Is there a role for thrombus aspiration in PCI?

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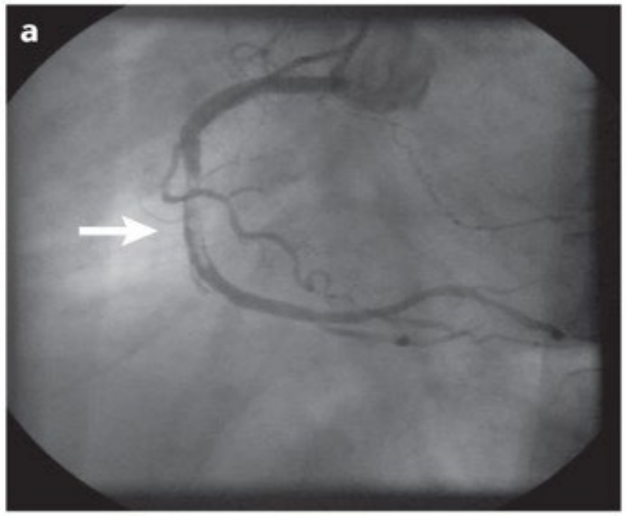
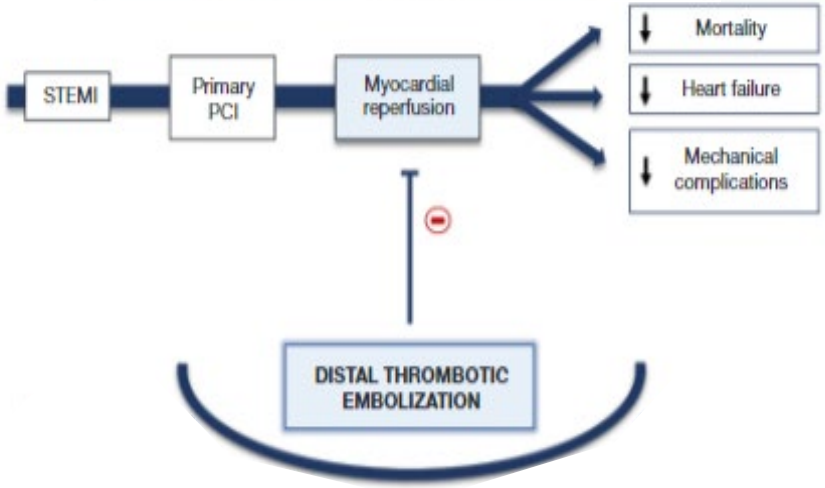
Disclosures

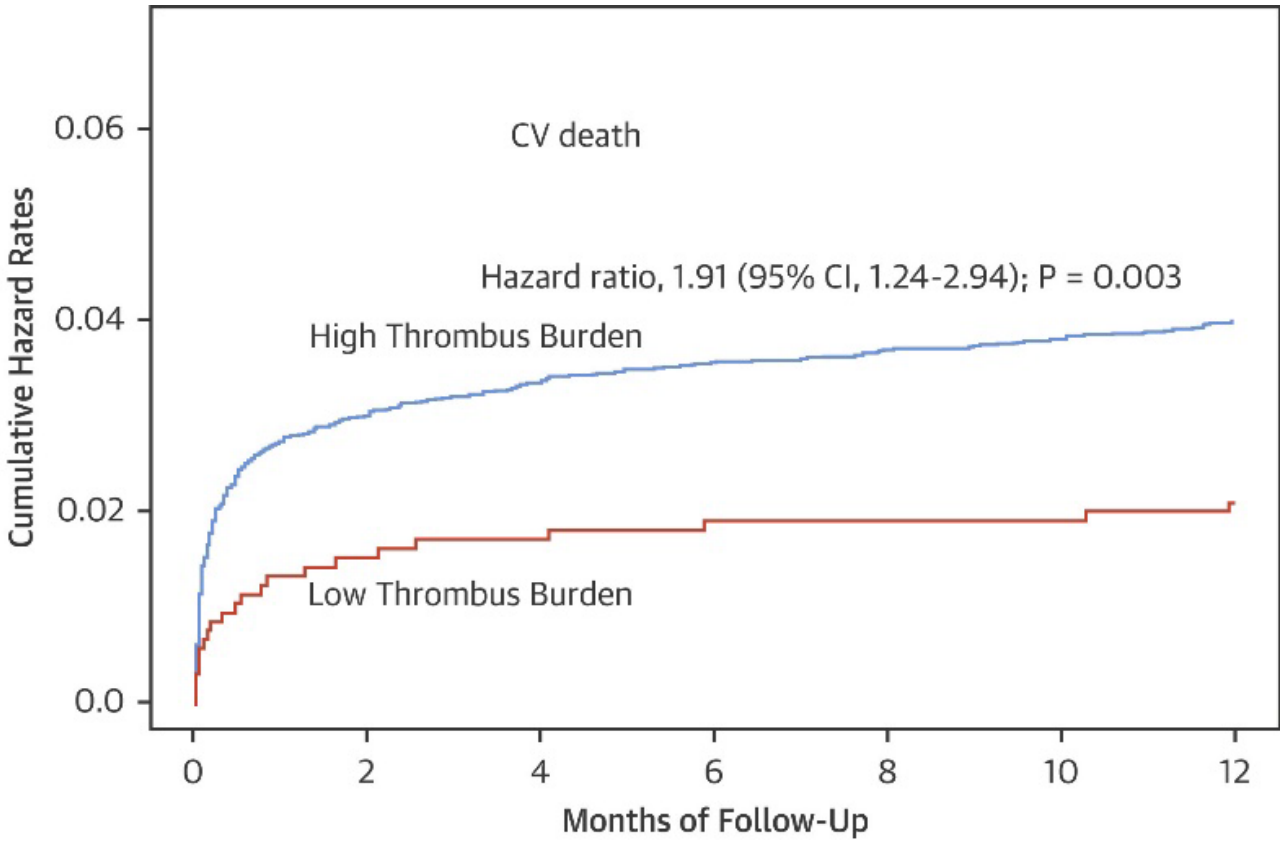
Affiliation/Financial Relationship	Company
Consultant/Advisory/Speaking Engagements:	Daiichi-Sankyo

Intracoronary thrombus during myocardial infarction





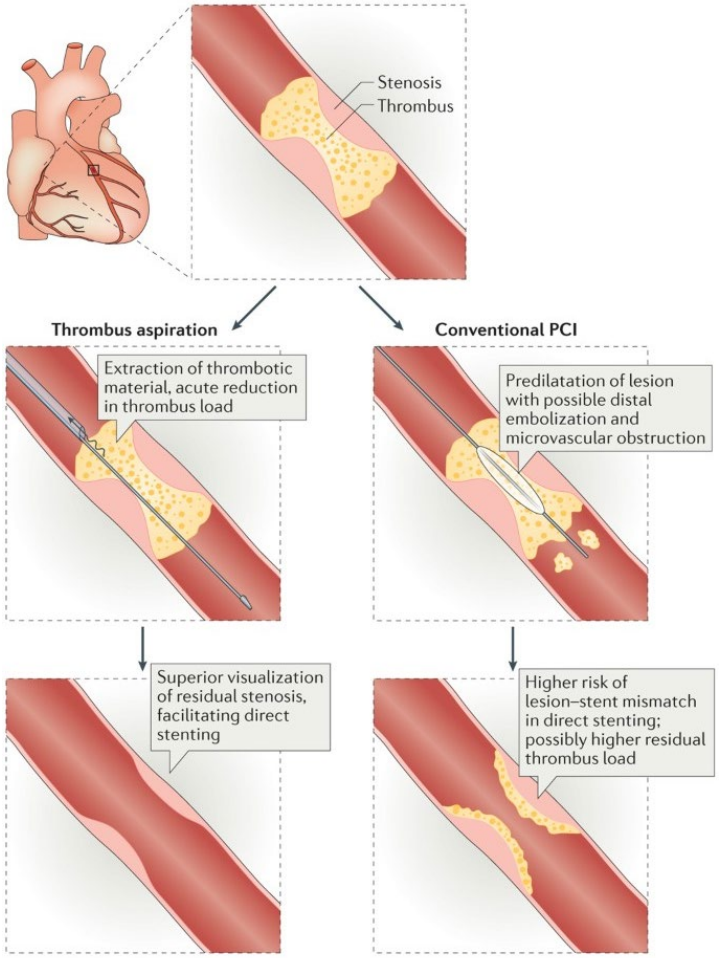
Increased rates of CV death according to the thrombus burden in the TOTAL trial

