = 3.4 x 2.5). **(D)** Transmission electron micrograph of **red thrombus** with loosely packed fibrin and many interspersed red blood cells (Magnification = 3.4 x 2.5)

PCI versus Thrombolysis in STEMI



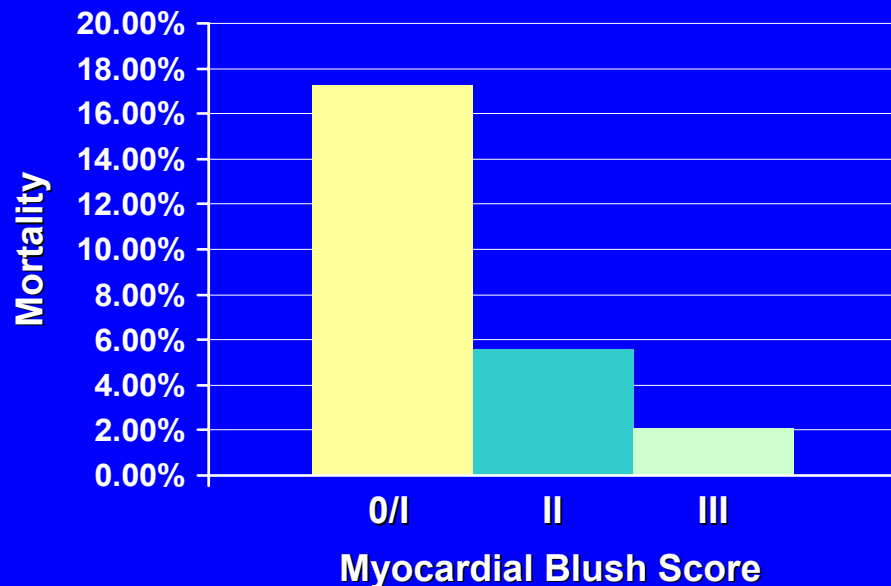
PCI in STEMI is superior to thrombolysis.

Myocardial Blush Score

TIMI-3 flow was restored in 94% of patients treated with PTCA after AMI – **in contrast**, **normal perfusion** was restored in **only 28%**:

Myocardial Blush Scores
Following PTCA in AMI

0/I	II	III
30%	42%	28%



Impaired perfusion despite normal epicardial coronary flow is consistent with microvascular obstruction due to microembolization.

Reduced myocardial blush correlates with an increased risk of death.

Limitations of PCI in AMI

“ The illusion of reperfusion ”

33% of post-PCI patients show a discrepancy

between :

PCI induced vessel patency vs. suboptimal degree of rescued myocardium.

- 1) Lincoff AM, Topol EJ “illusion of reperfusion”
Circulation 1993;88:1361-1374
- 2) Vont Hof AWJ Circulation 1998;97:2302-2306

Cause of discrepancy: damage to microvascular circulation

Contributing factors:

- endothelial damage
- tissue edema
- release of vasoconstrictive & inflammatory mediators
- leukocyte plug

Thrombus:

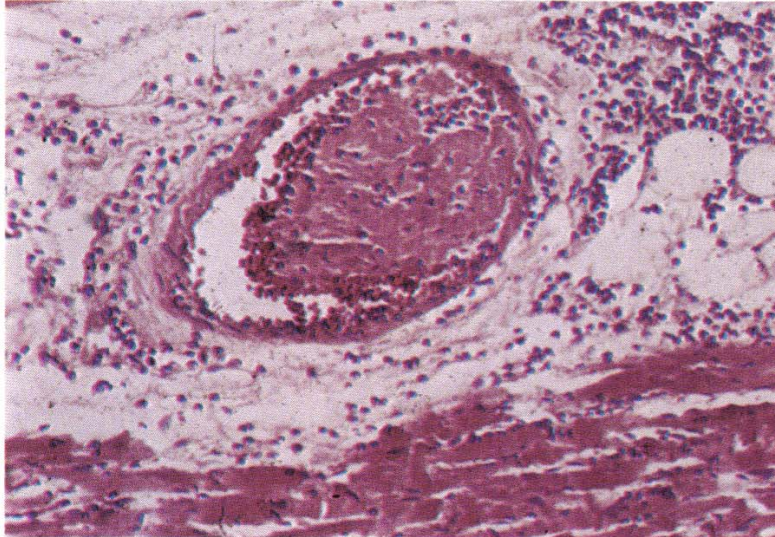
- platelet & fibrin aggregates
- embolization

Michaels AD et al. Am J Cardiol 2000;85:50b-60b

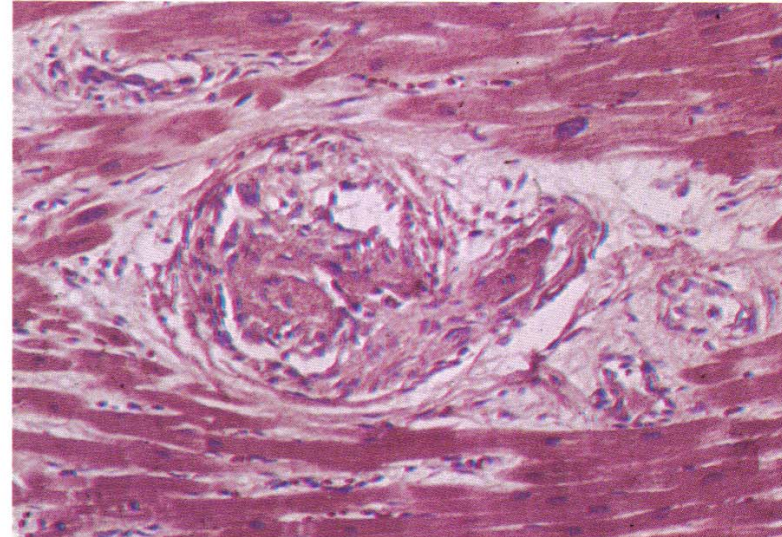
Henriques JP et al. Eur Heart J 2002;23:1112-1117

150–153 Myocardial small artery emboli The following four figures show varying appearances of small arteries in the myocardium that have been occluded by thrombotic emboli. The first vessel has been recently occluded while the thrombus in the second is partially organised. Organisation of the thrombus in the third and fourth arteries is complete with recanalisation by small channels. (× 88, × 140, × 88, × 88)

