Aspiration Thrombectomy in AMI

(After TOTAL Study)

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ACC Middle East Conference 2016

No disclosure

The NEW ENGLAND JOURNAL of MEDICINE

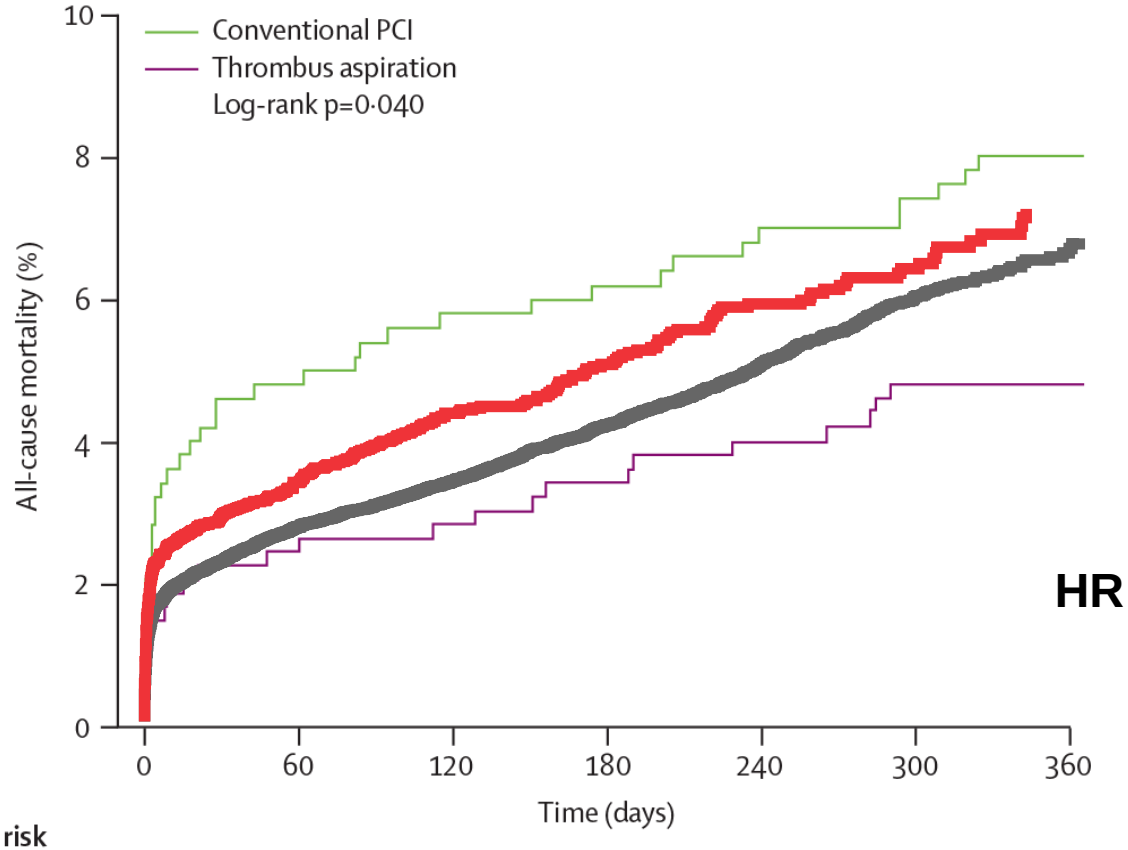
ORIGINAL ARTICLE

Randomized Trial of Primary PCI with or without Routine Manual Thrombectomy

S.S. Jolly, J.A. Cairns, S. Yusuf, B. Meeks, J. Pogue, M.J. Rokoss, S. Kedev, L. Thabane, G. Stankovic, R. Moreno, A. Gershlick, S. Chowdhary, S. Lavi, K. Niemelä, P.G. Steg, I. Bernat, Y. Xu, W.J. Cantor, C.B. Overgaard, C.K. Naber, A.N. Cheema, R.C. Welsh, O.F. Bertrand, A. Avezum, R. Bhindi, S. Pancholy, S.V. Rao, M.K. Natarajan, J.M. ten Berg, O. Shestakovska, P. Gao, P. Widimsky, and V. Džavík, for the TOTAL Investigators*

Jolly SS, et al. N Engl J Med. 2015;372:1389-98.

TAPAS / Swedish registry data



Number at risk							
Conventional PCI	536	506	501	499	495	494	489
Thrombus aspiration	535	519	517	514	510	506	505
Total	1071	1025	1018	1013	1005	1000	994

PCI alone (N=16 417)

TA+PCI (N=3 666)

HR (95% CI): 1.21 (1.08-1.35)