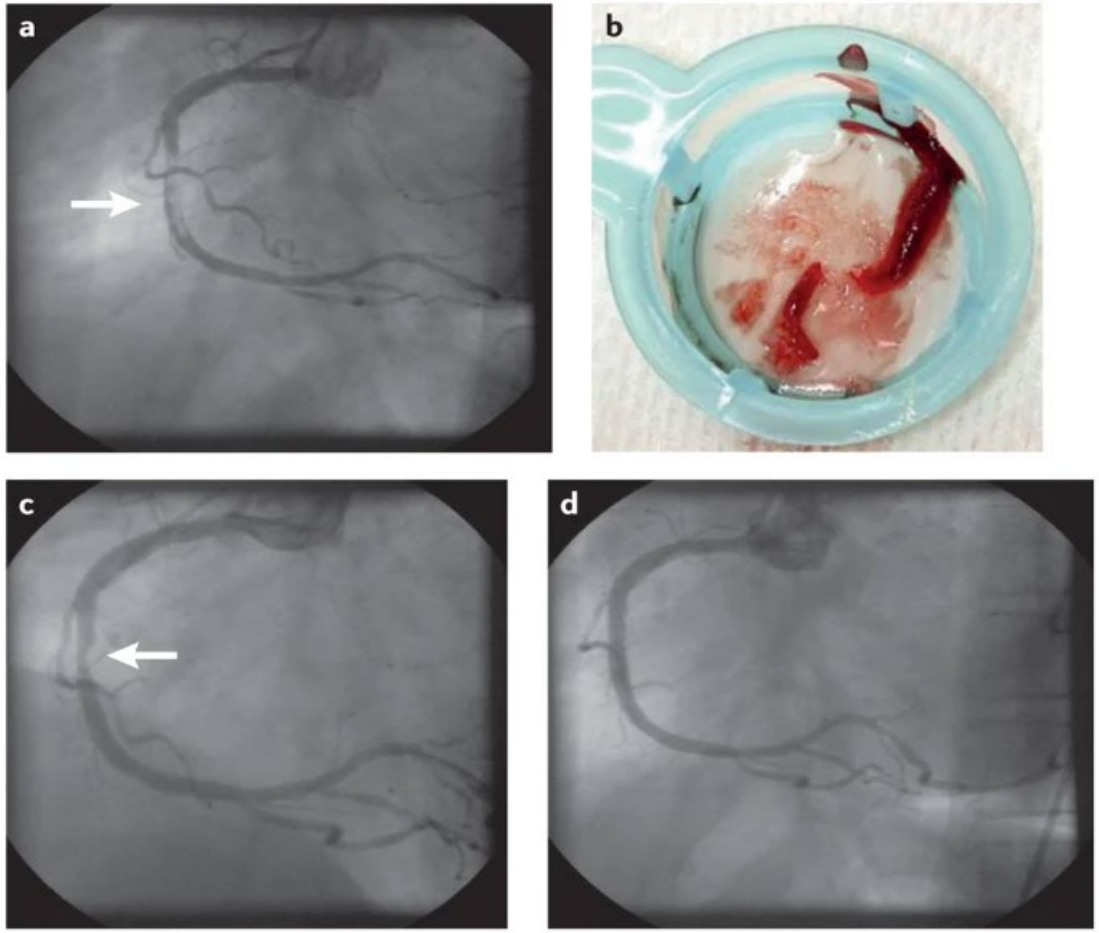


Distal embolization of thrombotic material during pPCI can lead to incomplete microvascular myocardial reperfusion, which jeopardizes clinical outcome

Lattuca B, Montalescot GJ Thorac Dis. 2018 Nov;10(Suppl 33):S4117-S4121; Mahmoud et al. *Nat Rev Cardiol* **13**, 418–428 (2016); Jolly SS, et al. JACC 2018; 72(14):1589-96