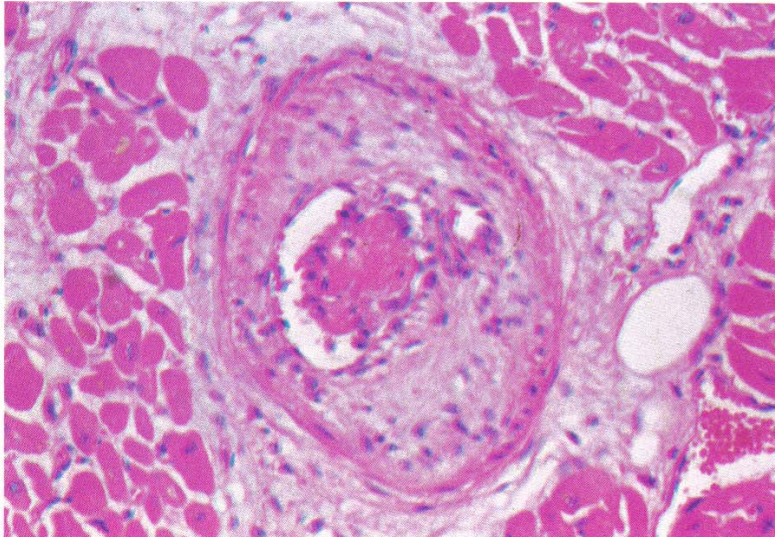
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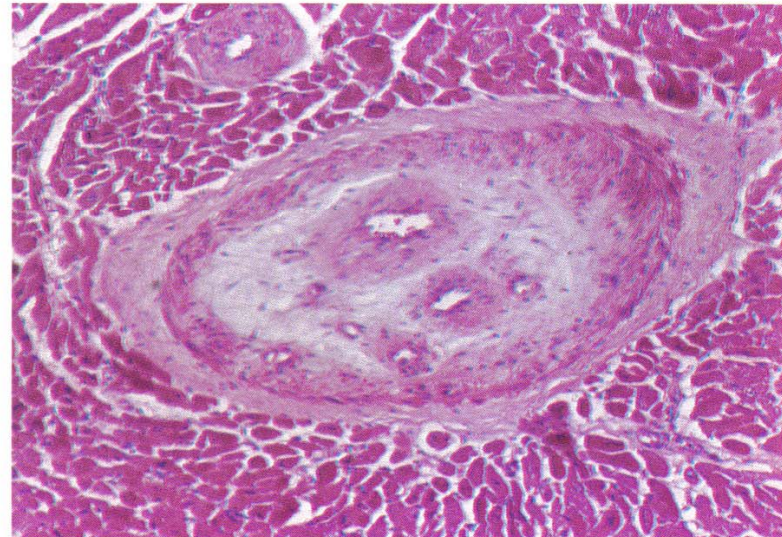
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151



153



Adjunct pharmacotherapy for thrombus burden in AMI

Traditional:

- ASA, Plavix, heparin
- Direct thrombin inhibitor
- IIb/IIIa Receptor Antagonists

**Platelet IIb/IIIa inhibitors less
effective in angiographic thrombus**

Silva JA et al CCI 2002; 56:8-9.

Eptifibatide Versus Abciximab in primary PCI for Acute ST elevation Mycocardial Infarction

-

EVA-AMI Trial

Uwe Zeymer

**on behalf of the EVA-AMI Investigators
Herzzentrum Ludwigshafen, Germany**



Institut für Herzinfarktforschung Ludwigshafen
an der Universität Heidelberg

2007 Scientific Sessions of the AHA, Late-breaking Clinical Trials 1
Orlando, FL, November 4th, 2007

EVA-AMI

**Sum ST resolution 60 mins after PCI
Intention-to-treat-analysis**

	Abciximab (n=200)	Eptifibatide (n=225)	p-value
Complete	47.5 %	50.2 %	n.s.
Partial	24.5 %	22.2 %	n.s.
No	28.0 %	27.6 %	n.s.
Single lead complete	41.0 %	46.2 %	n.s.

Adjunct pharmacotherapy for thrombus burden in AMI

Emerging role for intracoronary treatment:

Adenosine, Ca channel blockers, α -blockers, β 2-receptor activators, vasodilators & direct thrombolytics.

Kundadian V, C.Michael Gibson et al.

J Thrombosis Thrombolysis 2008; 26: 234-242

“ The Quest “

“An unequivocal clinical need exists for a thrombectomy device that can safely improve clinical outcomes in patients with thrombus containing lesions.”

Stone G et al. JACC 2003;42:2007-2013

Mechanical tools for thrombus management in AMI

Poor	<u>Compression</u>	Balloon
Acceptable	<u>Aspiration</u>	Export, Diver, Fetch
Good	<u>Extraction</u>	AngioJet, X-Sizer
Good	<u>Ablation</u>	Laser
Rarely used	<u>Dissolution</u>	Ultrasonic Energy

Advantages of Thrombectomy Devices in AMI

Direct contact with thrombus & underlying
plaque

Significant thrombus-burden & pro-coagulant
removal

Shorten **D2TIMI 3** time

Cont.

Advantages of Thrombectomy Devices in AMI

- **Rapid restoration of epicardial flow, lowering cTFC, improving myocardial blush score ¹**
- **Acceleration of ST-segment resolution.**
- **Reduced rate of distal embolization and “no reflow” ²**
- **Improved 1 yr. survival rate (range 90 – 96%)**

1. Beran et al. Circulation 2002; 105: 2355-2360

2. Napodano et al. J Am Coll Cardiol 2003; 42: 1395-1402

QCA PER TIMI THROMBUS

GRADE	0 No Thrombu s	1 Small Thrombus	2 Medium Thrombus	3 Large Thrombus	4 Extensive Thrombus
# of patients	11	14	28	45	63
<u>MLD:</u> <u>Baseline</u> (mm)	.87±.69	.72±.43	.65±.45	.59±.49	.37±.49
Post laser	1.74±.46	1.48±.49	1.51±.51	1.50±.41	1.62±.62
<u>Laser acute gain</u>	.90±.63	<u>.76±.52*</u>	.84±.60	.94±.48	<u>1.21±.72*</u>
Final	2.97±.60	2.54±.55	2.47±.62	2.62±.55	2.76±.62
<u>%DS:</u> <u>Baseline</u>	74%±21%	76%±16%	77%±16%	82%±16%	89%±15%
Post laser	47%±13%	51%±11%	52%±15%	51%±13%	53%±17%
<u>Laser acute reduction</u>	27%±18%	<u>25%±15%</u>	25%±19%	31%±16%	<u>36%±20%</u>
Final	16%±17%	15%±13%	22%±14%	16%±17%	22%±16%

* p=0.03

The NEW ENGLAND JOURNAL of MEDICINE

February 7, 2008 Vol 358; No. 6: 557-67

Thrombus Aspiration during Primary Percutaneous Coronary Intervention

Tone Svilaas, M.D., et al.