TASTE

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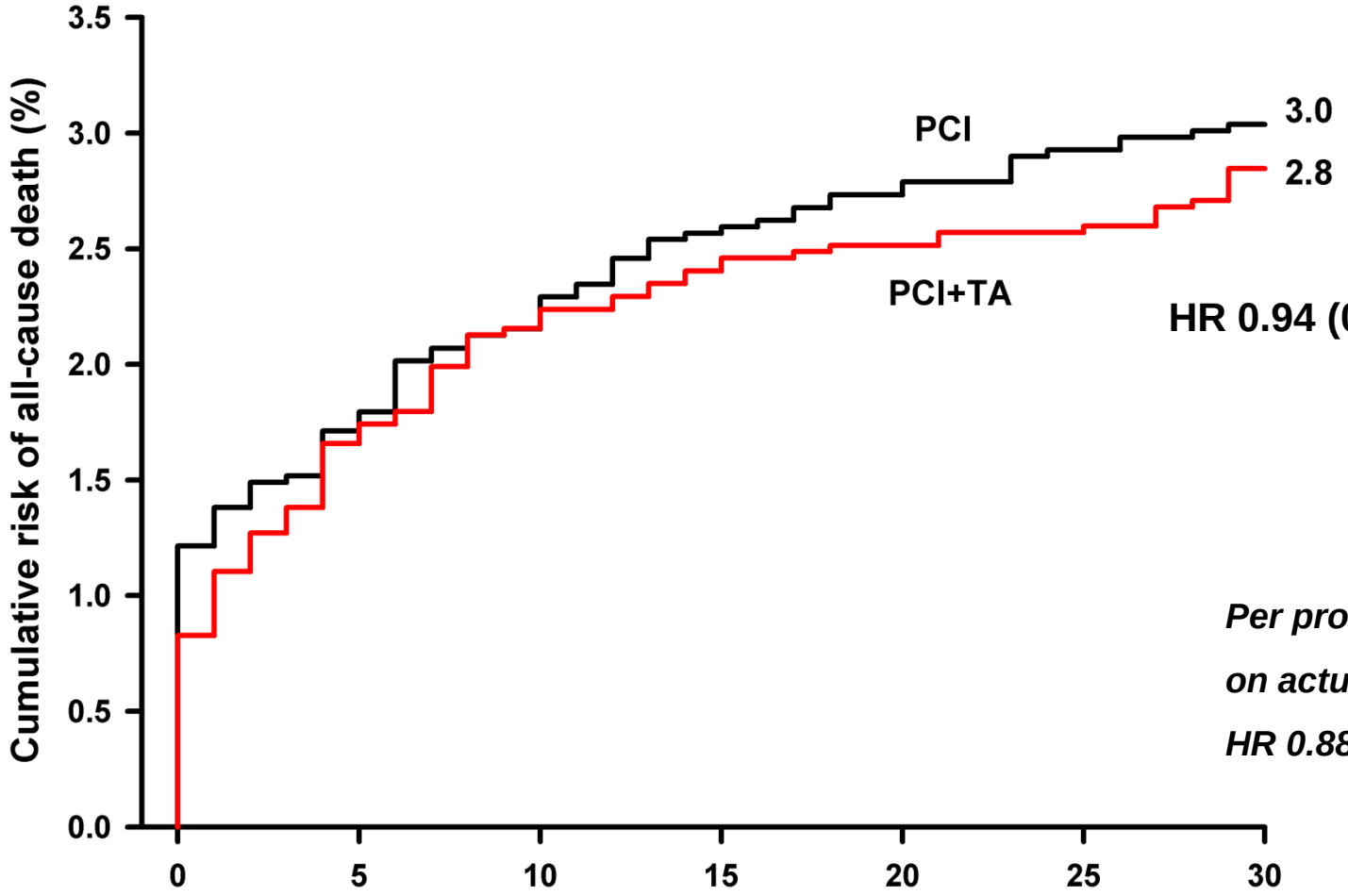
Vlaar, P.J. et al. The Lancet 2008; 371:1915-20

Fröbert, O. et al. Int J Cardiol. 2010; 145:572-3

Primary PCI Technique

Thrombus aspiration may be considered in selected patients.	IIb	A

All-cause mortality at 30 days



HR 0.94 (0.72 - 1.22), P=0.63

Per protocol analysis based on actual treatment:

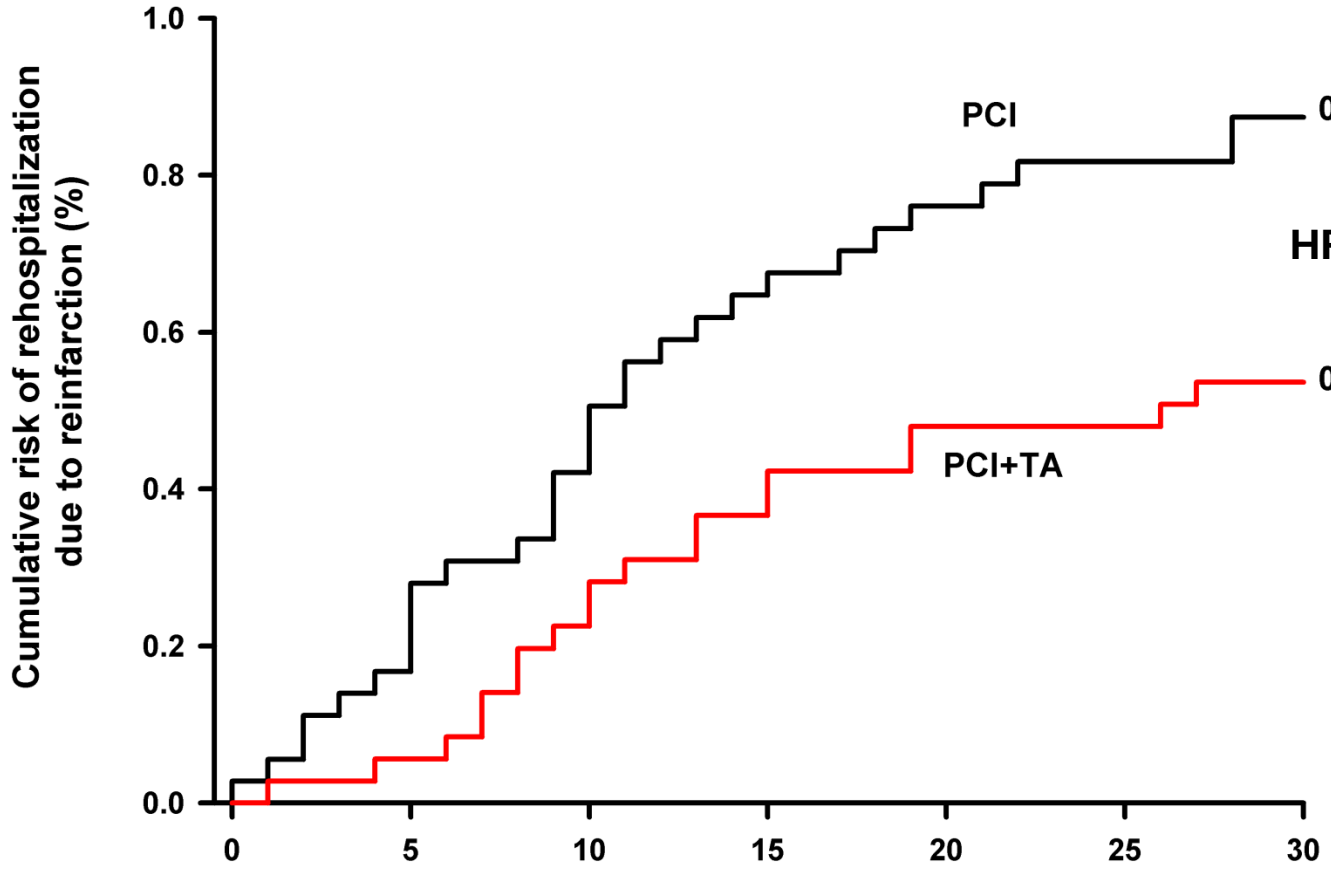
HR 0.88 (0.66 - 1.17), P=0.38

No. at Risk

PCI+TA	3621	3568	3540	3532	3526	3524	3519
PCI	3623	3567	3545	3530	3523	3517	3513

TASTE

Reinfarction at 30 days



HR 0.61 (0.34 - 1.07), P=0.09

Per protocol analysis based on actual treatment:

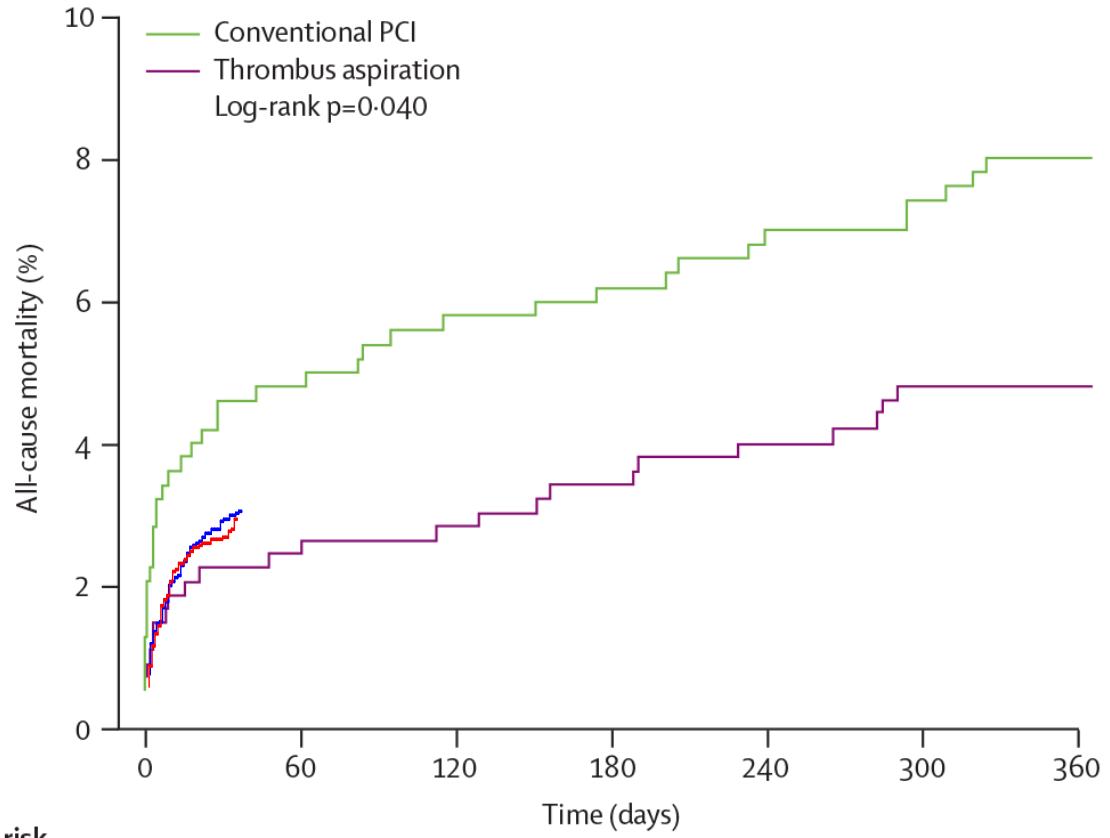
HR 0.67 (0.36 - 1.20), P=0.19

No. at Risk

PCI+TA	3621	3567	3533	3520	3512	3508	3501
PCI	3623	3562	3533	3509	3498	3489	3483

TASTE

TASTE vs. TAPAS



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Randomized trial of manual aspiration Thrombectomy + PCI vs. PCI Alone in STEMI (TOTAL)