Removal of thrombotic material - Thrombus aspiration

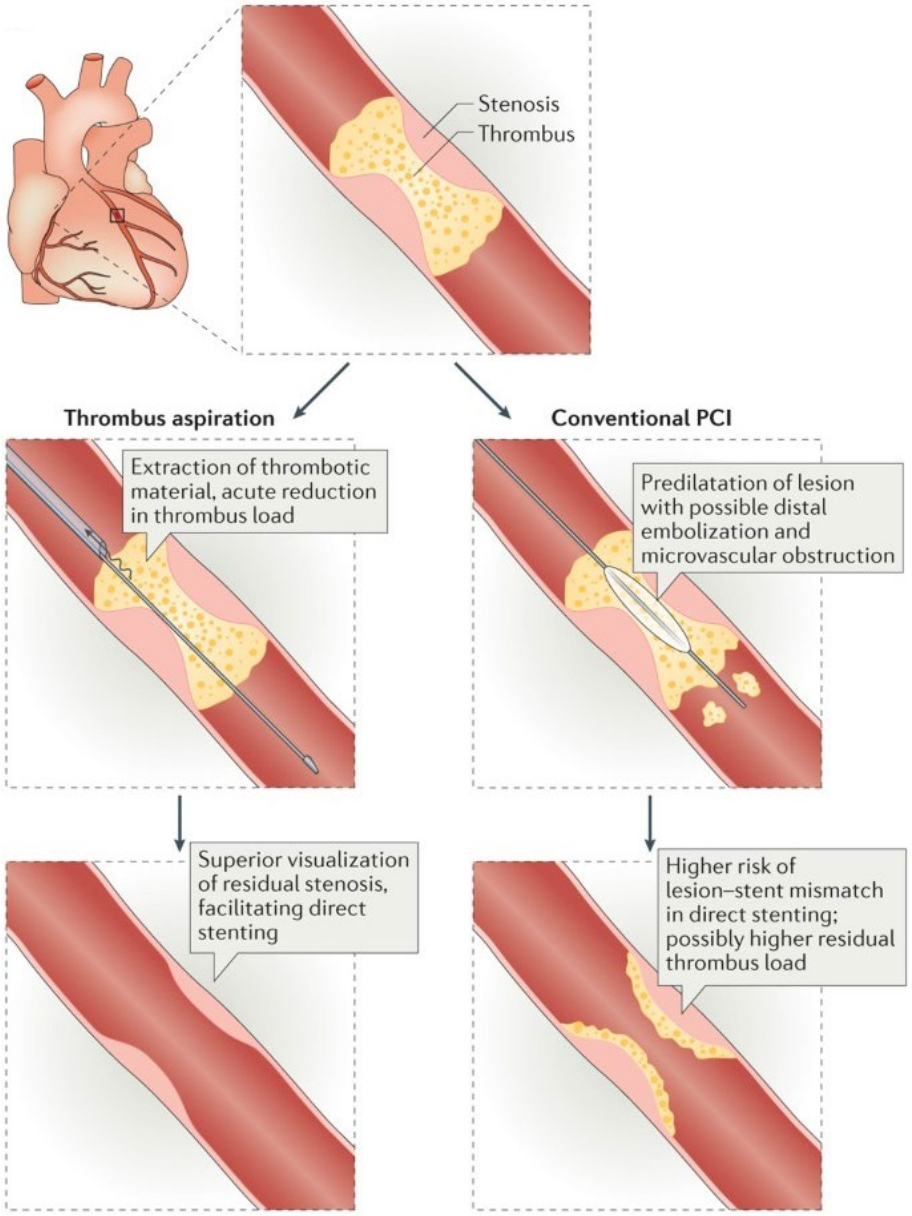




Thrombus aspiration — **the manual or mechanical evacuation of atherothrombotic material from the culprit coronary artery** — is the only adjunctive nonpharmacological strategy designed to improve myocardial reperfusion.

Mahmoud et al. *Nat Rev Cardiol* **13**, 418–428 (2016)

Advantages of Thrombus aspiration



Potential advantages

- Thrombus aspiration can decrease the thrombus burden and restore myocardial reperfusion.
- It reduces the need for lesion predilatation, preventing distal embolization.
- It facilitates direct stent implantation.

Mahmoud et al. *Nat Rev Cardiol* **13**, 418–428 (2016)

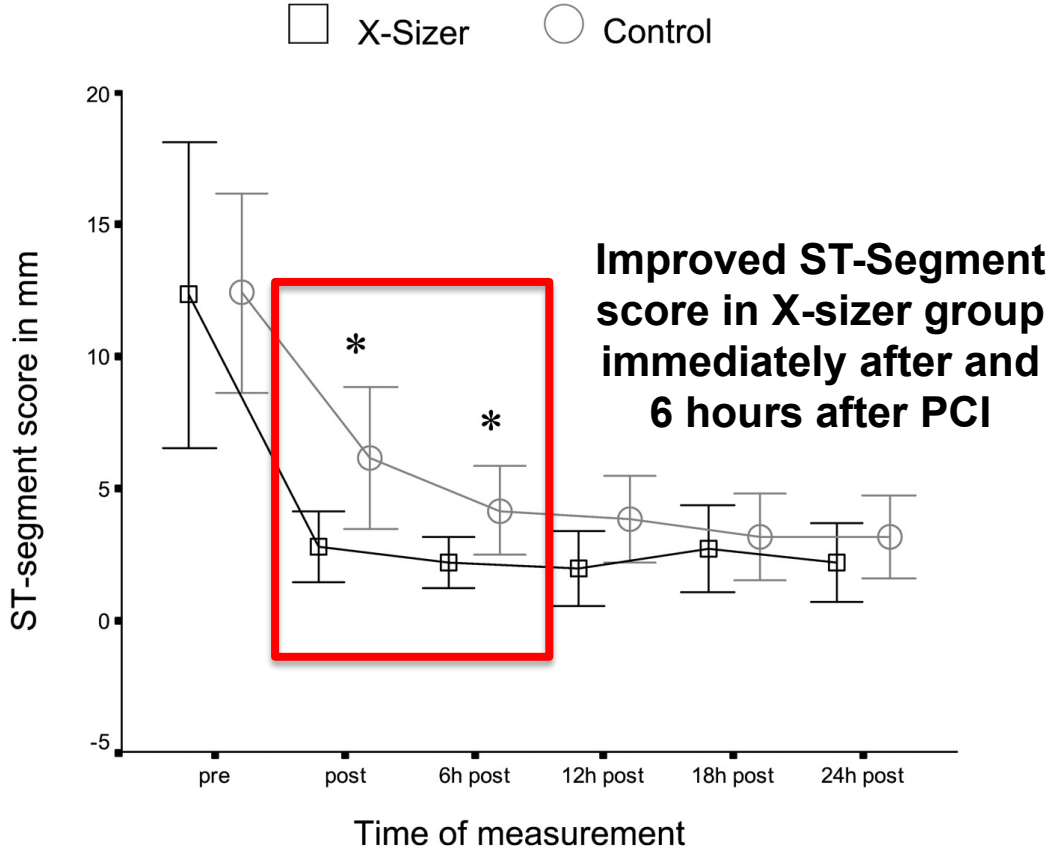
Initial promise…..

Circulation

RESEARCH ARTICLE | Originally Published 6 May 2002 | Check for updates

Intracoronary Thrombectomy With the X-Sizer Catheter System Improves Epicardial Flow and Accelerates ST-Segment Resolution in Patients With Acute Coronary Syndrome: A Prospective, Randomized, Controlled Study

Improvement of ST segment score (n=66 patients)



Improved ST-Segment score in X-sizer group immediately after and 6 hours after PCI

Pretreatment with the X-sizer catheter system improved epicardial flow and accelerated ST-segment resolution compared with conventional PCI alone

Beran G et al. Circulation. 2002 May 21;105(20):2355-60

Early doubts…. The Angiojet trial

Journal of the American College of Cardiology
Volume 48, Issue 2, 18 July 2006, Pages 244-252

Clinical Research
Clinical Trial

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

	RT (n = 197)	Control (n = 205)	p Value
Final infarct size, mean	12.5±12.13	9.8±10.92	0.03
Range	0.0–48.0	0.0–44.0	

Adverse Events to 30 Days*

Events	RT (n = 240)	Control (n = 240)	p Value
MACE, total	16(6.7)	4(1.7)	0.01
Death	11(4.6)	2(0.8)	0.02
Q-wave MI	0	0	–
Stroke	4(1.7)	2(0.8)	0.69

- Rheolytic thrombectomy **did not reduce infarct size or improve TIMI flow grade, TMP blush, ST-segment resolution, or 30-day MACE**.
- Surprisingly, an **increase in all-case mortality and MACE** was noted in the rheolytic thrombectomy group