ABSTRACT

BACKGROUND

Primary percutaneous coronary intervention (PCI) is effective in opening the infarct-related artery in patients with myocardial infarction with ST-segment elevation. However, the embolization of atherothrombotic debris induces microvascular obstruction and diminishes myocardial reperfusion.

METHODS

We performed a randomized trial assessing whether manual aspiration was superior to conventional treatment during primary PCI. A total of 1071 patients were randomly assigned to the thrombus-aspiration group or the conventional-PCI group before undergoing coronary angiography. Aspiration was considered to be successful if there was histopathological evidence of atherothrombotic material. We assessed angiographic and electrocardiographic signs of myocardial reperfusion, as well as clinical outcome. The primary end point was a myocardial blush grade of 0 or 1 (defined as absent or minimal myocardial reperfusion, respectively).

RESULTS

A myocardial blush grade of 0 or 1 occurred in 17.1% of the patients in the thrombus-aspiration group and in 26.3% of those in the conventional-PCI group ($P<0.001$). Complete resolution of ST-segment elevation occurred in 56.6% and 44.2% of patients, respectively ($P<0.001$). The benefit did not show heterogeneity among the baseline levels of the prespecified covariates. At 30 days, the rate of death in patients with a myocardial blush grade of 0 or 1, 2, and 3 was 5.2%, 2.9%, and 1.0%, respectively ($P=0.003$), and the rate of adverse events was 14.1%, 8.8%, and 4.2%, respectively ($P<0.001$). Histopathological examination confirmed successful aspiration in 72.9% of patients.

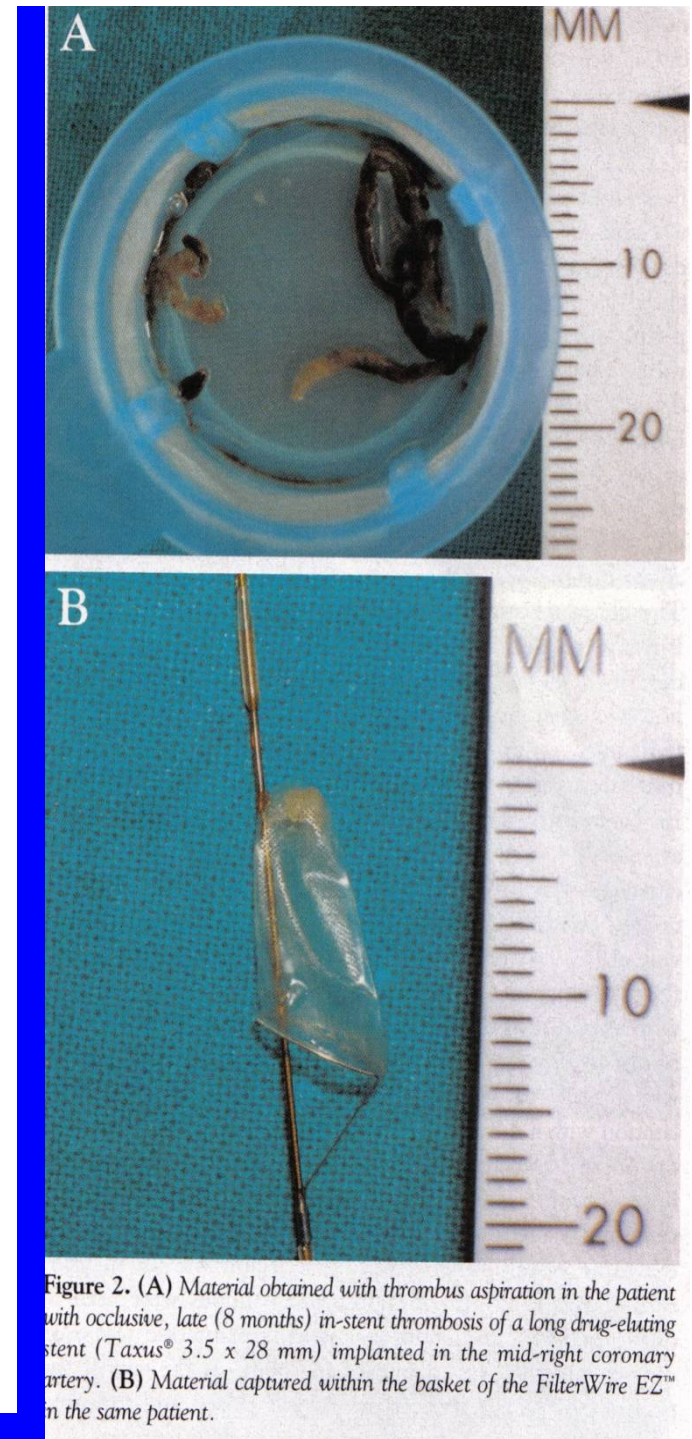
CONCLUSIONS

Thrombus aspiration is applicable in a large majority of patients with myocardial infarction with ST-segment elevation, and it results in better reperfusion and clinical outcomes than conventional PCI, irrespective of clinical and angiographic characteristics at baseline.

