Thrombus aspiration in STEMI: Routine or selective?

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Impact of Macroscopic Distal Emboli

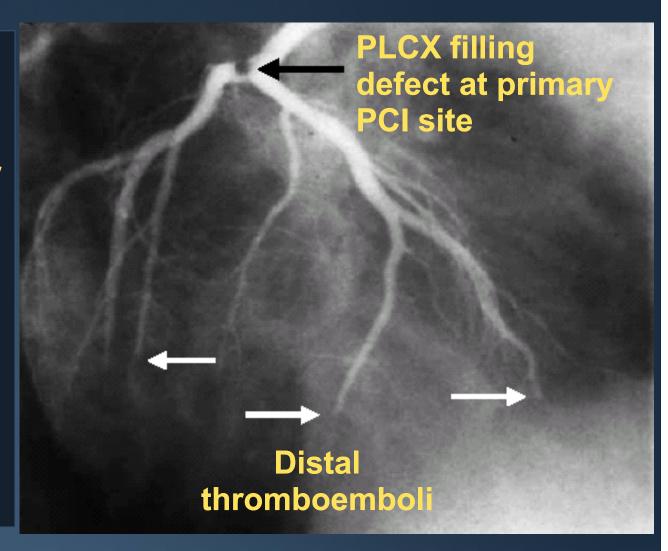
DE occurred in 27 of 178 (15%) pts after primary PTCA



↓ ST res

↑ Infarct size

↑ Mortality





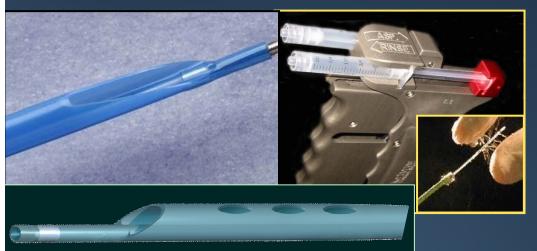


Mechanical Approaches to Thrombus

Thrombus aspiration

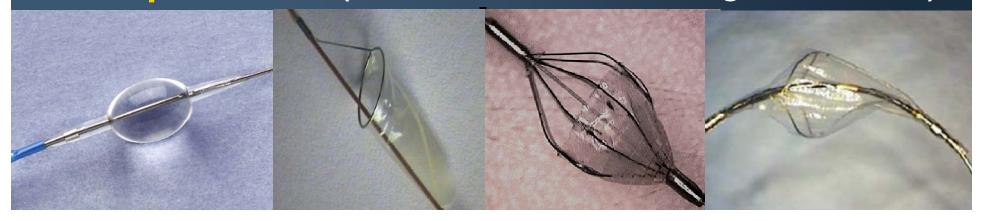
(Rinspirator, Pronto, Export, Rescue, Diver CE, etc.)

Thrombectomy (AngioJet, X-Sizer)





Distal protection (GuardWire, FilterWire, AngioGuard, etc.)



Distal Protection and Thrombectomy in AMI

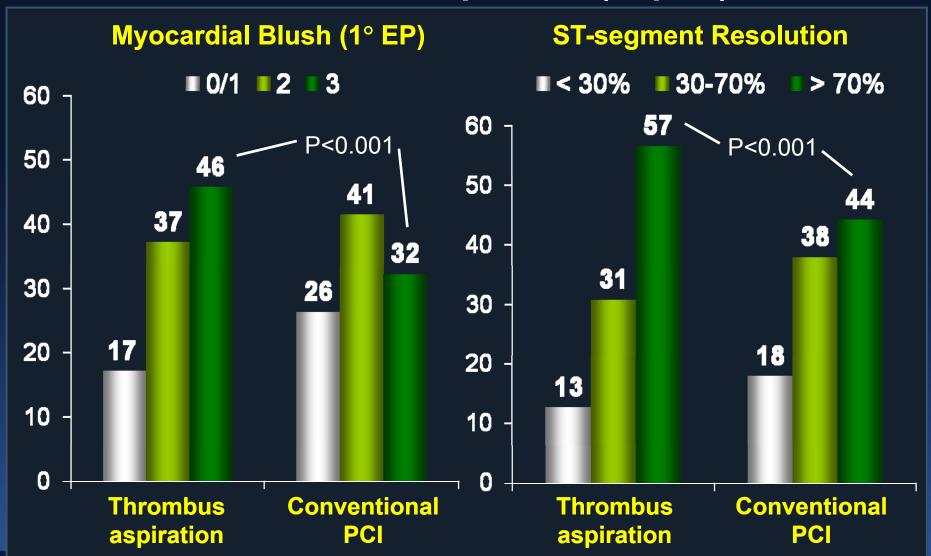
Macroscopic embolic debris can be retrieved from >75% of cases