SS Jolly, JA Cairns, S Yusuf, B Meeks, J Pogue, MJ Rokoss, S Kedev, L Thabane, G Stankovic, R Moreno, A Gershlick, S Chowdhary, S Lavi, K Niemelä, PG Steg,
I Bernat, Y Xu, WJ Cantor, C Overgaard, C Naber, AN Cheema, RC Welsh, OF Bertrand, A Avezum, R Bhindi, S Pancholy, SV Rao, MK Natarajan, JM ten Berg, O Shestakovska, P Gao, P Widimsky, V Džavík

on behalf of the TOTAL Investigators

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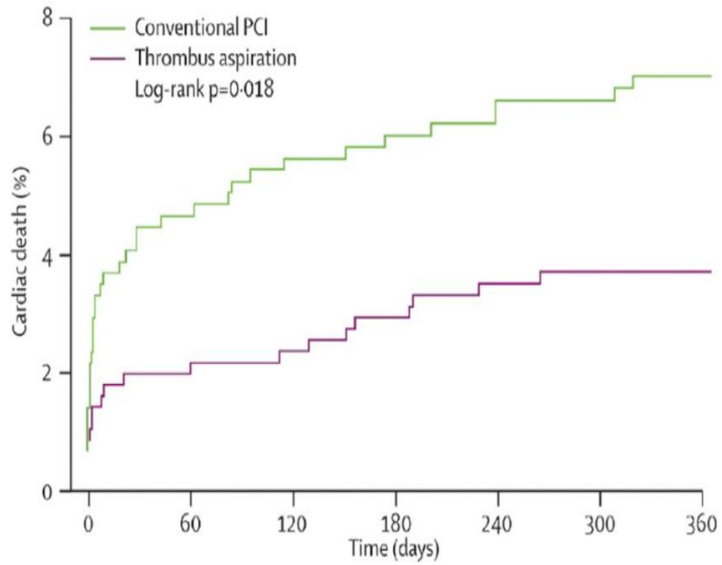
Population Health Research Institute
Health Through Knowledge
PHRI

Background

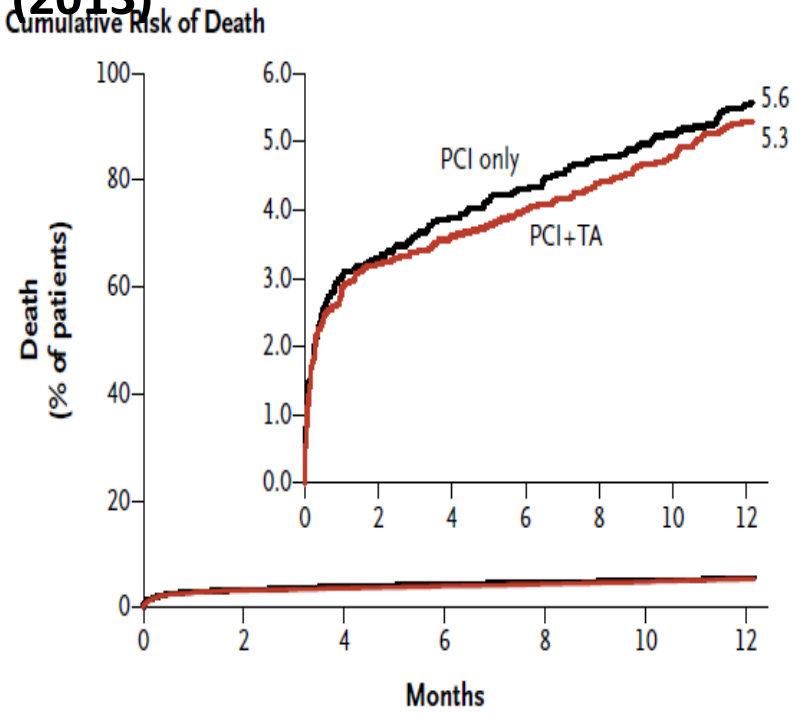
Large effect size in TAPAS (2008)



University Medical Center Groningen

Vlaar P, et al. TAPAS 1-year clinical outcome. Lancet 2008;371:1915-20

No difference in TASTE (2013)



TAPAS trial (N=1071) showed a large benefit vs. TASTE (N=7244) showed no benefit of thrombus aspiration