Feasibility of Sequential Thrombus Aspiration and Filter Distal Protection in the Management of Very High Thrombus Burden Lesions

Francesco Burzotta, MD, et al

ABSTRACT: Background. A series of thrombectomy and distal filter devices have been developed to limit distal embolization during percutaneous coronary interventions (PCI). **Objective.** To evaluate the feasibility of the combined use of thrombus-aspirating catheters and distal filter devices in patients at high risk of no-reflow. **Methods.** Thrombus aspiration (TA) and distal filter protection (DFP) were sequentially used in a series of patients undergoing urgent PCI within 48 hours of acute myocardial infarction (MI). Inclusion criteria were: (1) occlusion of the infarct-related artery; (2) at least 2 out of the 6 Yip's classification features of high thrombus burden. Coronary angiograms were evaluated off-line to assess thrombus score, coronary flow and distal embolization in different phases of the procedure. **Results.** TA followed by DFP prior to balloon dilatation or stent implantation was successfully performed in 20 patients with acute MI due to occlusion of *de novo* lesions (80%) or in-stent thrombosis (20%) located in a native coronary artery (90%) or a saphenous vein graft (10%). TA was associated with a significant acute reduction of TS and improvement of coronary flow (TIMI grade from 0.7 ± 0.8 to 1.6 ± 1.1 ; $p = 0.004$ and CTFC from 83 ± 29 to 52 ± 36 ; $p = 0.006$). This facilitated the deployment of DFP, which did not induce significant flow modification (TIMI grade: 2.3 ± 0.9 pre-DFP placement vs. 2.2 ± 1.0 post-DFP placement; $p = 0.20$; CTFC: 32 ± 28 pre-DFP placement vs. 35 ± 28 post-DFP placement; $p = 0.47$). Post-PCI angiography revealed a 90% TIMI 3 flow rate and 47% MBG 3 rate with only 1 case of angiographically evident distal embolization. **Conclusions.** **Sequential use of TA and DFP may be successfully used during PCI in patients at very high risk of distal embolization.** However, the possible benefits of such an approach should be weighted with the increased complexity of the procedure. Further evaluations of the clinical efficacy of this approach are needed. J INVASIVE CARDIOL 2007; 19:317-323



Intracoronary Thrombectomy Improves Myocardial Reperfusion in Patients Undergoing Direct Angioplasty for Acute Myocardial Infarction

Massimo Napodano, MD, Giampaolo Pasquetto, MD, Salvatore Saccà, MD, Carlo Cernetti, MD, Virginia Scarabeo, MD, Pietro Pascotto, MD, Bernhard Reimers, MD

Mirano, Italy

- OBJECTIVES** We sought to evaluate the effects of mechanical thrombectomy on myocardial reperfusion during direct angioplasty for acute myocardial infarction (AMI).
- BACKGROUND** Embolization of thrombus and plaque debris may occur during direct angioplasty for AMI. This may lead to distal vessel or side branch occlusion and to obstructions in the microvascular system, resulting in impaired myocardial reperfusion. Mechanical thrombectomy is used to reduce distal embolization.
- METHODS** Ninety-two patients with AMI and angiographic evidence of intraluminal thrombus were randomized to either intracoronary thrombectomy followed by stenting or to a conventional strategy of stenting. Thrombectomy was performed using the X-Sizer catheter (EndiCOR Inc., San Clemente, California). Myocardial reperfusion was assessed by myocardial blush and ST resolution.
- RESULTS** Postprocedure Thrombolysis in Myocardial Infarction-3 flow was not different between groups (93.5% vs. 95.7%, $p = 0.39$). Myocardial blush-3 was observed in 71.7% of patients undergoing thrombectomy and in 36.9% of patients undergoing conventional strategy ($p = 0.006$). ST-segment resolution $\geq 50\%$ occurred more often in patients undergoing thrombectomy (82.6% vs. 52.2%, $p = 0.001$). By multivariate analysis, adjunctive thrombectomy was an independent predictor of blush-3 (odds ratio, 3.27; 95% confidence interval, 1.06 to 10.05; $p = 0.039$).
- CONCLUSIONS** Intracoronary thrombectomy as adjunct to stenting during direct angioplasty for AMI improves myocardial reperfusion as assessed by myocardial blush and ST resolution. (J Am Coll Cardiol 2003;42:1395–402) © 2003 by the American College of Cardiology Foundation
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Efficacy X-sizer (Core lab)