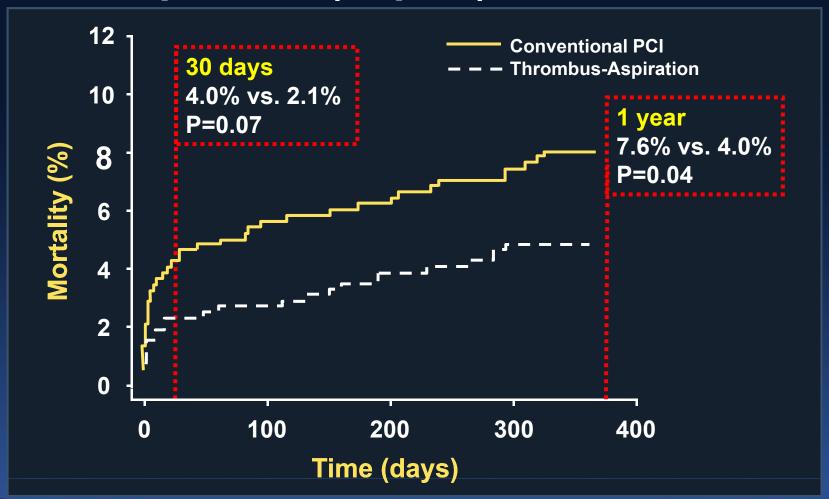
TAPAS: 1,071 pts with STEMI undergoing PCI randomized in the ER to aspiration (Export) vs. control







TAPAS: 1,071 pts with STEMI undergoing primary PCI randomized in the ER to manual aspiration (Export) vs. control