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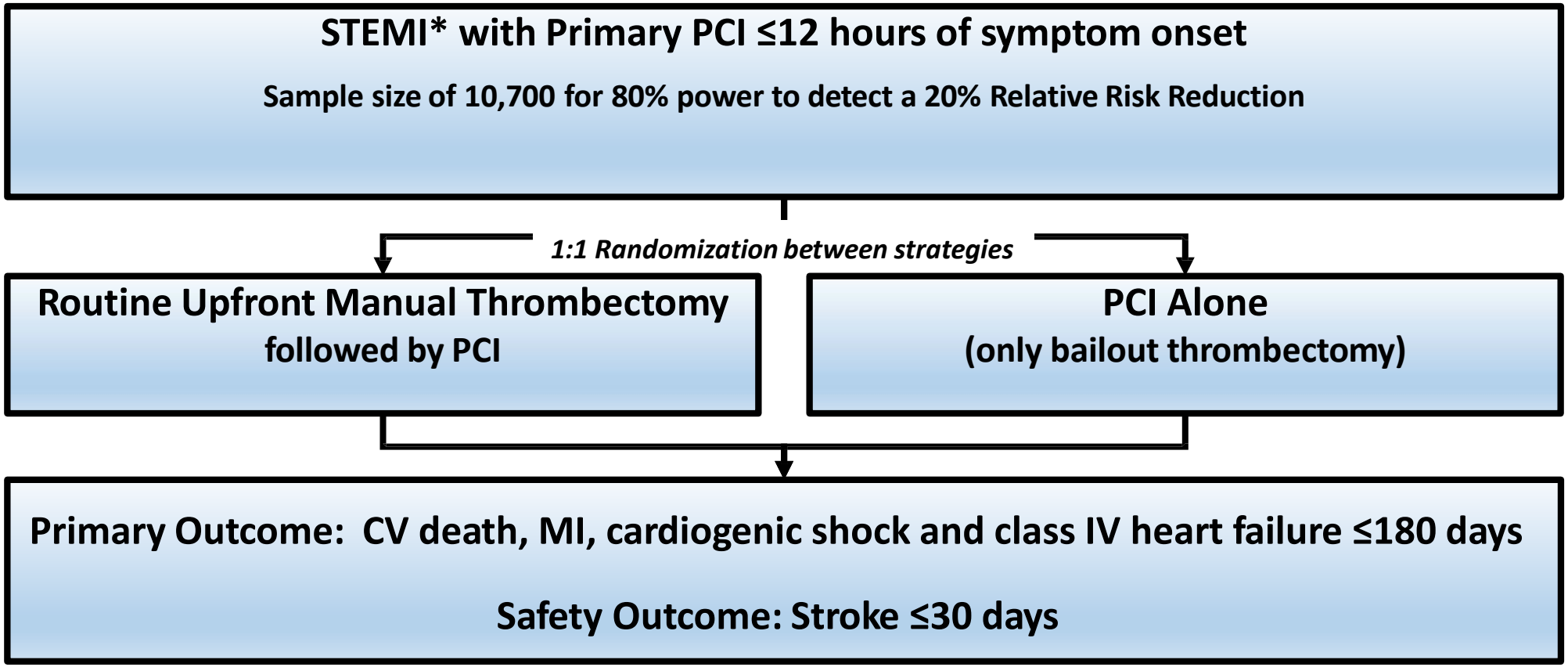
Vlaar PJ, et al. Lancet 2008;371:1915-20.
Frobert O, et al. N Engl J Med 2013.
Lagerqvist B, et al. N Engl J Med. 2014.

The TOTAL Trial Study Design



Bailout Thrombectomy allowed if PCI alone strategy fails:

- Persistent TIMI 0 or 1 flow with large thrombus after balloon pre-dilatation
- Persistent large thrombus after stent deployment at target lesion

Primary Outcome

Day 180	Thrombectomy (N=5033) (%)	PCI alone (N=5030) (%)	HR	95% CI	p
CV death, MI, shock or class IV heart failure	347 (6.9%)	351 (7.0%)	0.99	0.85-1.15	0.86
CV death	157 (3.1%)	174 (3.5%)	0.90	0.73-1.12	0.34
Recurrent MI	99 (2.0%)	92 (1.8%)	1.07	0.81-1.43	0.62
Cardiogenic Shock	92 (1.8%)	100 (2.0%)	0.92	0.69-1.22	0.56
Class IV heart failure	98 (1.9%)	90 (1.8%)	1.09	0.82-1.45	0.57

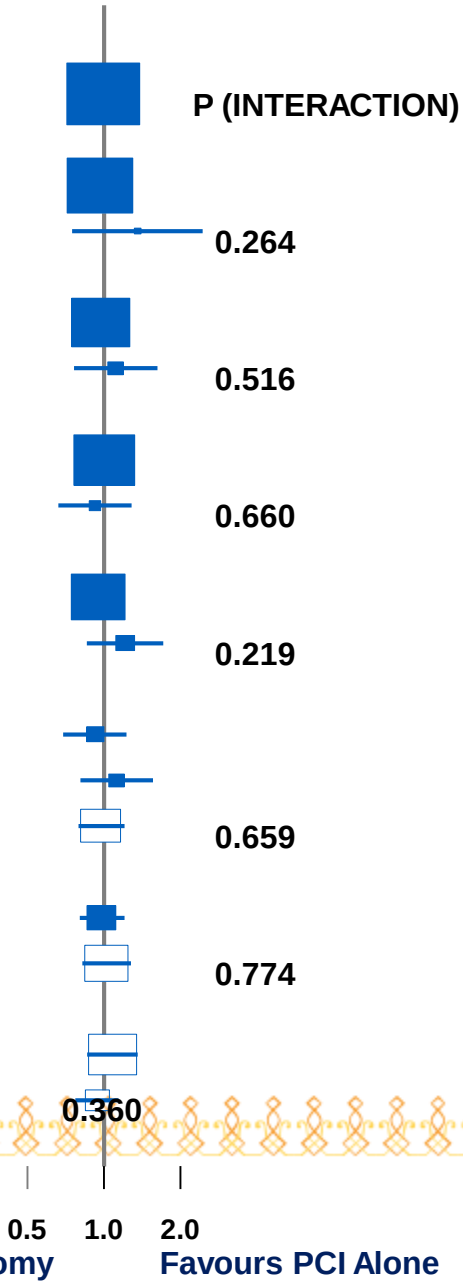
Jolly SS, et al. N Engl J Med. 2015;372:1389-98.