Ali A et al. J Am Coll Cardiol. 2006 Jul 18;48(2):244-52

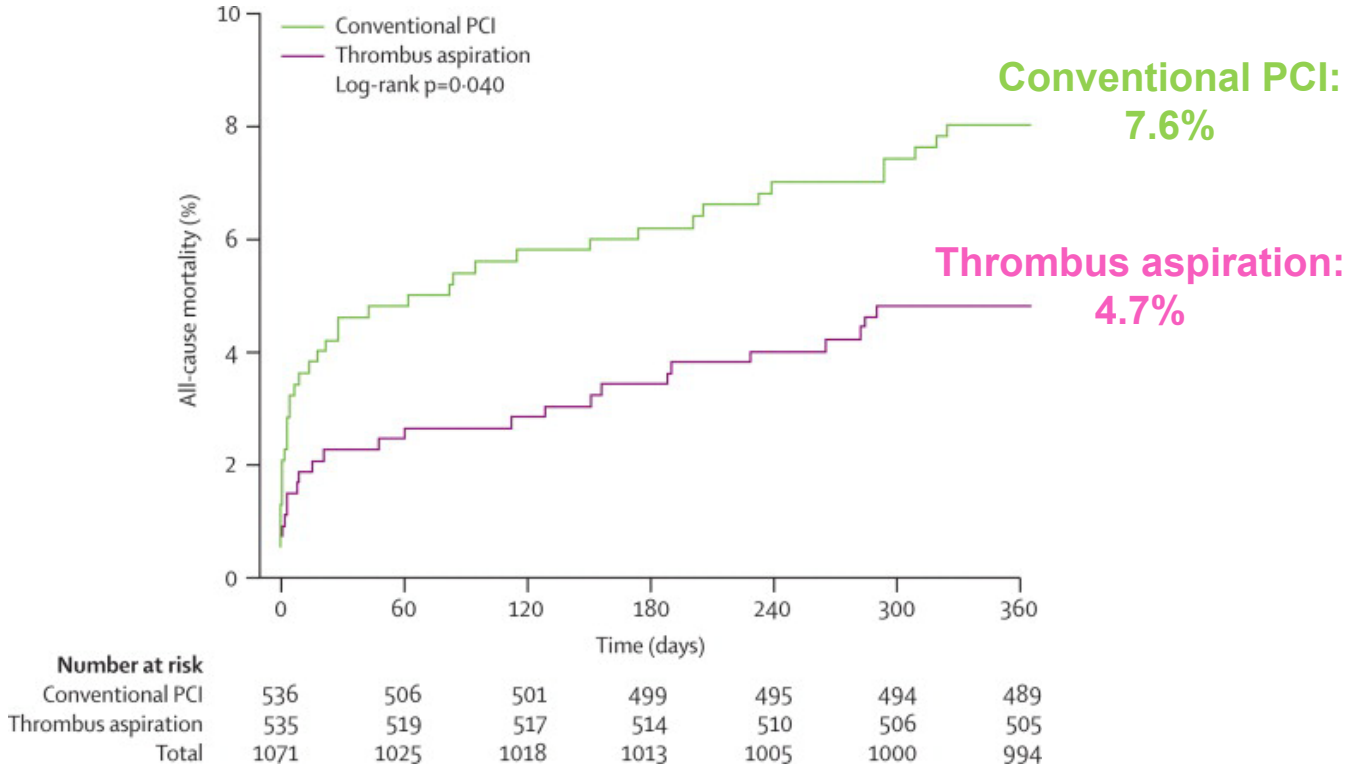
TAPAS and TASTE controversy

Thrombus Aspiration during Percutaneous coronary intervention in Acute myocardial infarction Study

TAPAS

1,071 STEMI patients randomized to thrombus aspiration or conventional PCI from 2005-2006

HR for all-cause mortality after 1 year: 1.67 (1.02–2.75), p=0.042



- On the basis of the positive TAPAS results, **guidelines recommended routine thrombus aspiration should be considered in primary PCI…..**
- …., however a subsequent meta-analysis **pointed to an increased risk of stroke after thrombus aspiration.**

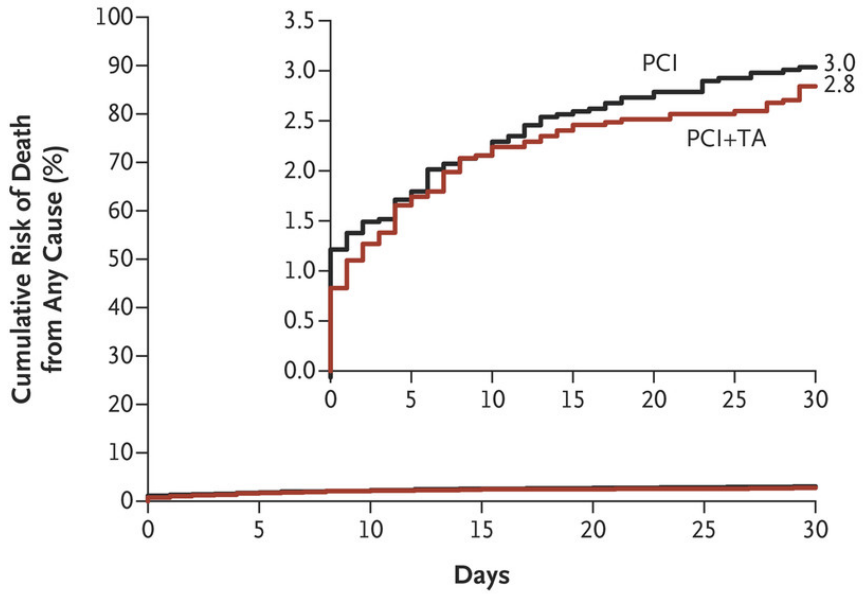
Vlaar PJ et al. Lancet. 2008 Jun 7;371(9628):1915-20

TAPAS and TASTE controversy

Thrombus Aspiration in ST-Elevation Myocardial Infarction in Scandinavia (TASTE) trial

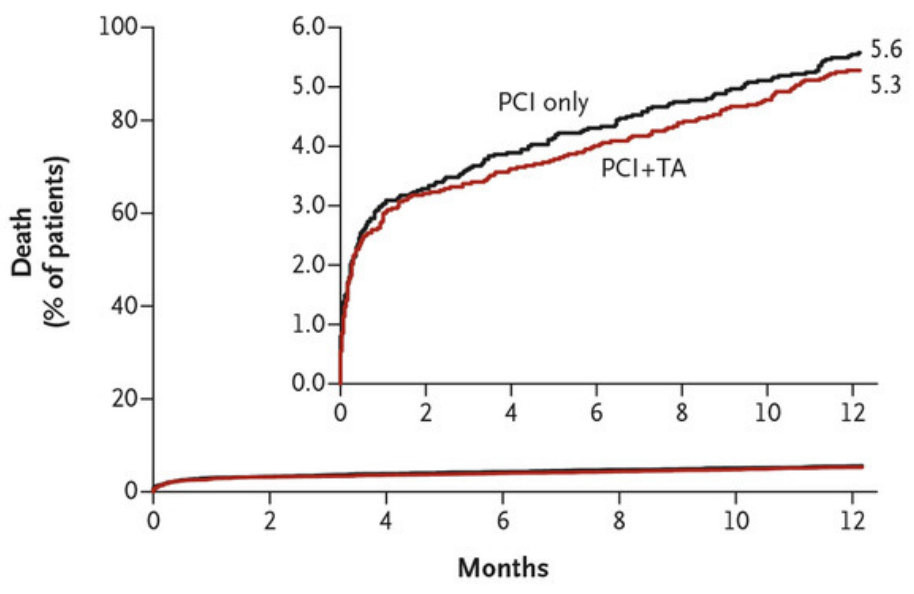
7244 patients with STEMI were assigned to manual thrombus aspiration followed by PCI or to PCI only

HR for all-cause mortality after 30 days:
0.94 (0.72 to 1.22), p=0.63



No. at Risk							
PCI+TA	3621	3568	3540	3532	3526	3524	3519
PCI	3623	3567	3545	3530	3523	3517	3513

HR for all-cause mortality after 1 year:
0.93 (0.80 to 1.10), p=0.40



No. at Risk							
PCI+TA	3621	3500	3485	3470	3456	3440	3425
PCI only	3623	3503	3481	3466	3450	3435	3420

There were **no significant differences between the groups with respect to the rate of stroke** or neurologic complications at the time of discharge (P=0.87).