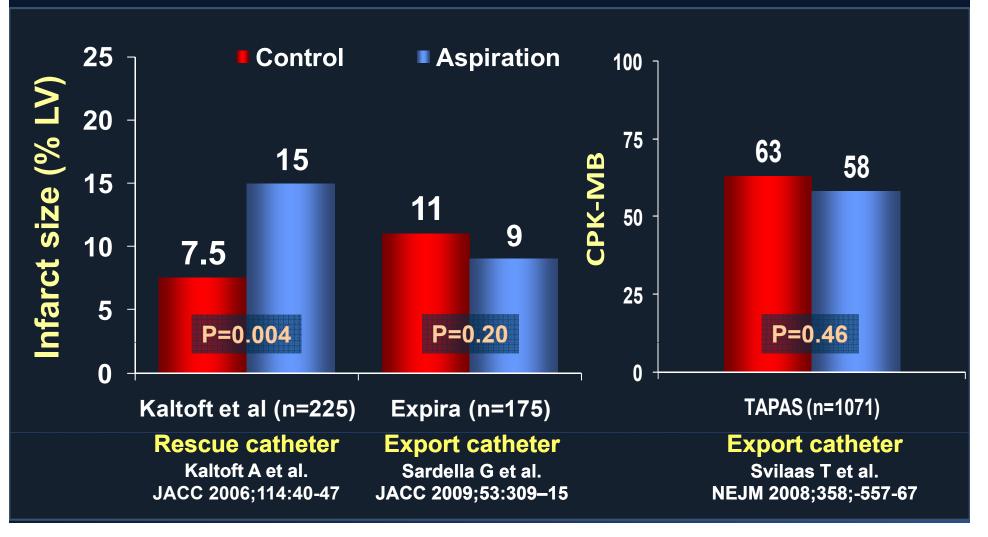




Aspiration Trials to Decrease Infarct Size Have been mostly met with frustration

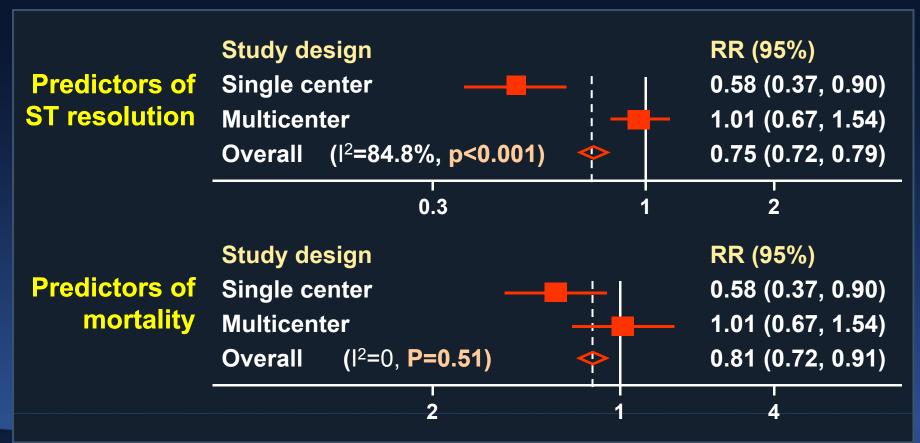
The concept of reducing embolic load





Embolic Protection During Primary PCI: Impact of single vs. multicenter studies 25 RCTs, 5919 pts

2460 pts in single center trials, 3459 pts in multicenter trials



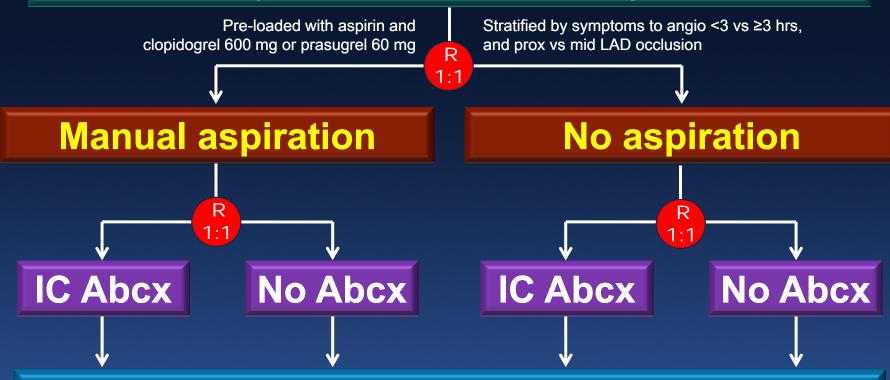




INFUSE-AMI Trial

452 pts with anterior STEMI

Anticipated Sx to PCI <5 hrs, TIMI 0-2 flow in prox or mid LAD Primary PCI with bivalirudin anticoagulation



Primary endpoint: Infarct size at 30 days (cMRI)

2° endpoints: TIMI flow, blush, ST-resolution, MACE (30d, 1 yr)