Safety Outcomes

	Thrombectomy (N=5033) (%)	PCI alone (N=5030) (%)	HR	95% CI	p
Stroke within 30 days	33 (0.7%)	16 (0.3%)	2.06	1.13-3.75	0.015
Stroke or TIA within 30 days	42 (0.8%)	19 (0.4%)	2.21	1.29-3.80	0.003
Stroke within 180 days	52 (1.0%)	25 (0.5%)	2.08	1.29-3.35	0.002

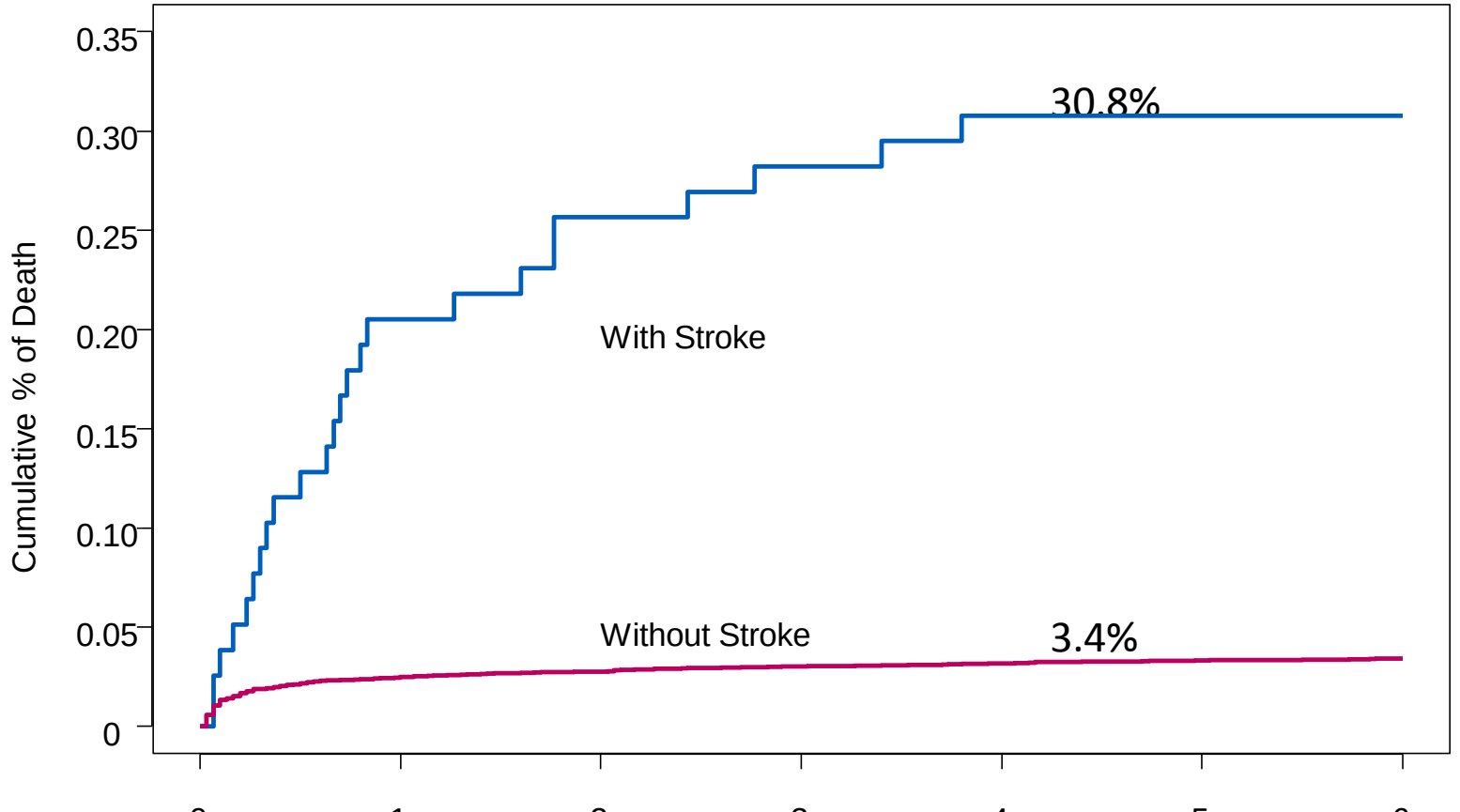
Subgroup Analysis Primary Outcome

		Thrombectomy (%)	PCI Alone (%)	P (INTERACTION)
OVERALL	10063	6.9	7.0	
TIMI Thrombus Grade:				
≥3	9052	7.0	7.3	
<3	998	5.2	3.9	0.264
TIMI Thrombus Grade:				
≥4	7943	7.3	7.5	
<4	2107	5.3	4.8	0.516
Symptom Onset:				
<6 hrs	8375	6.6	6.6	
6-12 hrs	1665	8.1	8.8	0.660
Initial TIMI Flow:				
0-1	7443	7.4	7.8	
2-3	2519	5.6	4.7	0.219
Site Primary PCI Volume:				
Tertile 1	2450	7.3	7.9	
Tertile 2	2139	7.2	6.5	
Tertile 3	5474	6.6	6.7	0.659
MI Type:				
Anterior	4016	9.0	9.2	
Non-Anterior	6037	5.6	5.5	0.774
Age:				
≤65 yrs	6662	4.7	4.3	
>65 yrs	3401	11.4	12.1	0.360
TOTAL				



