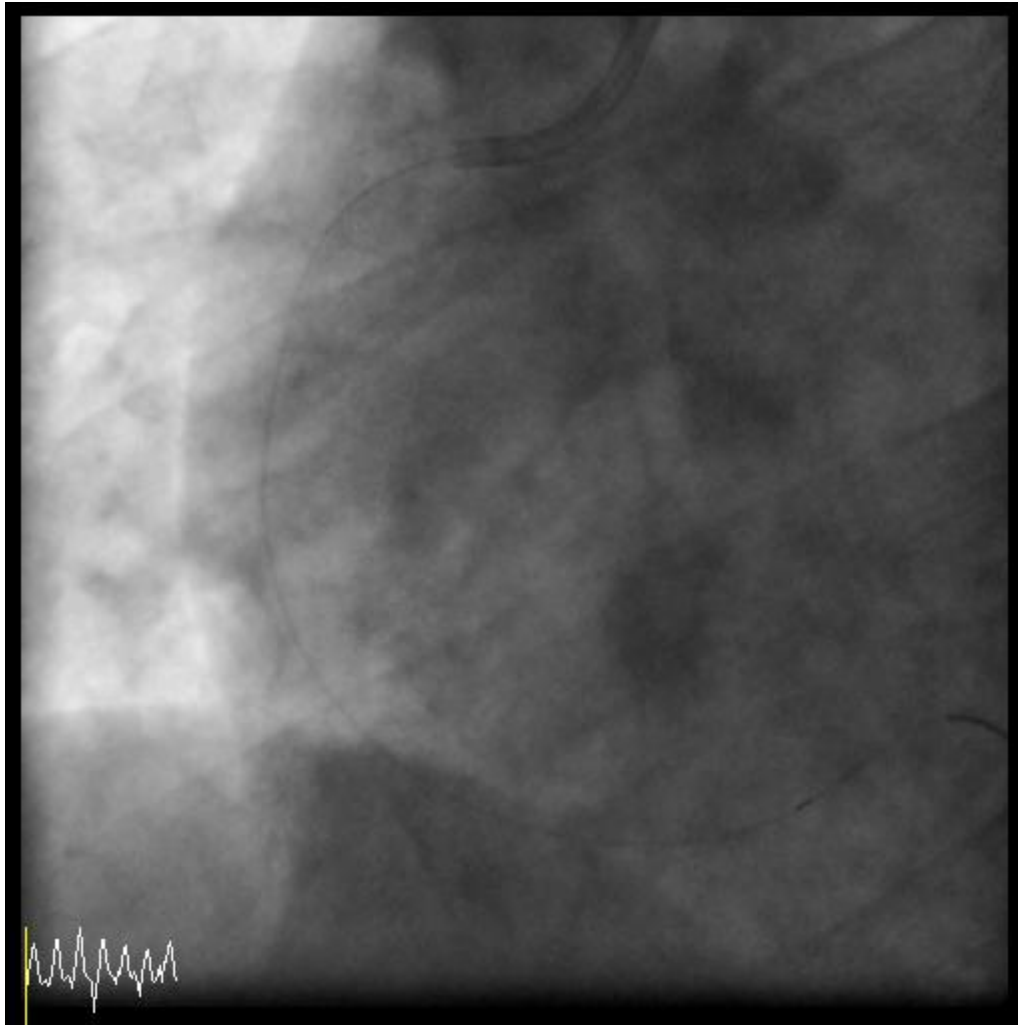


Do we have to Abandon Thrombus Aspiration?