Fröbert O et al. N Engl J Med. 2013 Oct 24;369(17):1587-97

Lagerqvist B et al. N Engl J Med. 2014 Sep 18;371(12):1111-20

The largest RCT in thrombus aspiration - TOTAL

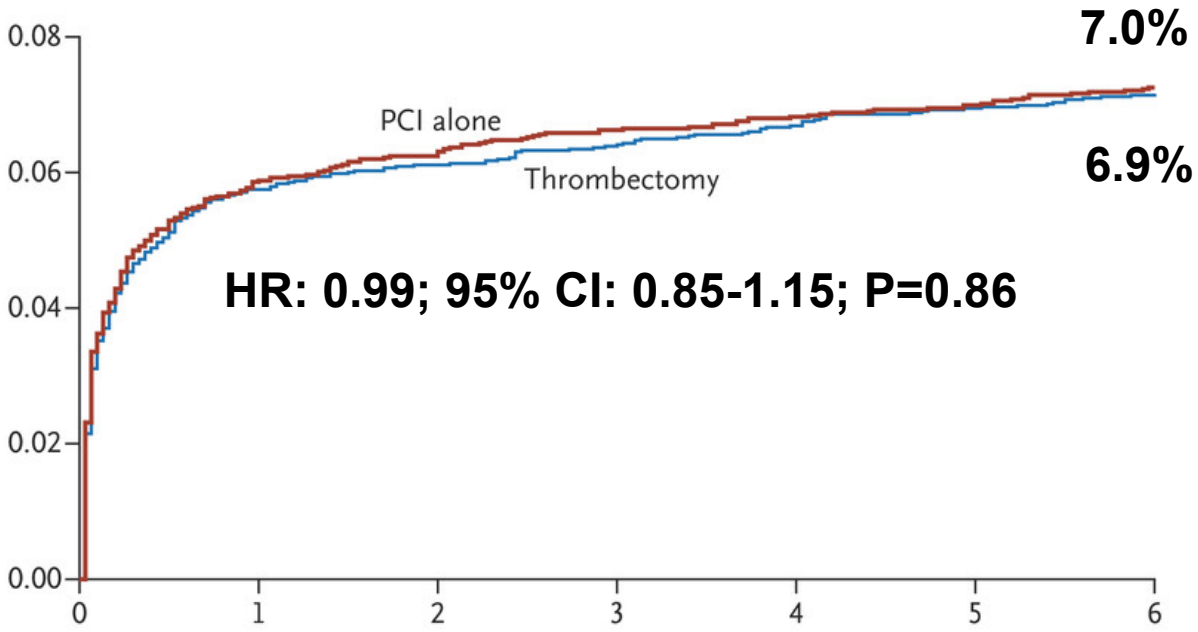
Trial of Routine Aspiration Thrombectomy with PCI versus PCI Alone in Patients with STEMI

TOTAL

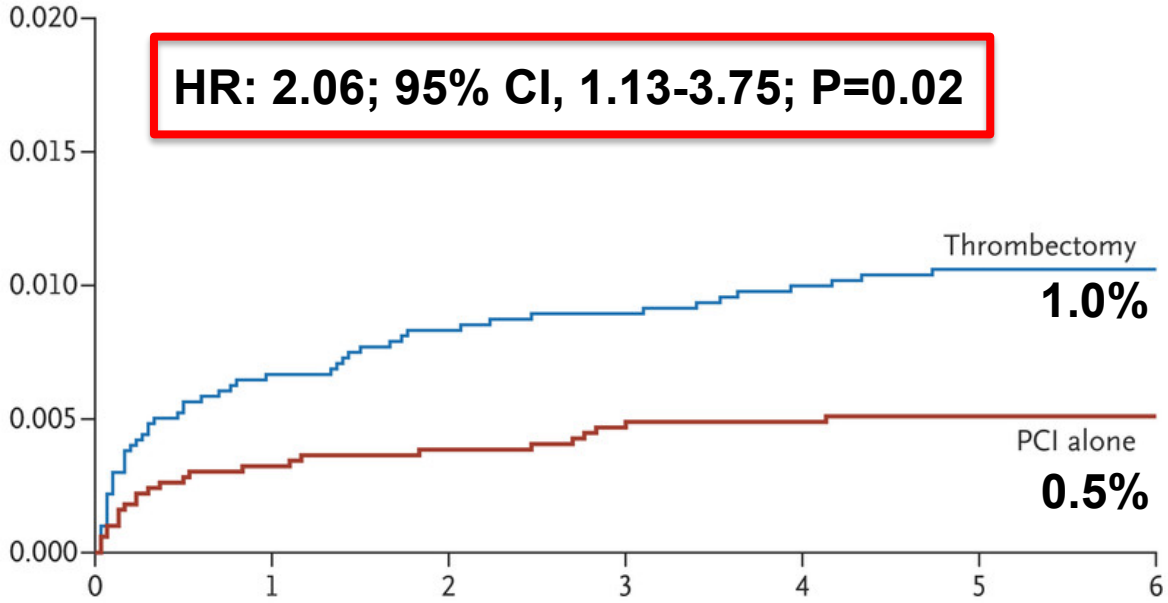
10,732 STEMI patients manual thrombectomy+PCI versus PCI alone