Mortality of Stroke within 180 days

Hazard ratio, 10.17 (95%CI, 6.70-15.45); P<0.0001)



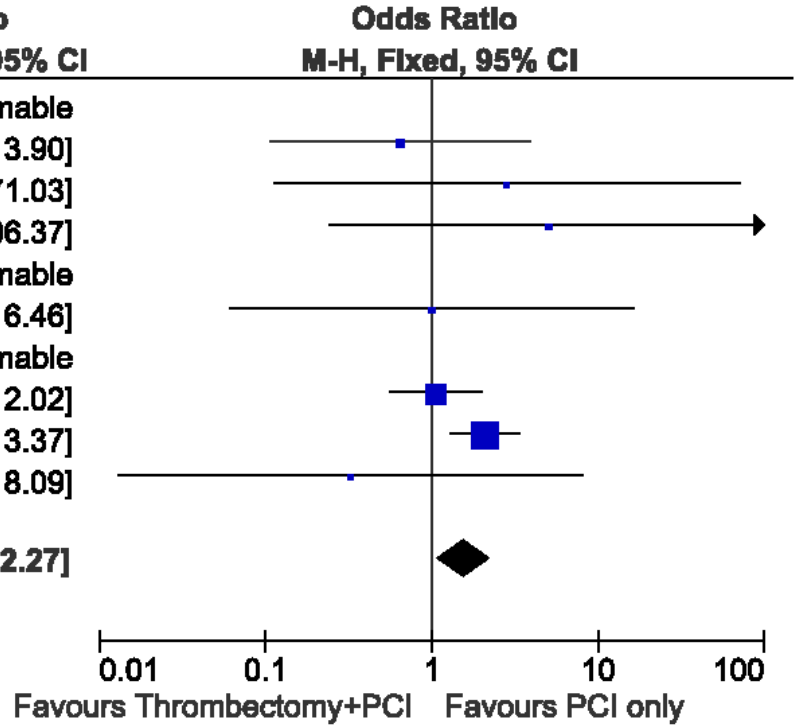
No. at Risk						
With Stroke	78	62	58	56	54	54	53
Without Stroke	9985	9713	9658	9630	9614	9597	9570

Meta-Analysis for Stroke

Study or Subgroup	Thrombectomy + PCI Events	Total	PCI only Events	Total	Weight	Odds Ratio M-H, Fixed, 95% CI
Bulum	0	30	0	30		Not estimable
INFUSE-AMI	2	229	3	223	6.1%	0.65 [0.11, 3.90]
ITTI	1	52	0	48	1.0%	2.83 [0.11, 71.03]
Kaltoft	2	108	0	107	1.0%	5.05 [0.24, 106.37]
MUSTELA	0	50	0	104		Not estimable
REMEDIA	1	48	1	48	2.0%	1.00 [0.06, 16.46]
TAPAS	0	529	0	531		Not estimable
TASTE	19	3621	18	3623	36.4%	1.06 [0.55, 2.02]
TOTAL	52	5033	25	5030	50.4%	2.09 [1.30, 3.37]
TROFI	0	71	1	70	3.1%	0.32 [0.01, 8.09]
Total (95% CI)		**9771**		**9814**	**100.0%**	**1.59 [1.11, 2.27]**
Total events	77		48			

Heterogeneity: Chi² = 5.47, df = 6 (P = 0.49); I² = 0%

Test for overall effect: Z = 2.53 (P = 0.01)