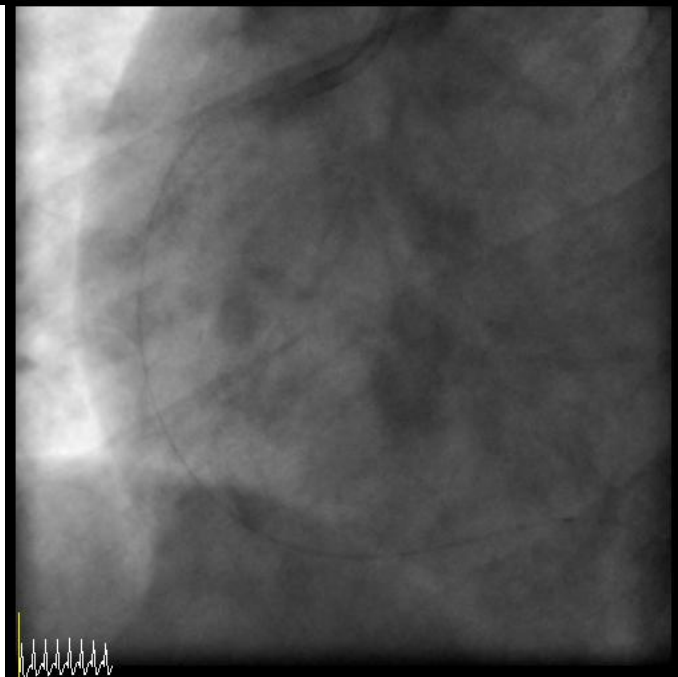
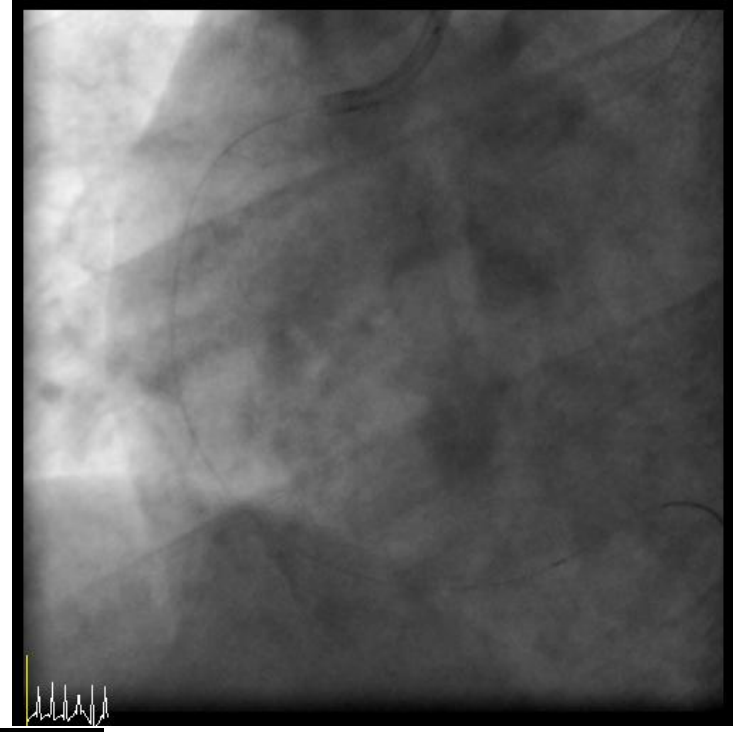
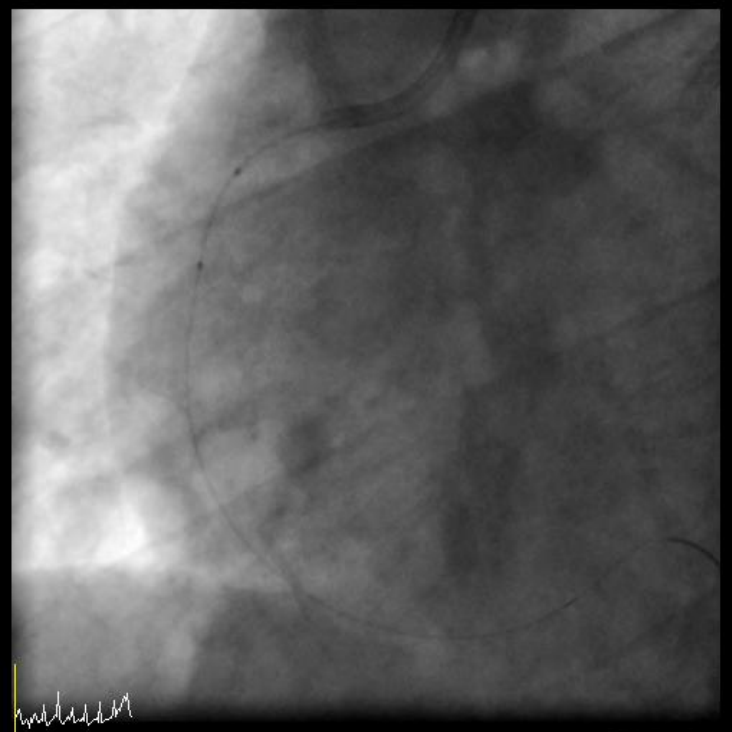
가톨릭의대 순환기내과
김동빈



72 yrs. Male, Inferior STEMI



Aspiration
or not?