Primary outcome after 6 months

CV death, MI, cardiogenic shock, or NYHA class IV heart failure



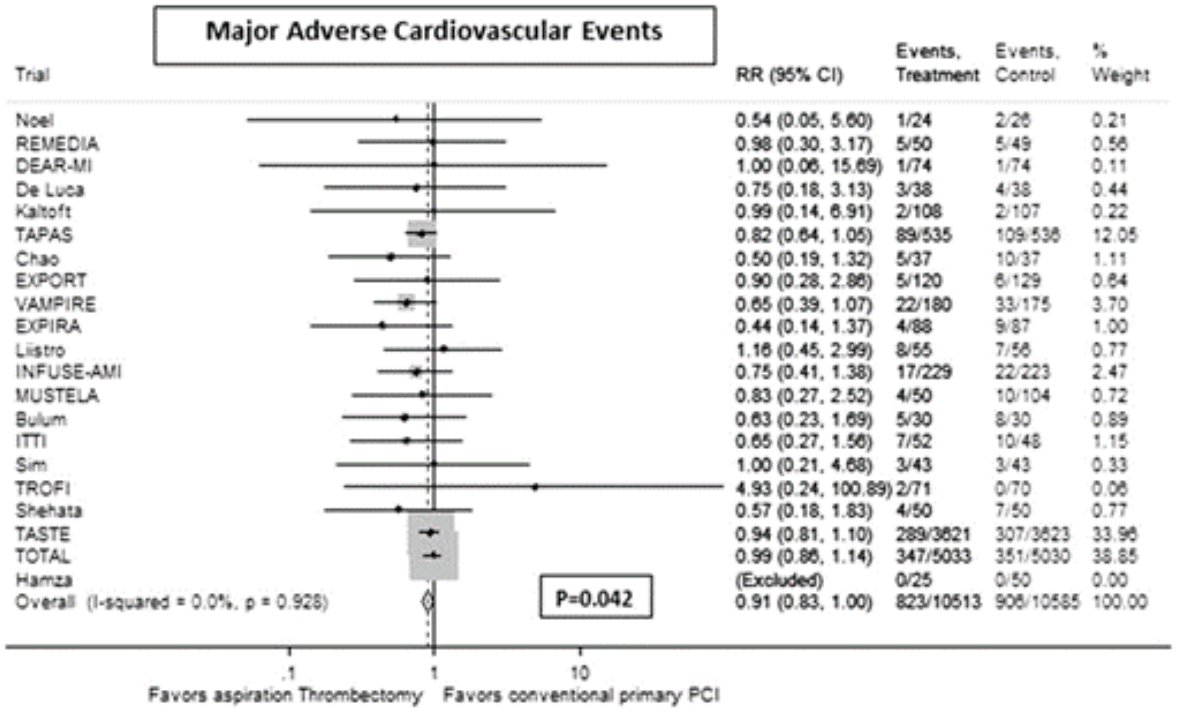
Stroke after 6 months

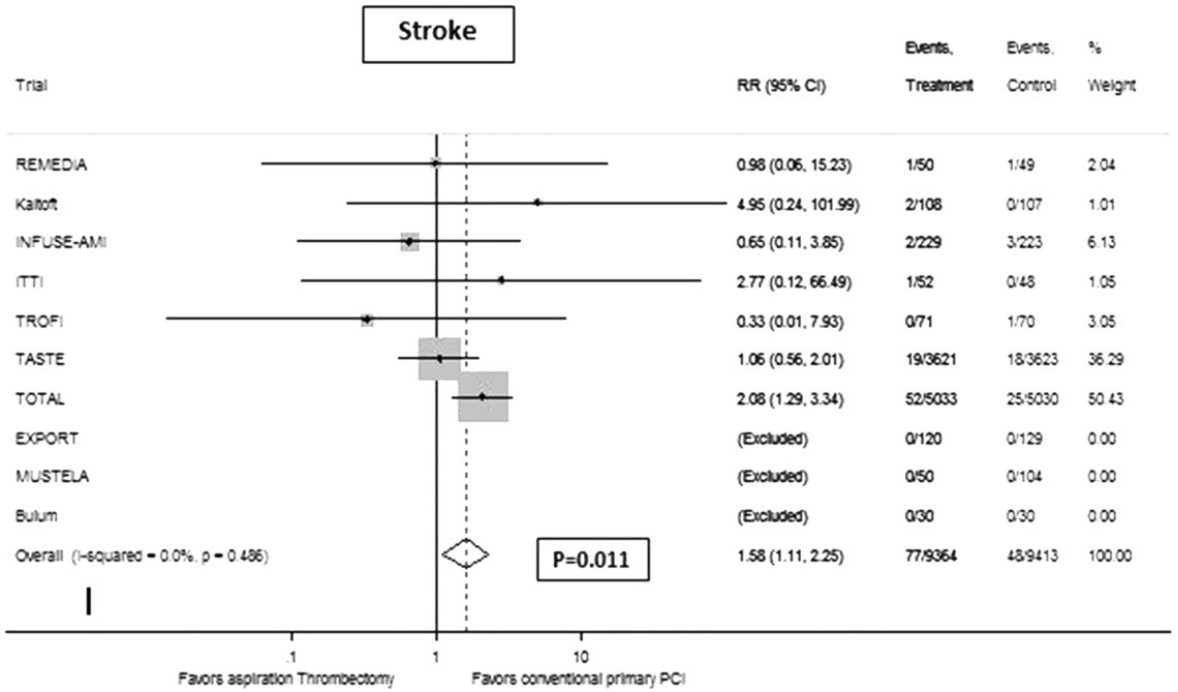


Jolly SS et al. N Engl J Med. 2015 Apr 9;372(15):1389-98

Study-level meta-analysis from 25 RCTs

involving 21,733 patients with STEMI and PPCI





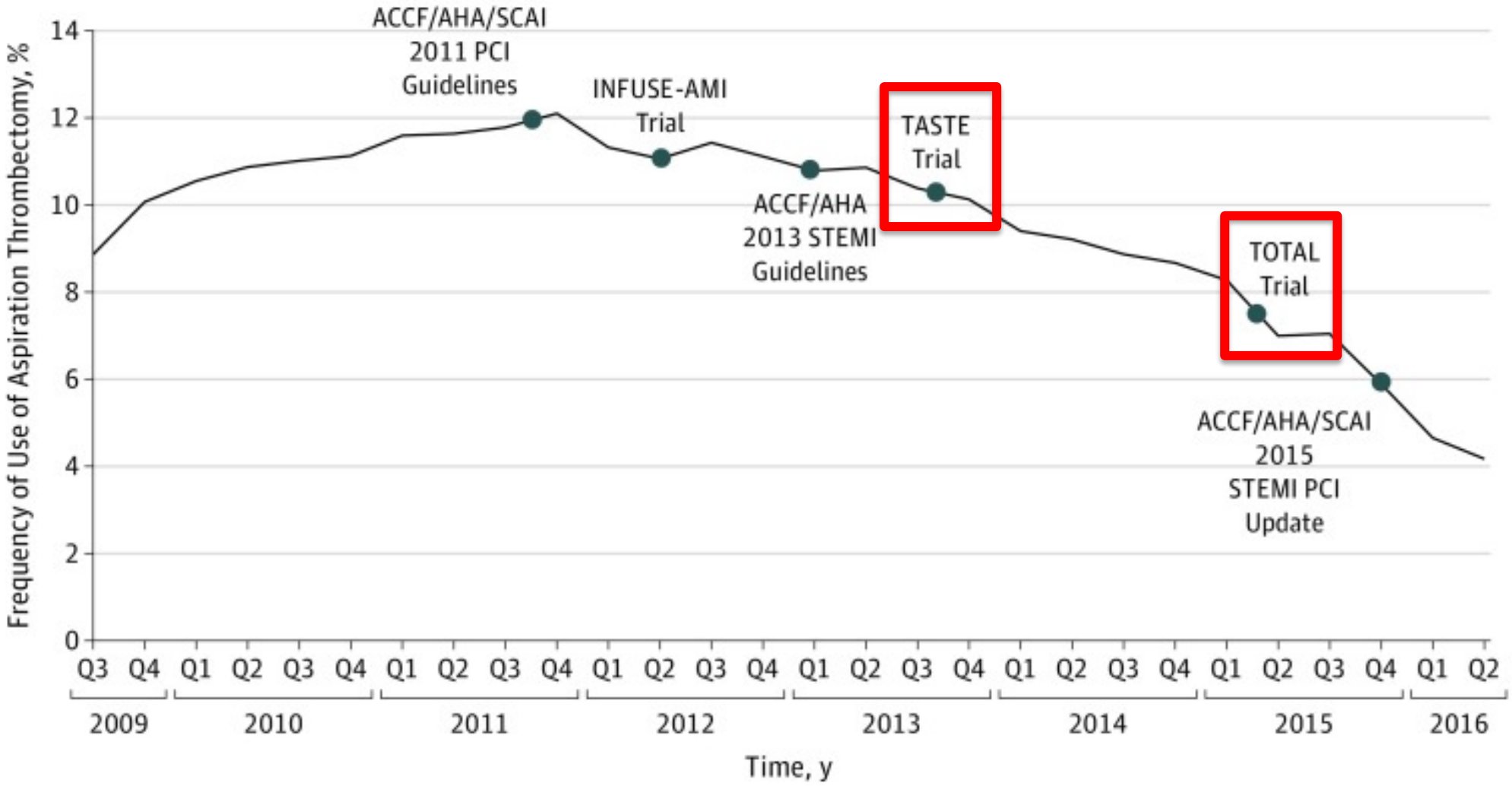
Thrombus aspiration was associated with significant lower risk for MACE….
(RR: 0.91; 95% CI: 0.83–1.00; *P* = 0.042)