Stone GW et al. JAMA 2012;307:0n-line

INFUSE-AMI

Manual aspiration vs.
no aspiration

Pooled across the abciximab randomization

INFUSE-AMI: Baseline characteristics

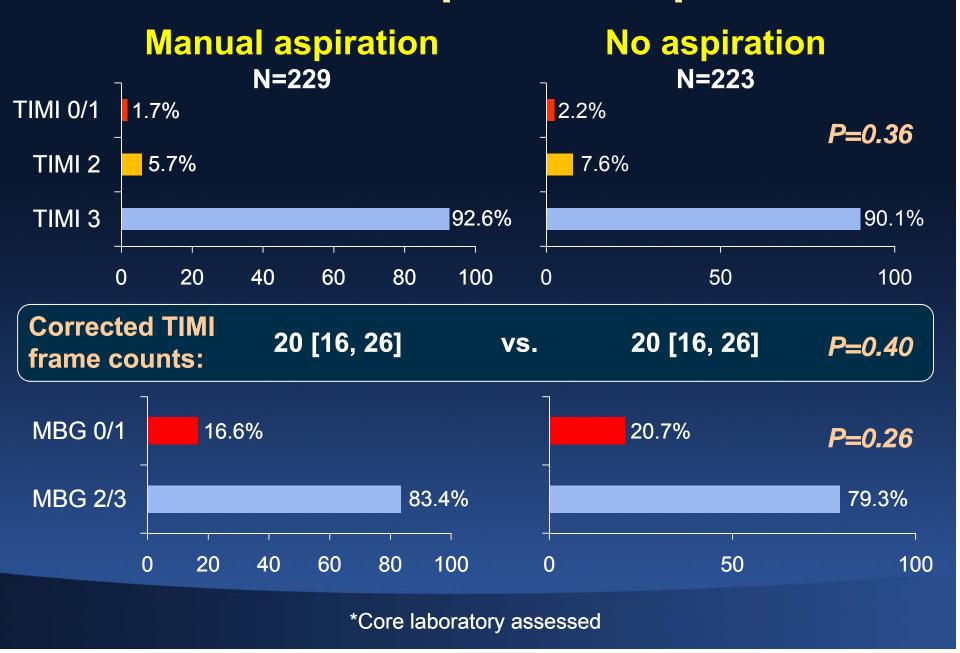
	Manual aspiration N=229	No aspiration N=223
Age (years)	61 [53, 70]	60 [51, 69]
Male	73.8%	74.0%
Hypertension	33.2%	29.6%
Hyperlipidemia	16.7%	14.8%
Diabetes mellitus	14.9%	7.6%
Cig. smoking, current	43.4%	48.9%
Prior MI	0.4%	1.4%
Prior PCI	2.2%	2.3%
Killip class II-IV	20.6%	16.6%
Sx - hosp arrival, mins	98 [65, 152]	100 [70, 145]
Infarct artery		
- Proximal LAD	64.6%	66.8%
- Mid LAD	35.4%	33.2%
LVEF, % (site)	40 [35, 50]	40 [35, 50]

INFUSE-AMI: Meds and procedures

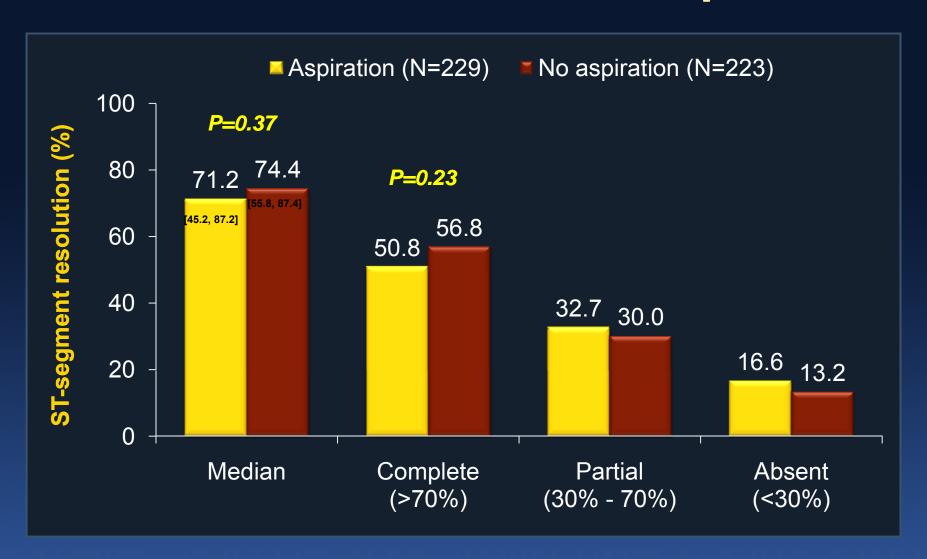
	Manual aspiration N=229	No aspiration N=223	P value
TIMI flow pre-PCI 0/1*	73.4%	70.0%	0.42
Blush pre-PCI 0/1*	85.5%	82.4%	0.37
Hospital - 1 st device, mins	43 [30, 63]	48 [35, 70]	0.02
Aspiration performed	98.3%**	4.0%	<0.001
Abciximab administered	50.7%	50.2%	0.93
N lesions treated	1.1 ± 0.4	1.1 ± 0.4	0.46
DES implanted	74.2%	70.9%	0.42
Stent length (mm)	24 [18, 32]	24 [18, 35]	0.30
Max stent diameter (mm)	3.0 [3.0, 3.5]	3.0 [3.0, 3.5]	0.20

^{*}Core laboratory assessed; **6F Export used in all but 3 cases, with thrombus retrieved in 78.9%