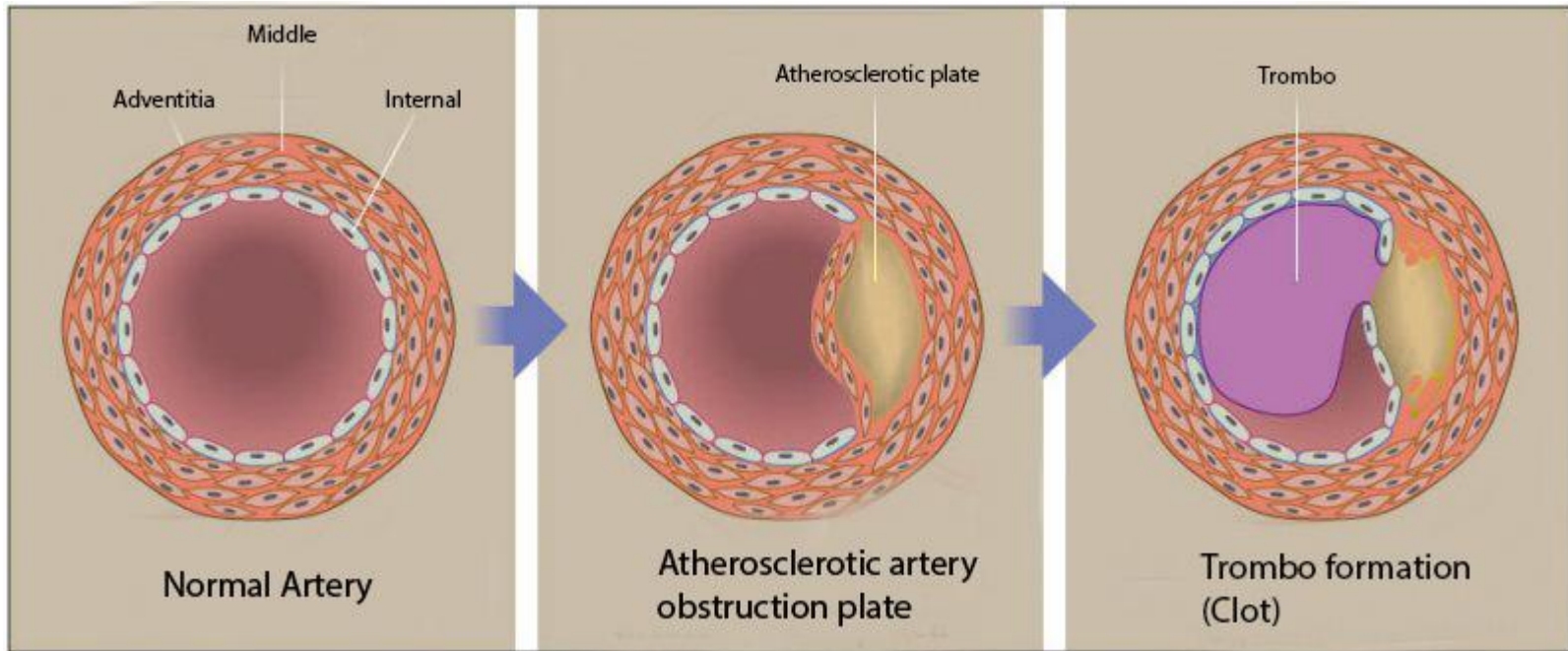


ST elevation MI

- Pathogenesis
 - Thrombus formation by plaque rupture
- Treatment
 - Thrombus remove
- Thrombus aspiration
 - Prevent distal embolism
 - Theoretically right