XAMINE ST

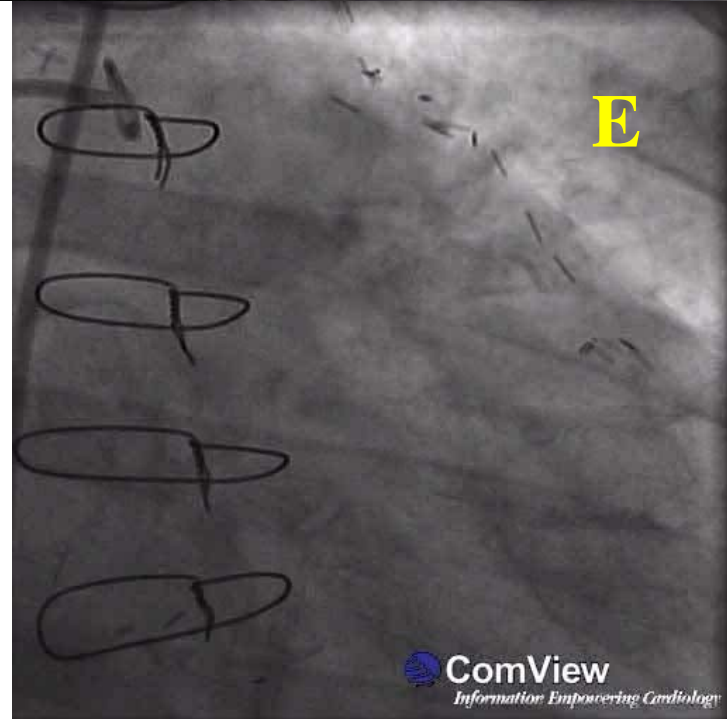
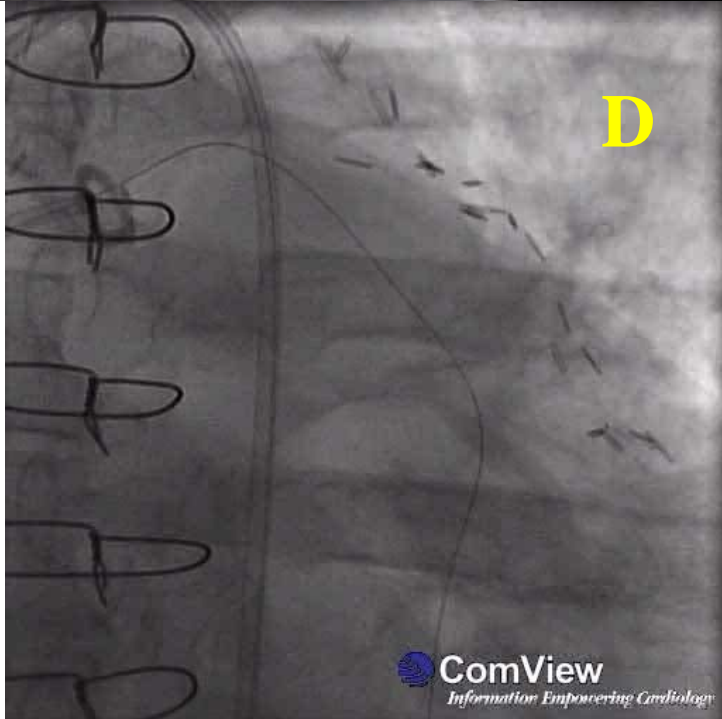
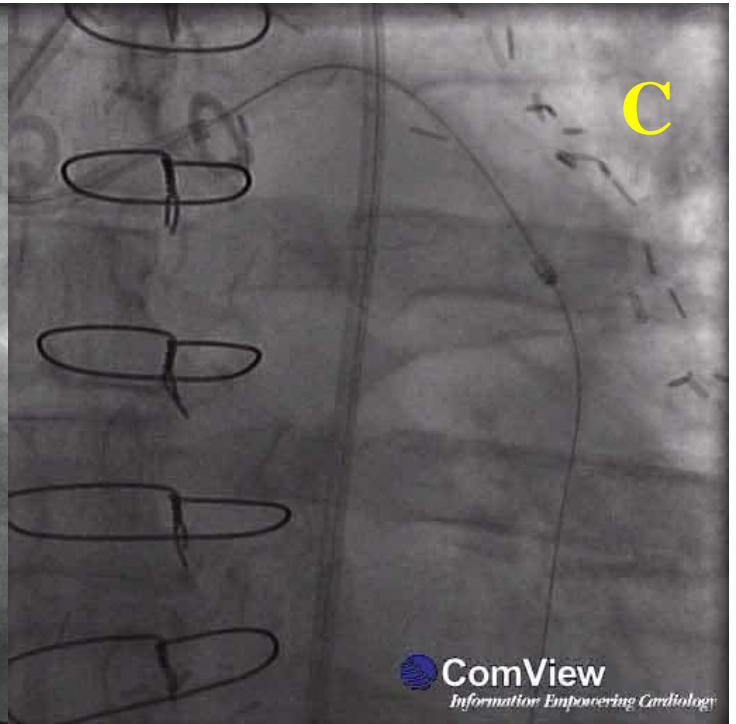
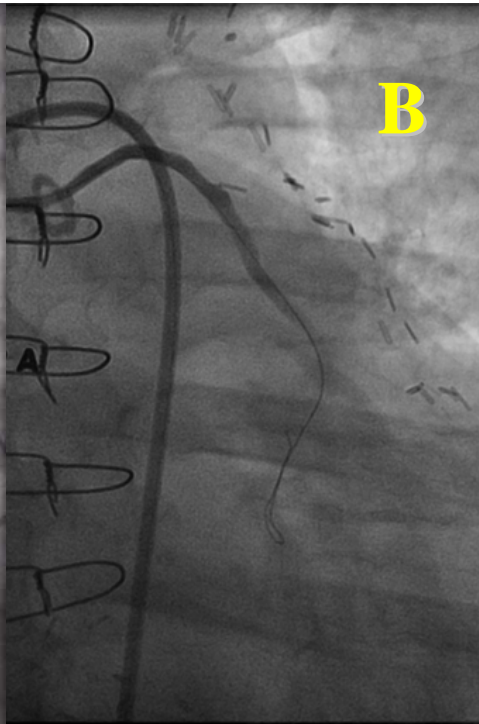
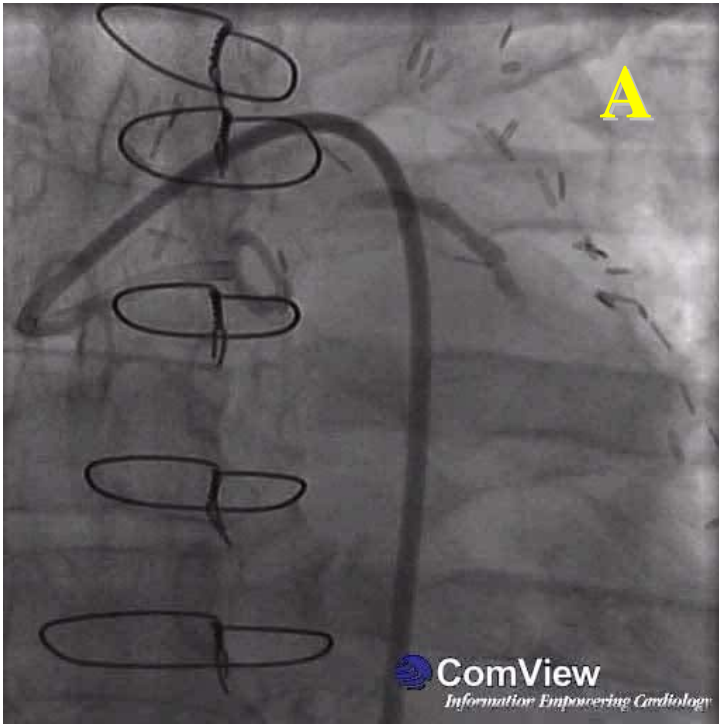
X-sizer success *

87 %

Thrombus removal

95%

*Successful delivery *X-SIZER* to target site and TIMI flow improvement > 1 grade.



FDA approved device

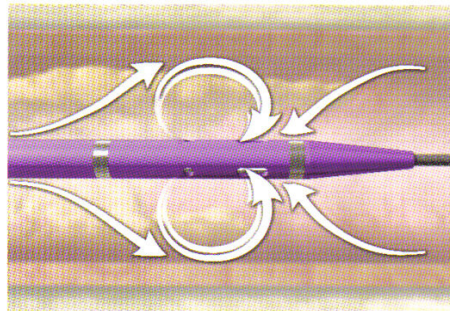
AngioJet[®] System Mechanism of Action

The Bernoulli Effect explains the relationship between velocity and pressure.