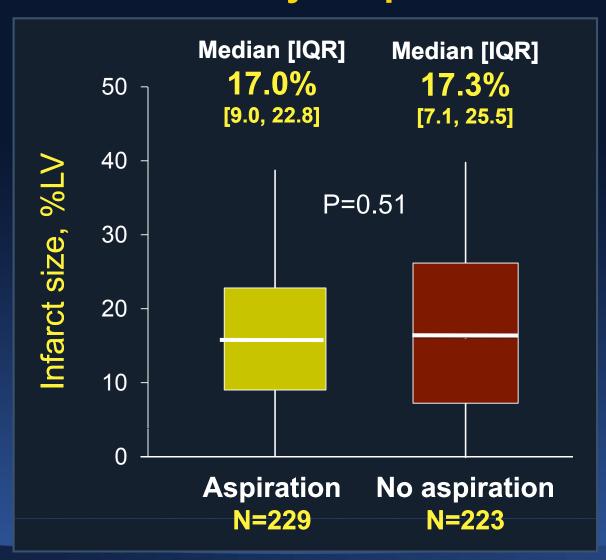
INFUSE-AMI: Reperfusion post-PCI*



INFUSE-AMI: STR 60 minutes post-PCI*



INFUSE-AMI: Infarct size at 30 days* - Primary endpoint -



*Core laboratory assessed. No interaction was present between the 2 randomization groups for the primary 30-day infarct size endpoint (p=0.46)

INFUSE-AMI: cMRI at 30 days*

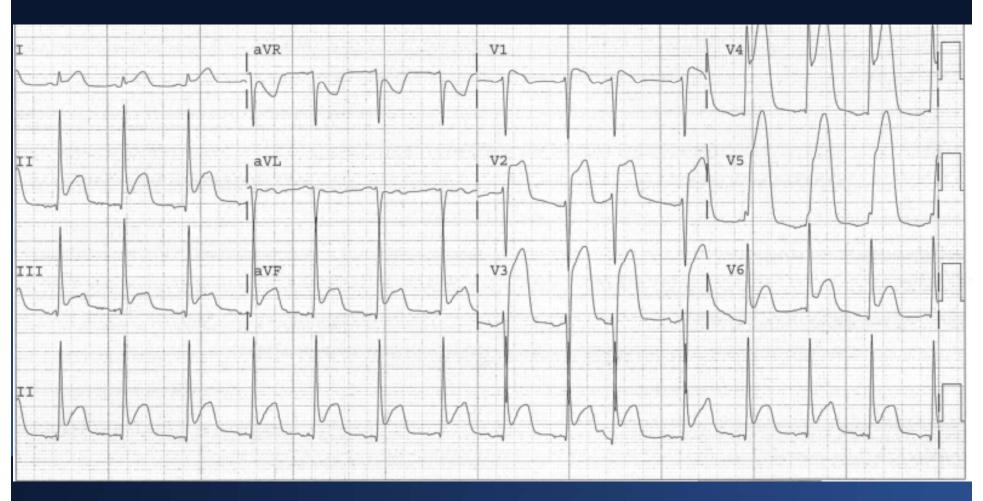
	Manual aspiration N=186	No aspiration N=186	P value
Total LV mass, grams	128.3 [108.9, 149.8]	132.0 [107.6, 156.1]	0.50
Infarct mass, grams	20.3 [9.7, 31.7]	21.0 [9.1, 34.1]	0.36
Infarct mass (% of total LV mass)	17.0 [9.0, 22.8]	17.3 [7.1, 25.5]	0.51
Total abnormal wall motion score	7.5 [2.0, 10.0]	7.5 [2.0, 10.0]	0.89
LVEF (%)	49.6 [43.3, 56.8]	49.5 [41.8, 57.6]	0.66

INFUSE-AMI: 30-day clinical efficacy

	Manual aspiration N=229	No aspiration N=223	P value
Death	3.1% (7)	2.7% (6)	0.81
Reinfarction	0.5% (1)	0.9% (2)	0.55
New onset severe HF	3.5% (8)	4.1% (9)	0.77
Rehospitalization for HF	0.0% (0)	0.9% (2)	0.15
Stroke	0.0% (0)	0.5% (1)	0.31
Clinically-driven TVR	0.5% (1)	1.8% (4)	0.17
Stent thrombosis, def/prob*	1.4% (3)	0.5% (1)	0.33
MACCE	3.1% (7)	5.0% (11)	0.31
MACE	6.6% (15)	7.2% (16)	0.81