0.8% Thrombectomy vs. 0.5% PCI alone, OR 1.59; 95% CI 1.11-2.27, p=0.01

TOTAL

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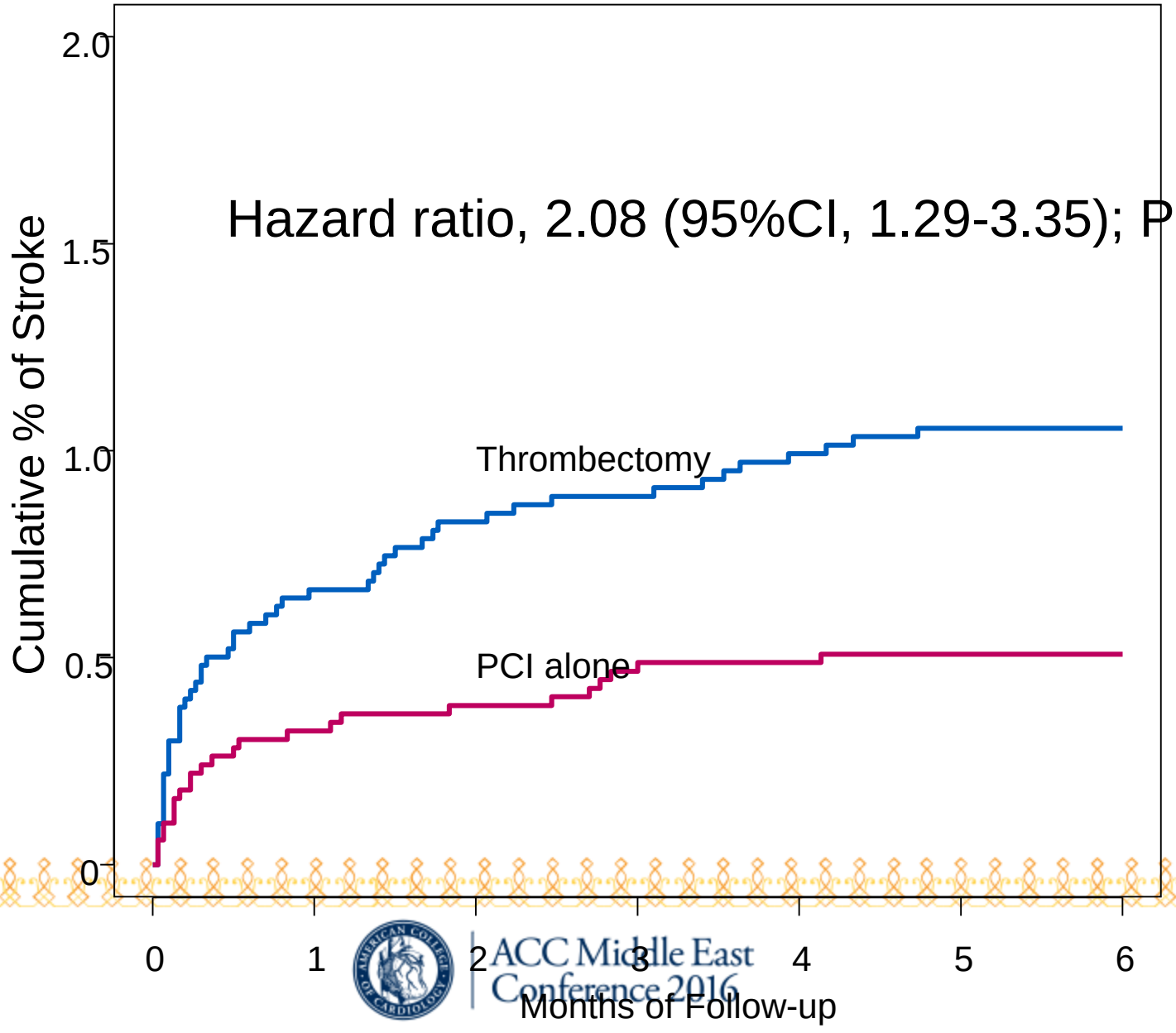
Jolly SS, et al. Eur Heart J. 2015; online

Time to Stroke



Conclusions

- Routine thrombectomy compared to PCI alone with only bailout thrombectomy did not reduce CV death, MI, shock or heart failure within 180 days
- Routine thrombectomy was associated with increased risk of stroke within 30 days
- TOTAL and TASTE emphasize the need to conduct large randomized trials of common interventions even when small trials appear positive

Table 2: Randomized Trials of Routine Aspiration Thrombectomy During Primary PCI in Patients With STEMI

Trial	Trial Design	Population	Intervention	Control	Crossover	Primary Endpoint	Results (Intervention vs. Control)
TAPAS[14]	Single-center, Netherlands, 1:1 randomization, open-label with blinded adjudication of endpoints	1,071	Routine aspiration thrombectomy	PCI alone	Intervention to control group 10%; Control to intervention group 1%	Myocardial blush grade of 0 or 1	17.1% vs 26.3%, p<0.001
INFUSE-AMI[17]	Multicenter, 6 countries, 2 × 2 factorial design, 1:1 randomization, open-label	452	Intracoronary abciximab and/or aspiration thrombectomy	PCI alone	1.7% for abciximab and 2.6% for aspiration	Infarct size (percentage of total left ventricular mass) using cardiac MRI (30 days)	1) Abciximab (median [IQR]): 15.1% [6.8%-22.7%] vs 17.9% [10.3%-25.4%]; p=0.03 2) Aspiration (median [IQR]): 17.0% [9.0%-22.8%] vs 17.3% [7.1%-25.5%]; p=0.51

TASTE[18]	Multicenter, Sweden, 1:1 randomization, open-label with registry-based follow-up	7,244	Routine aspiration thrombectomy	PCI alone	Intervention to control group 6%; Control to intervention group 5%	Death (30 days)	2.8% vs 3.0% (HR 0.94 [95% CI 0.72 to 1.22; p=0.63).
TOTAL[20]	Multicenter, 20 countries, 1:1 randomization, open-label with blinded adjudication of endpoints	10,732	Routine aspiration thrombectomy	PCI alone	Intervention to control group 4.6%; Control to intervention group 1.4%. Bailout thrombectomy 7.1%	Composite of cardiac death, recurrent MI, cardiogenic shock, or NYHA class IV heart failure (180 days)	6.9% vs 7.0% (HR 0.99 [95% CI 0.85 to 1.15; p=0.86).

CI = confidence interval; HR = hazard ratio; IQR = interquartile range; MI = myocardial infarction; MRI = magnetic resonance imaging; NYHA = New York Heart Association; PCI = percutaneous coronary intervention; STEMI = ST-elevation myocardial infarction.

Based on these Studies

- The recommendation to perform routine aspiration thrombectomy was appropriately changed from a *Class IIA to Class III (LOE A)* recommendation.
- However, the guidelines do still allow a provision to perform bailout thrombectomy in cases in which reperfusion is not successfully established *(Class IIB, LOE C)*.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