"Where velocity is greatest, the pressure is lowest"



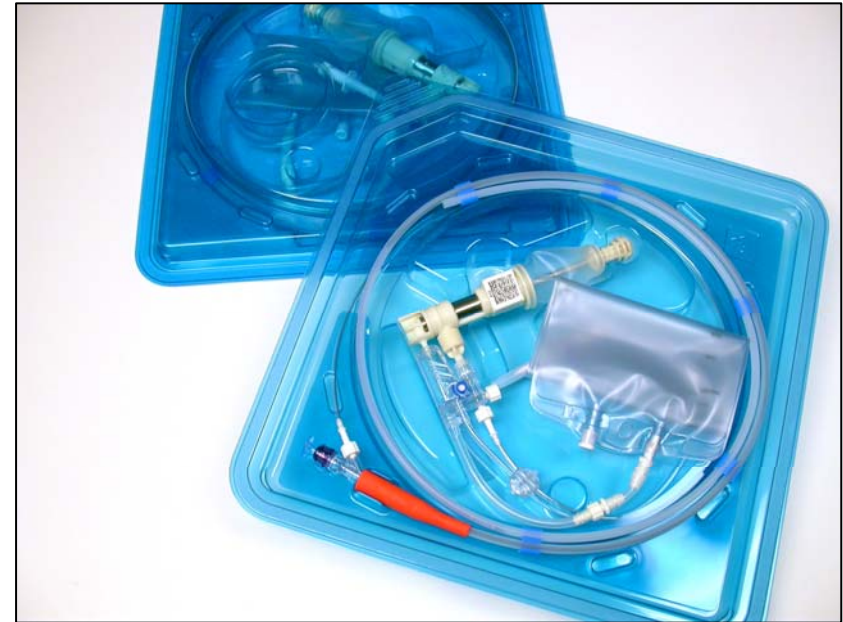
Saline jets travel backwards at 390mph to create a low pressure zone causing a vacuum effect.



Cross Stream[®] windows optimize the drawing action for more effective thrombus removal.

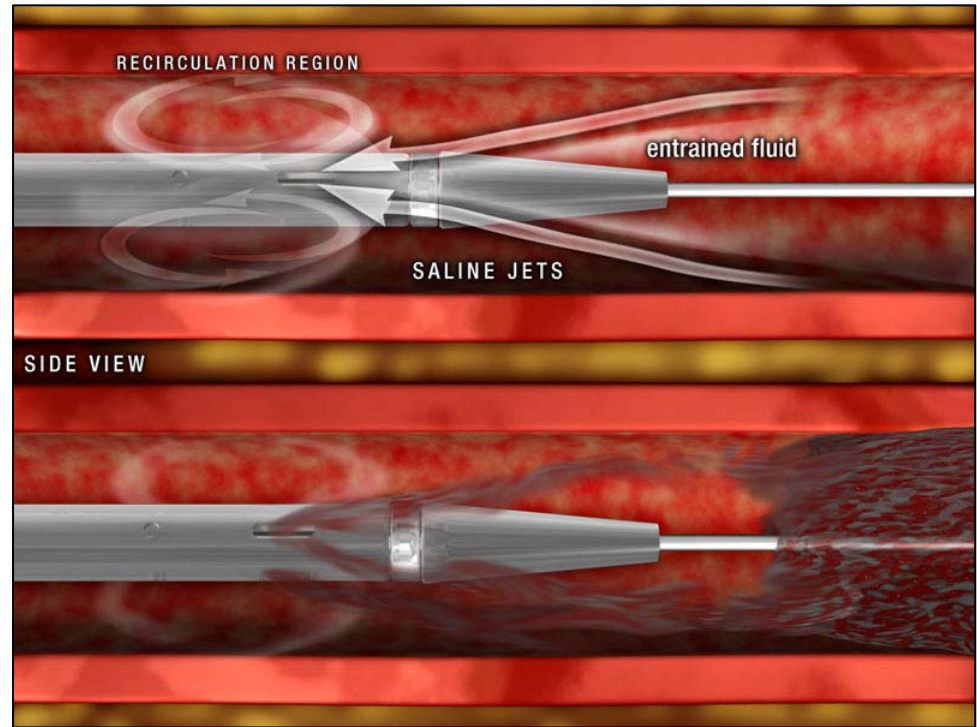


Thrombus is drawn into the catheter where it is fragmented by the jets and evacuated from the body.



AngioJet® Ultra Thrombectomy System

The new AngioJet Ultra console features automated set-up and supports a wide range of catheters with all disposable elements integrated into single-package thrombectomy sets.



Comparison of Rheolytic Thrombectomy Before Direct Infarct Artery Stenting Versus Direct Stenting Alone in Patients Undergoing Percutaneous Coronary Intervention for Acute Myocardial Infarction

David Antoniucci, MD, Renato Valenti, MD, Angela Migliorini, MD, Guido Parodi, MD, Gentian Memisha, MD, Giovanni Maria Santoro, MD, and Roberto Sciagrà, MD

This randomized trial compared rheolytic thrombectomy before direct infarct artery stenting with direct infarct artery stenting alone in 100 patients with a first acute myocardial infarction (AMI). The primary end point of the study was early ST-segment elevation resolution, and the secondary end points were corrected Thrombolysis In Myocardial Infarction (TIMI) frame count, infarct size, and 1-month clinical outcome. The primary end point rates were 90% in the thrombectomy group and 72% in the placebo group ($p = 0.022$). Randomization to thrombectomy was independently related to the primary end point (odds ratio 3.56, $p = 0.032$). The corrected Thrombolysis In Myocardial Infarction (TIMI) frame count was lower in the thrombectomy group (18.2 ± 7.7 vs 22.5 ± 11.0 , $p = 0.032$), and infarct size was smaller in the thrombectomy group ($13.0 \pm 11.6\%$ vs $21.2 \pm 18.0\%$, $p = 0.010$). At 1 month, there were no major adverse cardiac events.

Rheolytic thrombectomy before routine direct infarct-related artery (IRA) stenting is highly feasible and provides more effective myocardial reperfusion in patients undergoing percutaneous coronary intervention for AMI. ©2004 by Excerpta Medica, Inc.