Thrombus formation

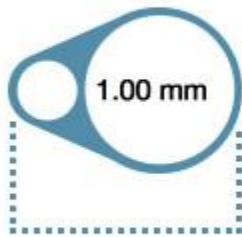




6 Fr

Distal part

Proximal part



1.70 mm

Extraction area
0.79 mm²



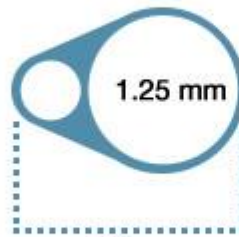
1.40 mm

Extraction area
0.95 mm²

7 Fr

Distal part

Proximal part



1.96 mm

Extraction area
1.23 mm²



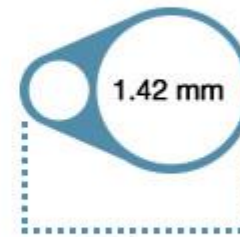
1.60 mm

Extraction area
1.33 mm²

8 Fr

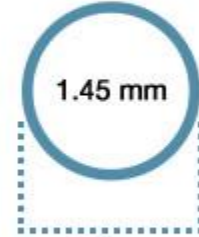
Distal part

Proximal part



2.15 mm

Extraction area
1.58 mm²



1.76 mm

Extraction area
1.65 mm²

TAPAS

TASTE

TOTAL



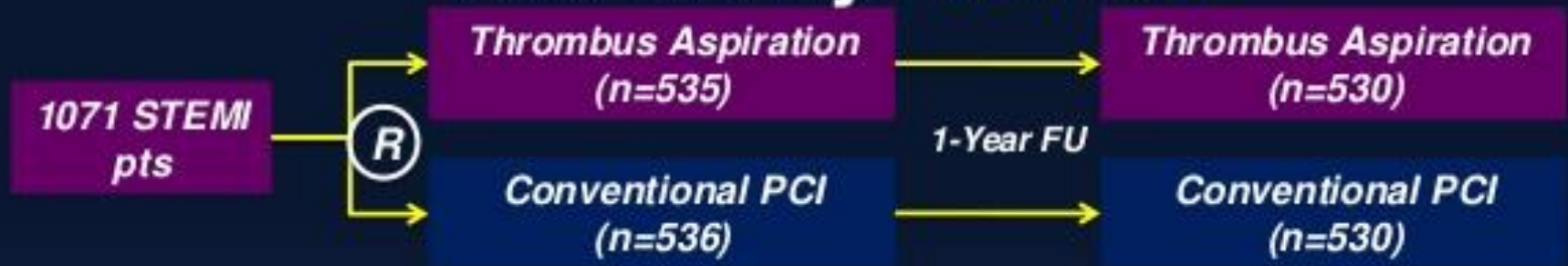
TAPAS

2008

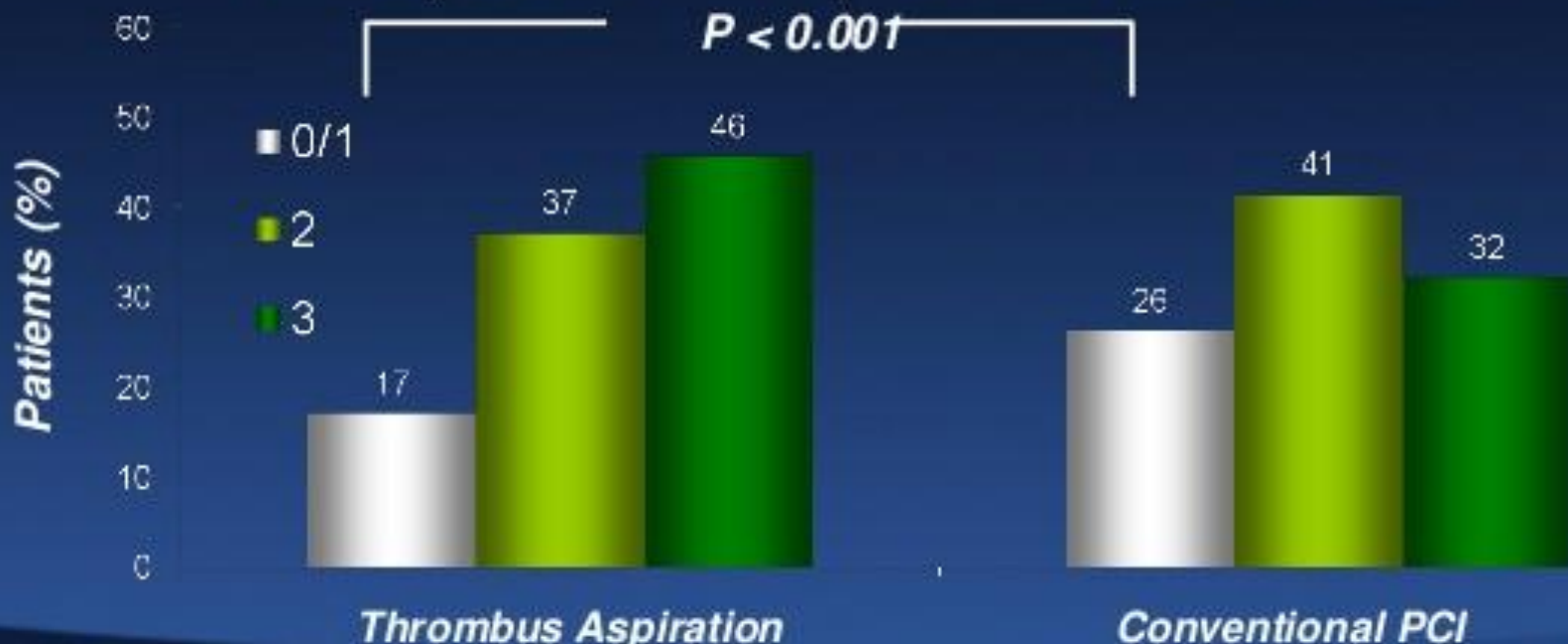
Netherland



Thrombus Aspiration During PCI in AMI Study: **TAPAS**

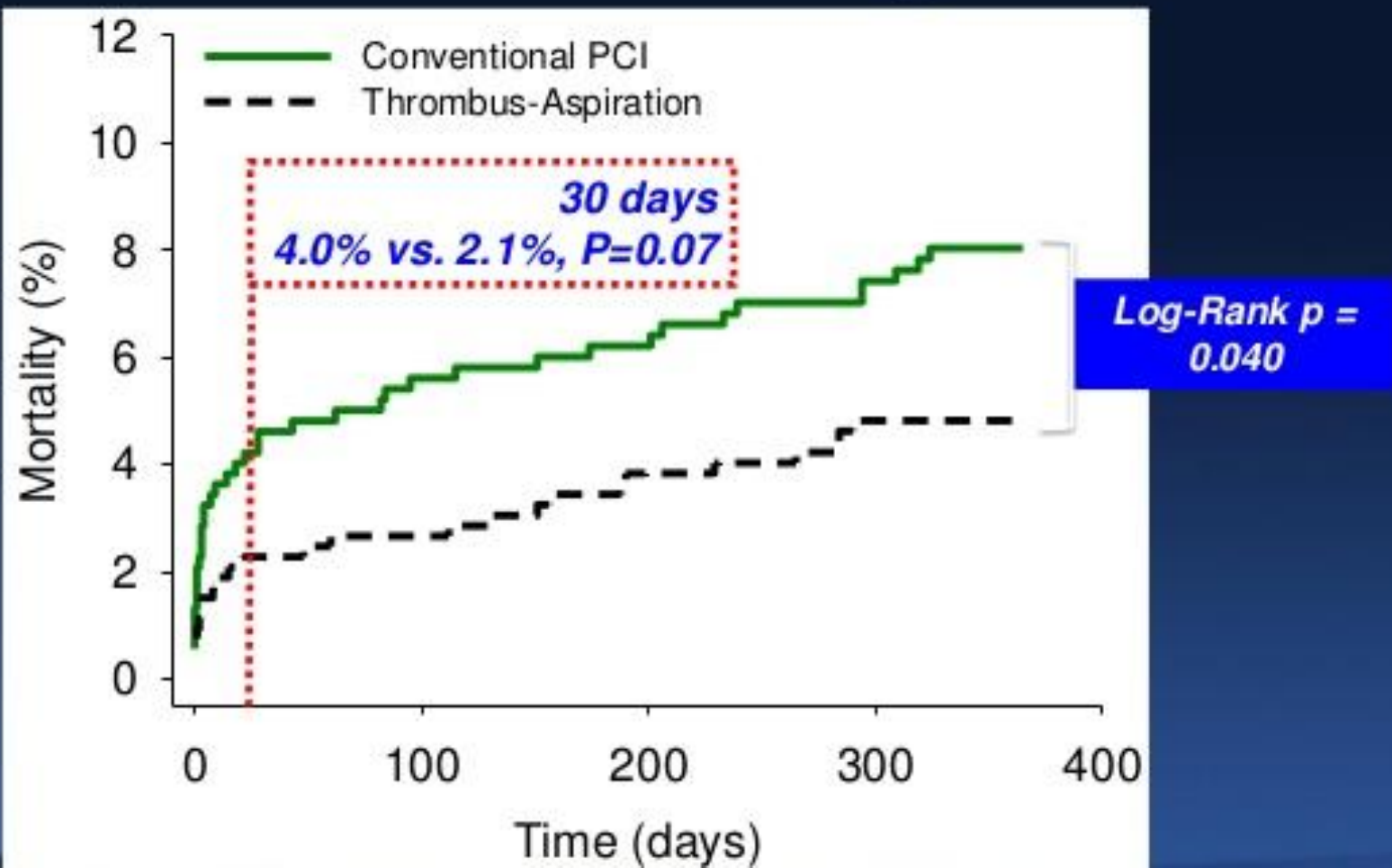


Primary End-Point: Myocardial Blush Grade



Thrombus Aspiration During PCI in AMI Study: **TAPAS**

1-Year Mortality



2011 STEMI Update

Thrombus Aspiration During PCI for STEMI

NEW
Recommendation



***Aspiration thrombectomy
is reasonable for patients
undergoing primary PCI***

2012 STEMI ESC Guidelines

Recommendations	Class ^a	Level ^b	Ref ^c
Indications for primary PCI			
Primary PCI is the recommended reperfusion therapy over fibrinolysis if performed by an experienced team within 120 min of FMC.	I	A	69, 99
Primary PCI is indicated for patients with severe acute heart failure or cardiogenic shock, unless the expected PCI related delay is excessive and the patient presents early after symptom onset.	I	B	100
Procedural aspects of primary PCI			
Stenting is recommended (over balloon angioplasty alone) for primary PCI.	I	A	101, 102
Primary PCI should be limited to the culprit vessel with the exception of cardiogenic shock and persistent ischaemia after PCI of the supposed culprit lesion.	IIa	B	75, 103–105
If performed by an experienced radial operator, radial access should be preferred over femoral access.	IIa	B	78, 79
If the patient has no contraindications to prolonged DAPT (indication for oral anticoagulation, or estimated high long-term bleeding risk) and is likely to be compliant, DES should be preferred over BMS.	IIa	A	80, 82, 106, 107
Routine thrombus aspiration should be considered.	IIa	B	83–85
Routine use of distal protection devices is not recommended.	III	C	86, 108
Routine use of IABP (in patients without shock) is not recommended.	III	A	97, 98