…., but was also associated with a significant increase in the risk for stroke.
(RR: 1.58; 95% CI: 1.11–2.25; *P* = 0.011)

Mastoris I, Dangas G et al. Catheter Cardiovasc Interv. 2016 Mar;87(4):650-60

Temporal Trends in Use of Manual Aspiration During Primary PCI

Data from the National Cardiovascular Data Registry CathPCI Registry



In the second quarter of 2016, manual aspiration was used in only 4.7% of all primary PCIs

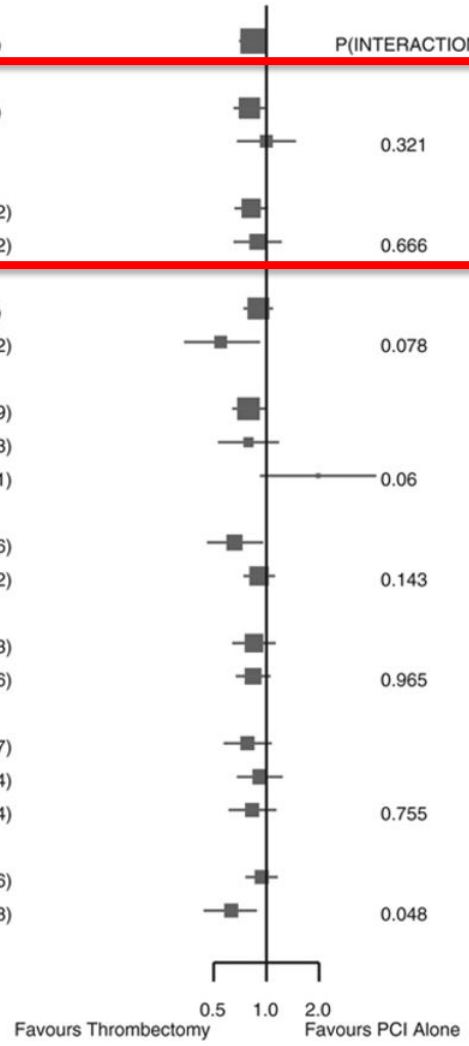
Secemsky EA et al. JAMA Cardiol. 2019 Feb 1;4(2):110-118

Who might still benefit from thrombus aspiration?

Meta-analysis from TAPAS, TASTE and TOTAL, 19,047 patients overall

Subgroup analysis for cardiovascular mortality at 30 days

		Thrombectomy	PCI Alone	Hazard Ratio(95%CI)	P(INTERACTION)
		no. of events/total no. (%)			
OVERALL	18306	221/9155 (2.4)	262/9151 (2.9)	0.84(0.7-1.01)	
TIMI Thrombus Grade:					
>=3	13576	170/6892 (2.47)	205/6684 (3.07)	0.8(0.65-0.98)	
<3	4635	49/2224 (2.2)	53/2411 (2.2)	1(0.68-1.47)	0.321
TIMI Thrombus Grade:					
>=4	10739	144/5376 (2.68)	174/5363 (3.24)	0.82(0.66-1.02)	
<4	7472	75/3740 (2.01)	84/3732 (2.25)	0.89(0.65-1.22)	0.666
Initial TIMI Flow:					
0-1	13678	195/6808 (2.86)	219/6870 (3.19)	0.9(0.74-1.09)	
2-3	4515	24/2286 (1.05)	42/2229 (1.88)	0.55(0.34-0.92)	0.078
Symptom onset (h):					
<6	14016	142/6958 (2.04)	181/7058 (2.56)	0.79(0.64-0.99)	
6-12	2615	44/1359 (3.24)	51/1256 (4.06)	0.79(0.53-1.18)	
>12	629	20/317 (6.31)	10/312 (3.21)	1.97(0.92-4.21)	0.06
Vessel:					
Non-proximal	7234	48/3618 (1.33)	72/3616 (1.99)	0.66(0.46-0.96)	
Proximal	11072	173/5537 (3.12)	190/5535 (3.43)	0.91(0.74-1.12)	0.143
Lesion:					
Non LAD lesion	10322	91/5210 (1.75)	105/5112 (2.05)	0.85(0.64-1.13)	
LAD lesion	7984	130/3945 (3.30)	157/4039 (3.89)	0.84(0.67-1.06)	0.965
Site PCI Volume:					
Tertile 1	5879	67/2952 (2.27)	85/2927 (2.9)	0.78(0.57-1.07)	
Tertile 2	6861	81/3417 (2.37)	89/3444 (2.58)	0.92(0.68-1.24)	
Tertile 3	5514	73/2759 (2.65)	87/2755 (3.16)	0.83(0.61-1.14)	0.755
Glycoprotein inhib:					
No	12137	170/6198 (2.74)	174/5939 (2.93)	0.94(0.76-1.16)	
Yes	6166	51/2957 (1.72)	88/3209 (2.74)	0.63(0.44-0.88)	0.048



High thrombus burden group:

- Trend toward reduced cardiovascular death
- But increased stroke or transient ischemic attack

Jolly SS et al. Circulation. 2017 Jan 10;135(2):143-152

The State of Coronary Thrombus Aspiration

COR	LOE	Recommendation
STEMI		
2021 ACC/AHA Revascularization Guidelines		
3: No Benefit	**A**	In patients with STEMI, routine aspiration thrombectomy before primary PCI is not useful
2015 ACC/AHA Focused Updated on Primary PCI for STEMI		
IIb	**C-LD**	The usefulness of selective and bailout aspiration thrombectomy in patients undergoing primary PCI is not well established
2017 ESC STEMI Guidelines		
III	**A**	Routine use of thrombus aspiration is not recommended