(Am J Cardiol 2004;93:1033-1035)

thrombectomy in the setting of AMI.^{5,6} This randomized trial assessed the efficacy of rheolytic thrombectomy before direct infarct artery stent implantation in patients who underwent PCI for AMI.

•••

Criteria for enrollment included chest pain persisting >30 minutes associated with an ST-segment elevation of ≥ 0.1 mV in ≥ 2 contiguous electrocardiographic leads. The exclusion criteria included (1) previous myocardial infarction, (2) administration of fibrinolytic therapy, (3) bundle branch block or ventricular pacing on the baseline electrocardiogram preventing analysis of the ST-segment changes, (4) infarct-related artery (IRA) diameter <2.5 mm on visual angiographic assessment, and (5) inability to obtain informed consent. Patients with cardiogenic shock due to predominant ventricular failure were included, as were patients with high-risk coronary anatomy. After coronary angiography, eligible patients were randomly assigned to direct IRA stenting alone or thrombectomy before stenting. Computer-generated sequences and assignments using a closed envelope system were used to perform randomization. Thrombectomy was accomplished with the second-generation rheolytic thrombectomy 4Fr catheter (AngioJet, Possis Medical, Minneapolis, Minnesota). Two types of stents were used: a tubular closed-cell carbon-coated stent (Techno, Sorin,

Rheolytic Thrombectomy With Percutaneous Coronary Intervention for Infarct Size Reduction in Acute Myocardial Infarction 30-Day Results From a Multicenter Randomized Study

Arshad Ali, MD et al.

OBJECTIVES

The goal of this work was to determine whether rheolytic thrombectomy (RT) as an adjunct to primary percutaneous coronary intervention (PCI) reduces infarction size and improves myocardial perfusion during treatment of ST-segment elevation myocardial infarction (STEMI).

BACKGROUND

Primary PCI for STEMI achieves brisk epicardial flow in most patients, but myocardial perfusion often remains suboptimal. Distal embolization of thrombus during treatment may be a contributing factor.

METHODS

This prospective, multicenter trial enrolled 480 patients presenting within 12 h of symptom onset and randomized to treatment with RT as an adjunct to PCI (n = 240) or to PCI alone (n = 240). **Visible thrombus was not required.** The primary end point was infarct size measured by sestamibi imaging at 14 to 28 days. Secondary end points included final Thrombolysis In Myocardial Infarction (TIMI) flow grade, tissue myocardial perfusion (TMP) blush, ST-segment resolution, and major adverse cardiac events (MACE), defined as the occurrence of death, new Q-wave myocardial infarction, emergent coronary artery bypass grafting, target lesion revascularization, stroke, or stent thrombosis at 30 days.

RESULTS

Final infarct size was higher in the adjunct RT group compared with PCI alone ($9.8 \pm 10.9\%$ vs. $12.5 \pm 12.13\%$; $p = 0.03$). Final TIMI flow grade 3 was lower in the adjunct RT group (91.8% vs. 97.0% in the PCI alone group; $p < 0.02$), although fewer patients had baseline TIMI flow grade 3 in the adjunct RT group (44% vs. 63% in the PCI alone group; $p < 0.05$). There were no significant differences in TMP blush scores or ST-segment resolution. Thirty-day MACE was higher in the adjunct RT group (6.7% vs. 1.7% in the PCI alone group; $p = 0.01$), a difference primarily driven by very low mortality rate in patients treated with PCI alone (0.8% vs. 4.6% in patients treated with adjunct RT; $p = 0.02$).

CONCLUSIONS

Despite effective thrombus removal, RT with primary PCI did not reduce infarct size or improve TIMI flow grade, TMP blush, ST-segment resolution, or 30-day MACE.

J Am Coll Cardiol 2006;48:244-52

AngioJet Thrombectomy is a significant independent predictor of reduced risk for Stent Thrombosis and MACE events in Large Thrombus Burden STEMI patients.

¹Sianos G, Papafaklis M, Daemen J, Vaina S, van Mieghem C, van Domberg R, Michalis L, Serruys P. Angiographic Stent Thrombosis After Routine Use of Drug-Eluting Stents in ST-Segment Elevation Myocardial Infarction: The Importance of Thrombus Burden. *J Am Coll Cardiol*, 2007;50;572-583

Table 5 Independent Predictors of Infarct-Related Artery Stent Thrombosis

Variable*	Hazard Ratio	95% Confidence Interval	p Value
Age (per 10-yr increase)	0.55	0.37-0.82	0.003
Stent thrombosis at presentation	6.24	2.06-18.92	0.001
Bifurcational stenting	4.06	1.64-10.02	0.002
Rheolytic thrombectomy	0.11	0.01-0.81	0.03
Large thrombus burden	8.73	3.39-22.47	<0.001

*Additional variables entered in the multivariate model but not found to be significant were diabetes mellitus, previous myocardial infarction, previous percutaneous coronary intervention, and direct stenting.

Benefits of rheolytic thrombectomy in patients with STEMI and **high thrombus burden**: findings from the cardioquest interventional database

	Low Thrombus n=223	High Thrombus AJet n=53	High Thrombus No AJet n=122	
30-d mortality	13 (5.8%)	5 (9.4%)	17 (13.9%)	p=NS
Angiographic adverse events	24 (10.8%)	8 (15.1%)	49 (40.2%)	p=0.001

F Matar et al Cardiovasc Revasc Med 2008; 9: 113-114.

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

Dimitri A. Sherev, MD et al.

ABSTRACT: Background. Previous studies have shown the efficacy of Angiojet⁹ Rheolytic™ Thrombectomy (RT) in reducing thrombus burden and improving coronary flow in acute myocardial infarction (MI). No study 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 thrombolysis in MI (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. 56%, $p < 0.001$, 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.