TASTE

2014

SWEDEN



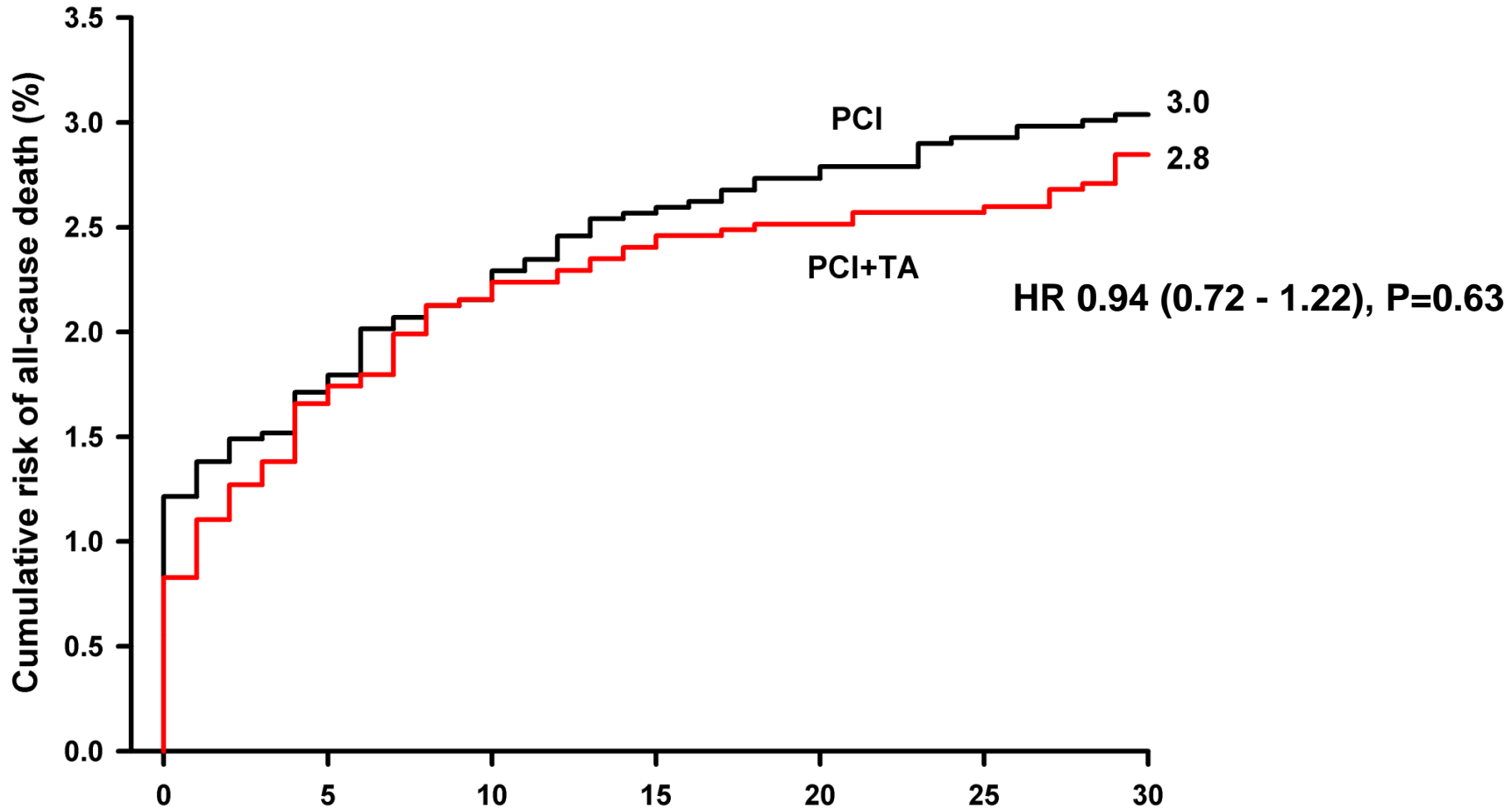
TASTE Trial

- 7244 pts with STEMI
 - randomly assigned to manual thrombus aspiration + PCI or PCI only