Data are Kaplan-Meier estimates (n of events). *No cases of acute (<24 hr) stent thrombosis occurred. MACE = death, reinfarction, new onset severe heart failure (HF) or rehospitalization for HF; MACCE = death, reinfarction, stroke or clinically-driven TVR

Baseline ECG

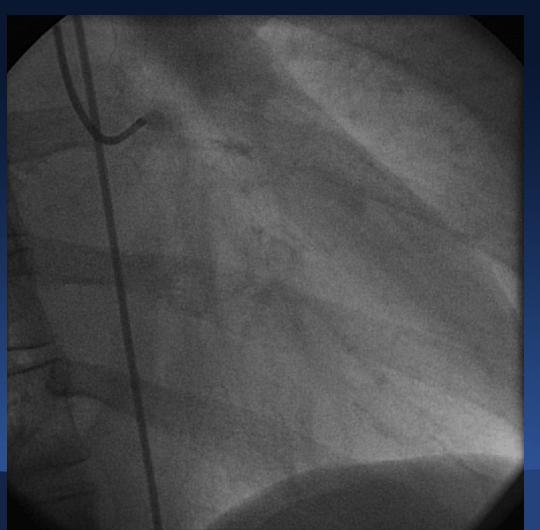


Baseline LV gram



Anterior, apical akinesis LVEF 33%

Baseline LCA



Aspiration with the Export

ER to device 45 mins



55 yo man with crushing chest pain Symptoms to ER 78 min; ER to device 45 min

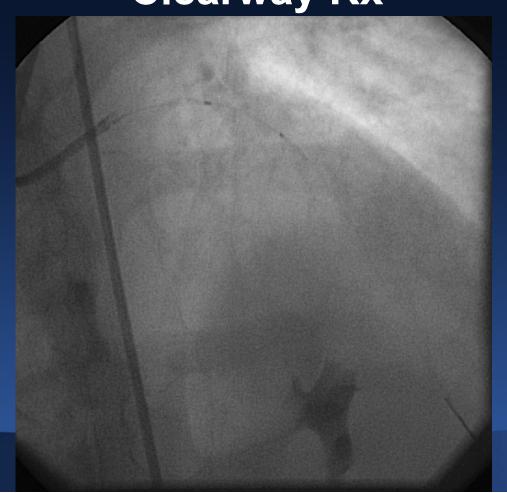
Post aspiration



TIMI 2 flow MBG 0

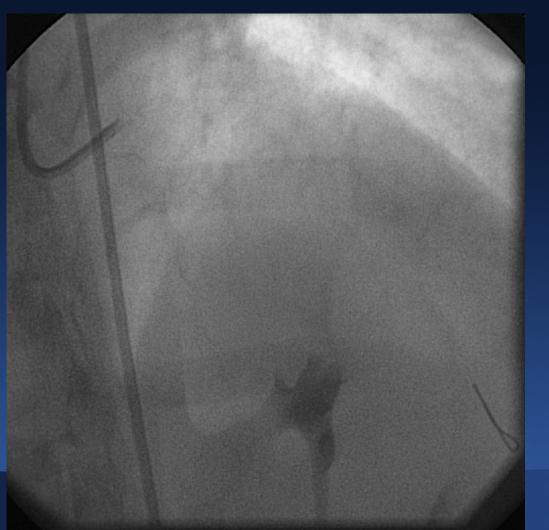
55 yo man with crushing chest pain Symptoms to ER 78 min; ER to device 45 min

Bolus abciximab infusion through the Clearway Rx



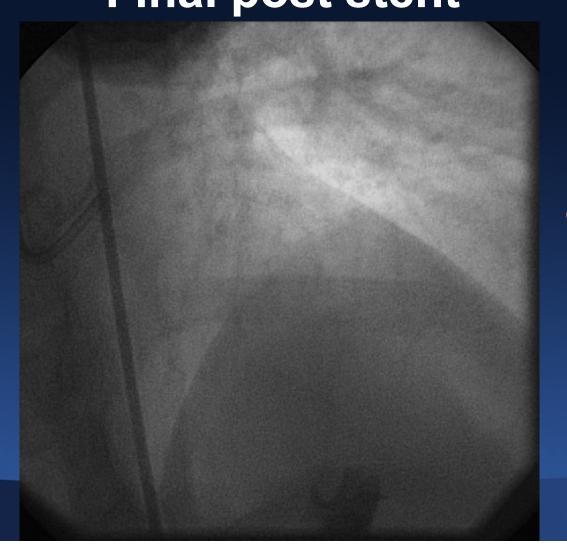
55 yo man with crushing chest pain Symptoms to ER 78 min; ER to device 45 min