J Invasive Cardiol 2006; 18: 12c-16c

Treatment of Coronary Stent Thrombosis With Rheolytic Thrombectomy: Results From a Multicenter Experience

Jose A. Silva,^{1*} MD, Christopher J. White,¹ MD, Stephen R. Ramee,¹ MD, Tyrone J. Collins,¹ MD, J. Stephen Jenkins,¹ MD, Kalon Ho,² MD, Donald S. Baim,³ MD, Joseph P. Carrozza,³ MD, Stephane Rinfret,³ MD, Cindy M. Setum,⁴ PhD, Jeffrey J. Popma,² MD, and Richard E. Kuntz,² MD

The objective of this study was to assess the feasibility, efficacy, and safety of rheolytic thrombectomy (RT) for treatment of coronary stent thrombosis. Stent thrombosis is an infrequent but potentially devastating complication. Conventional treatment with balloon angioplasty and/or thrombolysis has yielded suboptimal results. RT was used to treat 18 patients (mean age, 62 ± 8 years; 72% male) with in-stent thrombosis (mean time to stent thrombosis, 2.4 ± 1.8 days). Device success, procedure success, in-hospital and 30-day major cardiovascular events (MACE) were assessed in the hospital and at 30 days. Device success was obtained in 94% and procedure success was achieved in 100% of patients. Following RT, 11 patients underwent balloon angioplasty and 7 patients received additional stents. TIMI 3 coronary flow was obtained in 94.4% and all (100%) patients achieved either TIMI 2 or 3 coronary flow. The angiographic thrombus area decreased from 113.7 ± 79 to 5.5 ± 5.7 mm² after RT, and to 0.9 ± 2.1 mm² ($P < 0.001$) after final treatment. Procedural complications were limited to transient no-reflow in five patients. Only one patient evolved a Q-wave MI. At 30 days of follow-up, no patients suffered death, emergent bypass surgery, or stroke. Our data suggest that the adjunctive use of rheolytic thrombectomy offers improved outcomes compared to prior results of intervention after coronary stent thrombosis and should be strongly considered as a treatment option for this complication. *Cathet Cardiovasc Intervent* 2003;58:11–17. © 2003 Wiley-Liss, Inc.

Catheterization and Cardiovascular Interventions 58:18–19 (2003)

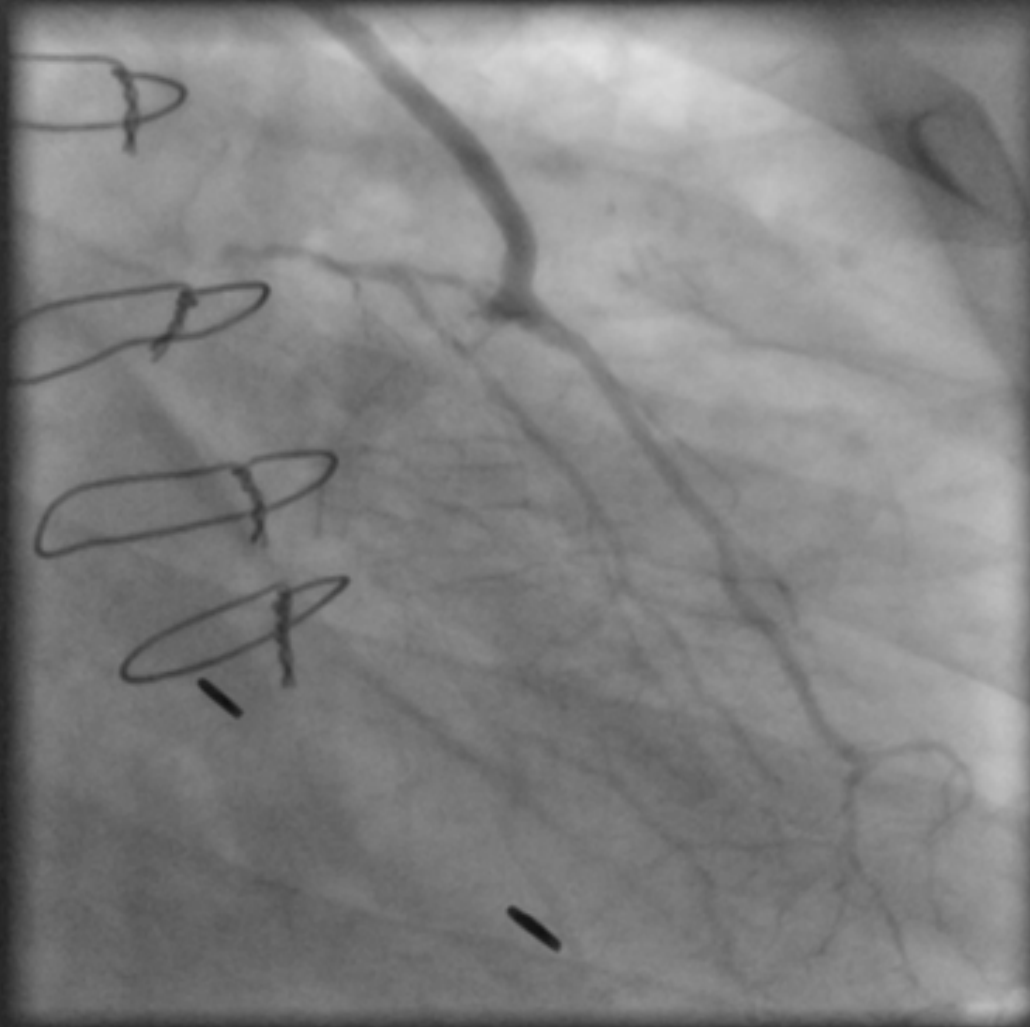
Editorial Comment

Late Stent Thrombosis: Is AngioJet the Preferred Revascularization Technique?

On Topaz, MD

Interventional Cardiovascular Laboratory,
McGuire VA Medical Center,
Division of Cardiology, Medical College of Virginia,
Virginia Commonwealth University,
Richmond, Virginia

Thrombectomy devices in AMI



Thrombectomy devices in AMI



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Thrombectomy devices in AMI





Conclusions:

- State-of-the-art AMI management should include a dedicated [mechanical ?] **thrombectomy** strategy.
- **Thrombectomy devices** provide direct thrombus contact, safe & effective extraction.
- **Thrombus removal** in AMI improves TIMI flow, ST- segment resolution, myocardial blush and cTFC.
- Re-emerging technique: Power Thrombolysis – incorporation of thrombectomy devices with direct lytics.
- Finally, In order **to achieve its goal**, the most important aspect of **thrombectomy** is...



謝謝

Thank you

Kiitos

Obrigado

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شُكراً

Asante

धन्यवाद

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Hvala

អរគុណ

Dziękuję

Grazie

धन्यवाद

Εὐχαριστώ

Merci

ขอบคุณ



DANKE



ありがとうございました

आभार

Спасибо

Salamat

감사합니다

Gracias

감사합니다