- Primary end points
 - 30 day mortality



All-cause mortality at 30 days

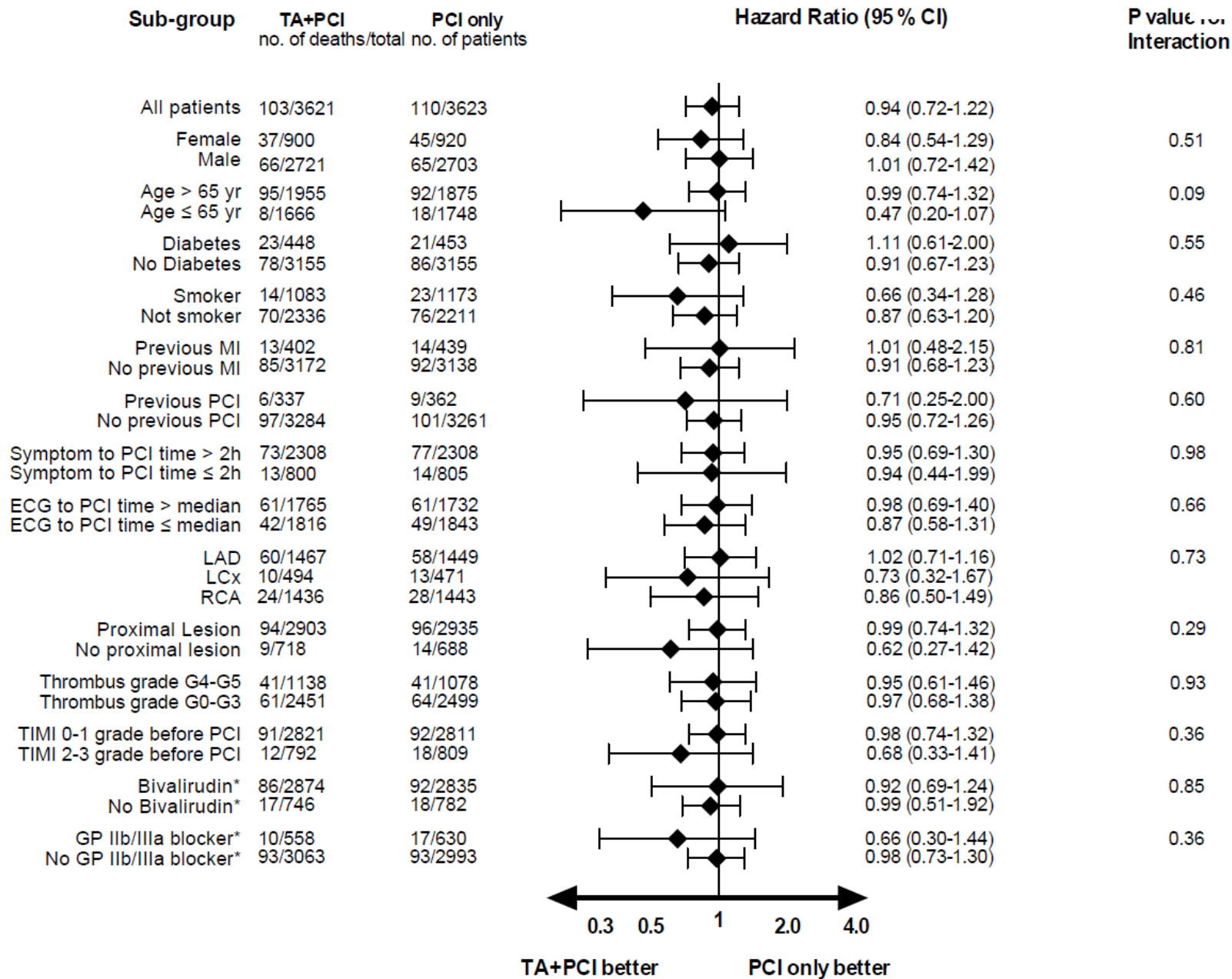


No. at Risk

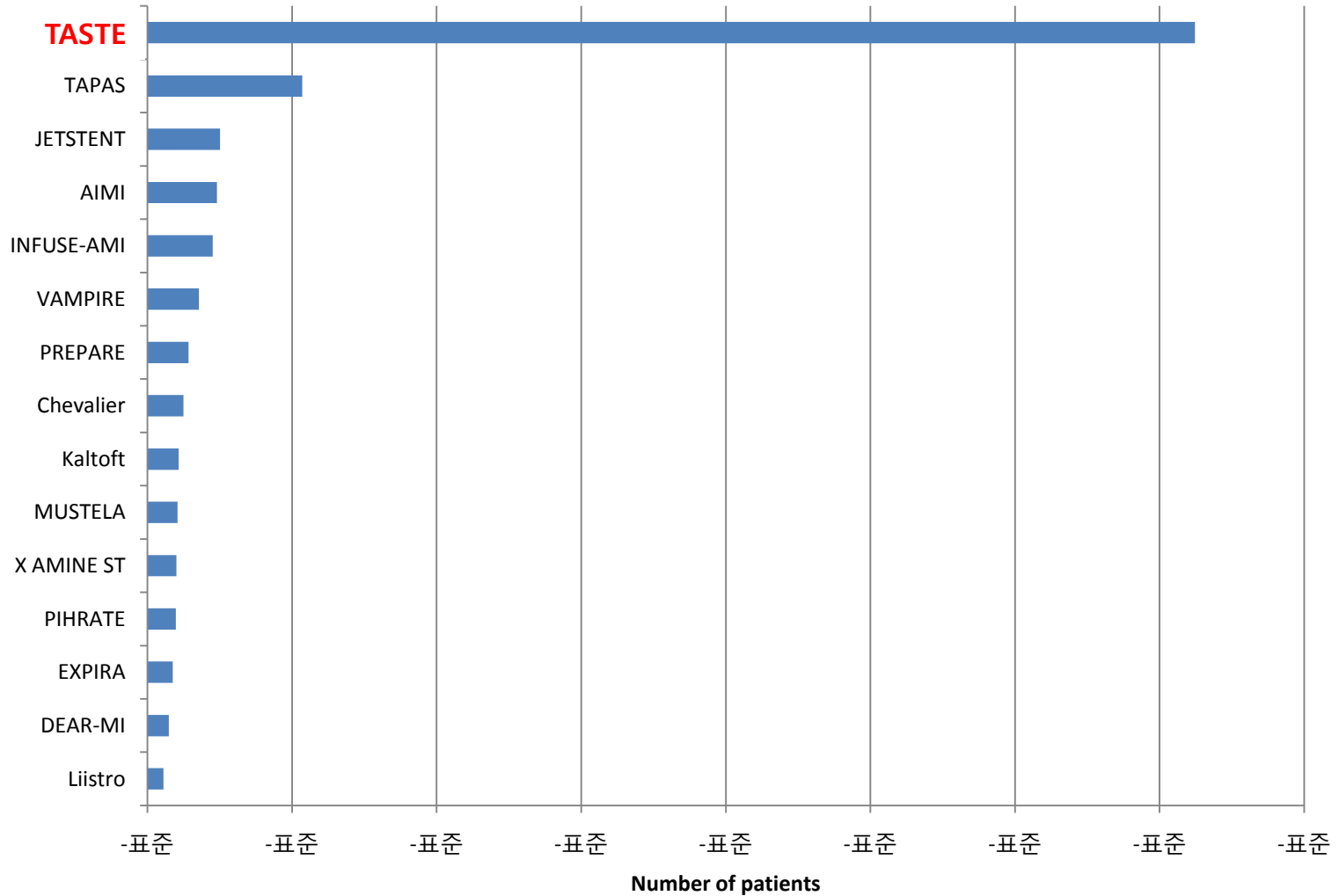
PCI+TA	3621	3568	3540	3532	3526	3524	3519
PCI	3623	3567	3545	3530	3523	3517	3513