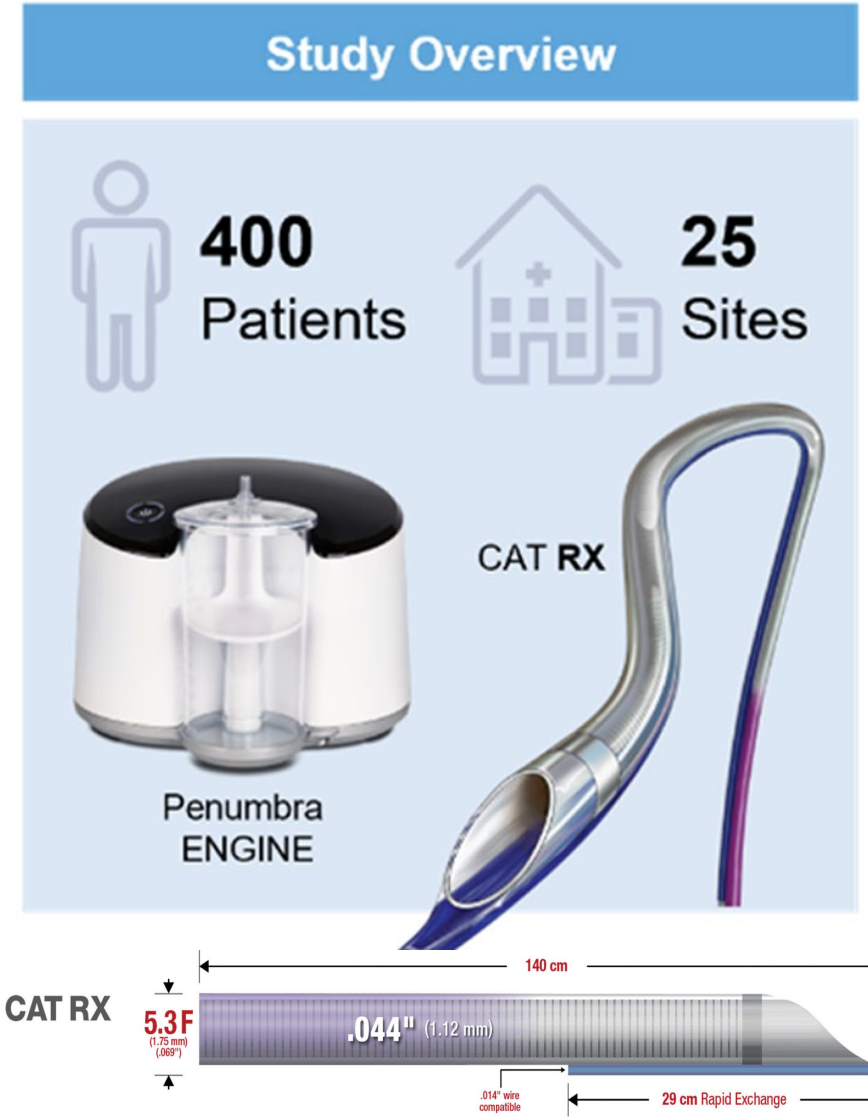
Pruthi S, Bangalore S. J Am Heart Assoc. 2022 Aug 16;11(16):e026849

New devices - the CHEETAH Study

A Prospective, Multicenter Study to Evaluate the Safety and Performance of the CAT RX Aspiration Catheter in Patients With a High Thrombus Burden Acute Coronary Vessel Occlusion

Study design

- Single-arm, postmarket registry study
- Evaluation of the Indigo CAT RX Aspiration System (Penumbra Inc, Alameda CA) for sustained mechanical aspiration thrombectomy before PCI
- 25 hospitals across the USA
- August 2019 through December 2020



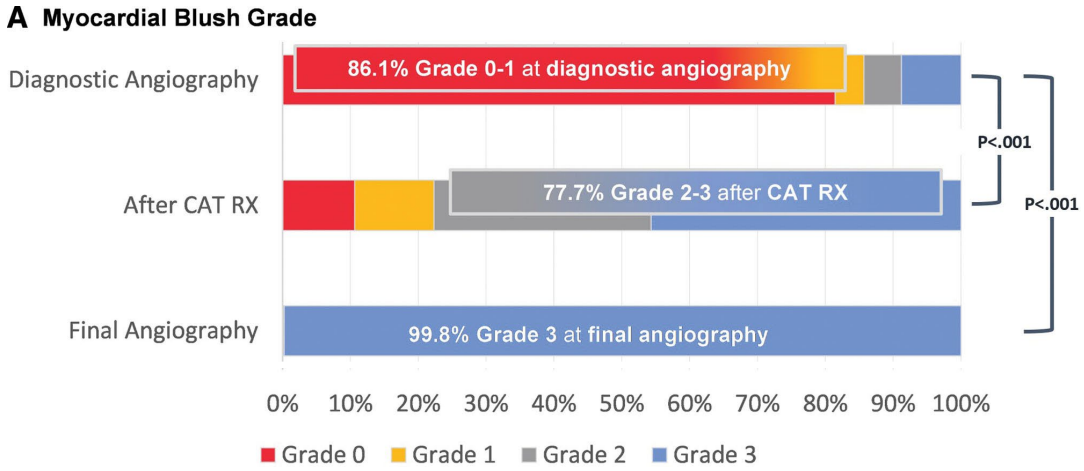
Technical aspects

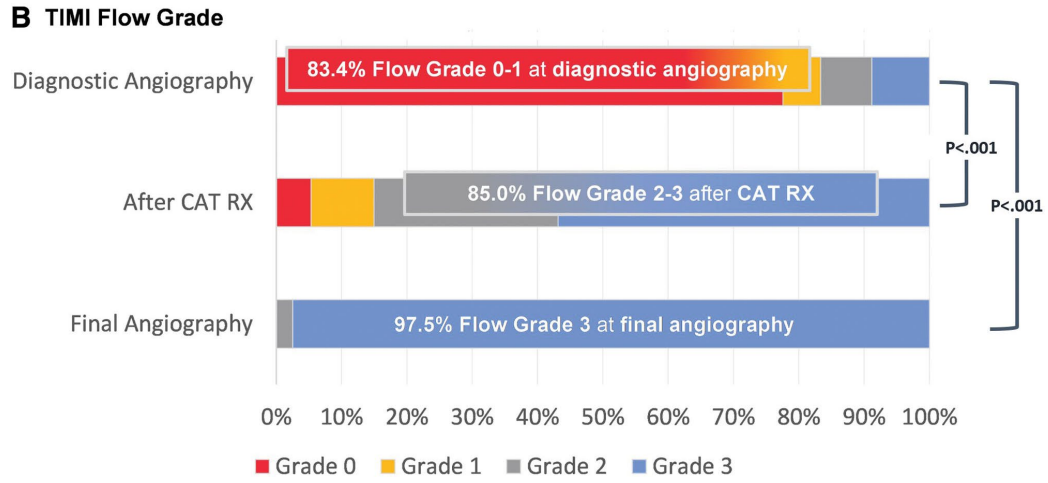
- Penumbra engine: sustained mechanical aspiration with a dedicated vacuum pump delivers constant aspiration force
- **No exchange of synringes**
- CAT RX aspiration rapid exchange catheter compatible with a 0.014″ guidewire and a 6F guide catheter
- FDA clearence in 2017

Mathews SJ et al. Circ Cardiovasc Interv. 2023 Feb;16(2):e012433

CHEETAH Study - Results

Key Endpoints, per IMR	All Patients (N=400)	95% CI
Primary composite endpoint:	**3.60%** (14/389)	2.0%, 6.0%
Cardiovascular Death within 30 days	**0.51%** (2/389)	0.1%, 1.8%
Recurrent MI within 30 days	**1.80%** (7/389)	0.7%, 3.7%
Cardiogenic Shock within 30 days	**1.80%** (7/389)	0.7%, 3.7%
New or worsening NYHA Class IV heart failure within 30 days	**0.77%** (3/389)	0.2%, 2.2%
Stroke within 30 days	**0.77%** (3/389)	0.2%, 2.2%
Major Bleeding within 30 days	**1.03%** (4/389)	0.3%, 2.6%
Incidence of device related SAE(s)	**0.00%** (0/389)	N/A
Distal Embolization Rate (per core lab)	**0.75%** (3/400)	0.2%, 2.2%





Sustained mechanical aspiration was safe and was associated with high rates of thrombus removal, flow restoration, and normal myocardial perfusion on final angiography

Mathews SJ et al. Circ Cardiovasc Interv. 2023 Feb;16(2):e012433

Conclusion

- Thrombus aspiration aims to decrease the thrombotic burden in pPCI patients.
- Routine thrombus aspiration is not supported by randomized trial data.
- Utilization can be considered for high thrombus burden with measures to prevent stroke.
- Current newer devices, such as continuous mechanical aspiration thrombectomy devices, are currently under investigation.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