Post IC abciximab



TIMI 3
flow
cTFC 32
MBG 2

55 yo man with crushing chest pain Symptoms to ER 78 min; ER to device 45 min Final post stent



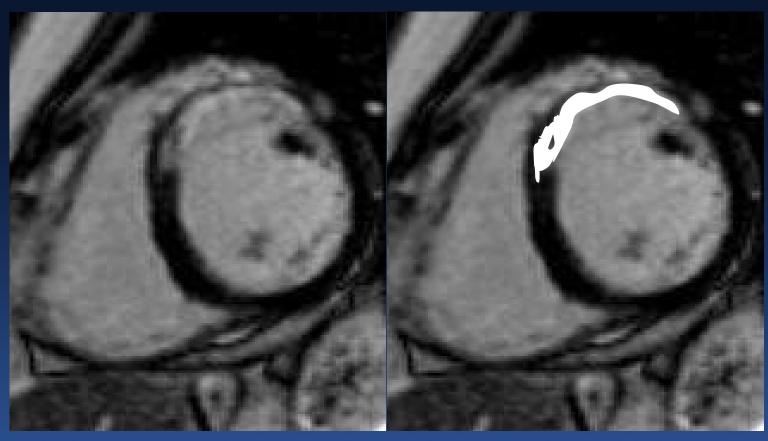
TIMI 3
flow
cTFC 17
MBG 3

55 yo man with crushing chest pain Symptoms to ER 78 min; ER to device 45 min 60' Post-PCI ECG



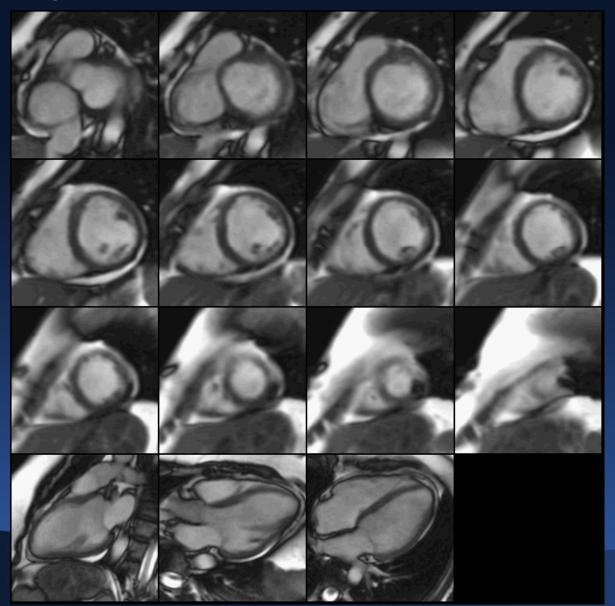
ST-segment resolution 92%

55 yo man with crushing chest pain: Symptoms to ER 78 min; ER to device 45 min 30-day cMRI



Total myocardial mass = 79.9 g; infarct size = 27.6 g; sz = 34.6% of LV

55 yo man with crushing chest pain: Symptoms to ER 78 min; ER to device 45 min



30-day cMRI

LVEDV = 147.2 ml; LVESV = 72.1 ml; LVEF 51.0% Anterior, apical and septal akinesis

INFUSE-AMI: Conclusions & Implications

In patients presenting early in the course of a large evolving anterior STEMI undergoing primary PCI with bivalirudin anticoagulation:

Manual aspiration with the 6F Export Catheter did not reduce infarct size

- The final word on aspiration in STEMI awaits the ongoing large-scale randomized TOTAL and TASTE trials
- Until this time, aspiration in STEMI should be used selectively, in cases of massive thrombus after wire passage, or refractory thrombus after PCI