Reinfarction, Stent thrombosis

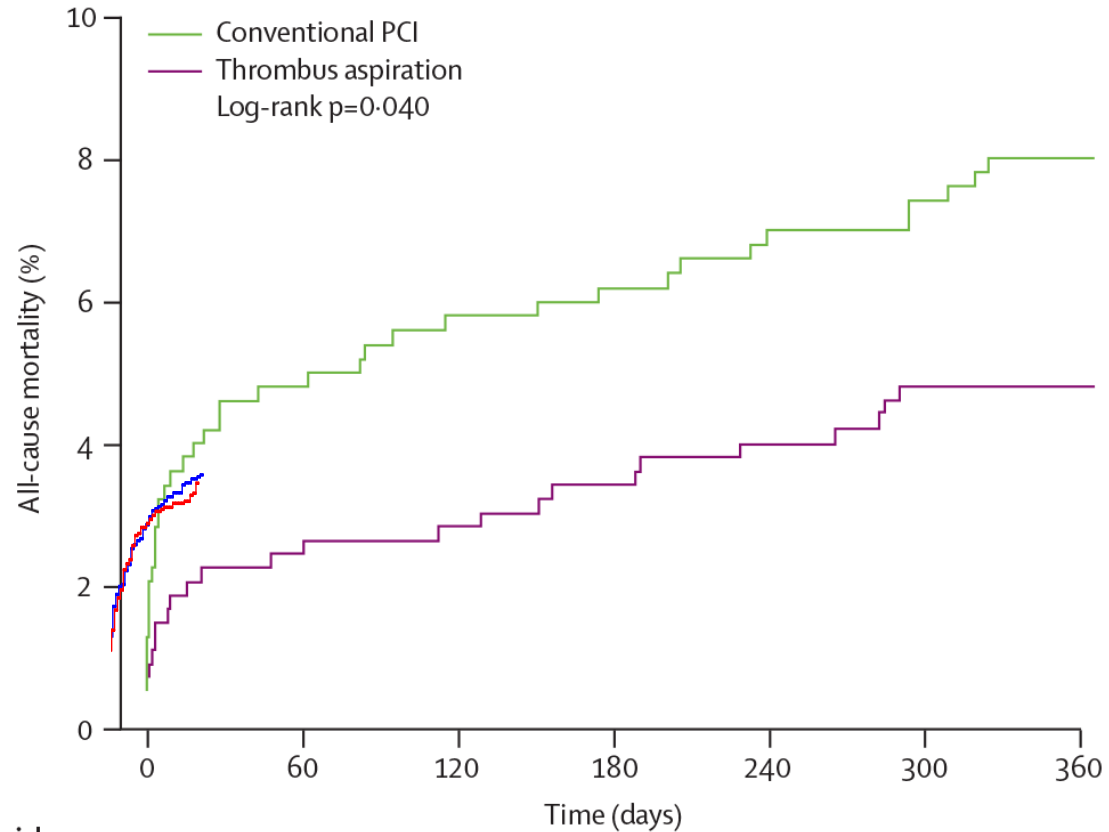
End Point	Patients Who Underwent Randomization				Patients Who Did Not Undergo Randomization	
	Thrombus Aspiration (N=3621)	PCI Only (N=3623)	Point Estimate (95% CI)	P Value	Thrombus Aspiration (N=1162)	PCI Only (N=3535)
30 days						
All-cause death — no./total no. (%)	103/3621 (2.8)	110/3623 (3.0)	Hazard ratio, 0.94 (0.72–1.22)	0.63	124/1138 (10.9)*	362/3442 (10.5)*
Rehospitalization due to reinfarction — no. (%)	19 (0.5)	31 (0.9)	Hazard ratio, 0.61 (0.34–1.07)	0.09	10 (0.9)	38 (1.1)
All-cause death or myocardial infarction — no./total no. (%)	121/3621 (3.3)	140/3623 (3.9)	Hazard ratio, 0.86 (0.67–1.10)	0.23	134/1138 (11.8)*	398/3442 (11.6)*
Stent thrombosis — no. (%)†	9 (0.2)	19 (0.5)	Hazard ratio, 0.47 (0.20–1.02)	0.06	5 (0.4)	18 (0.5)
Target-vessel revascularization — no./total no. (%)	63/3498 (1.8)‡	76/3499 (2.2)‡	Hazard ratio, 0.83 (0.59–1.15)	0.27	30/1162 (2.6)	80/3535 (2.3)
Target-lesion revascularization — no./total no. (%)	43/3498 (1.2)‡	57/3499 (1.6)‡	Hazard ratio, 0.75 (0.51–1.12)	0.16	25/1162 (2.2)	64/3535 (1.8)
Index hospitalization						



TASTE and previous studies



TASTE vs. TAPAS



	0	60	120	180	240	300	360
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

Conclusions

- large, prospective, registry-based randomized clinical trial
 - no reduction of mortality at 30 days
 - no significant reduction of hospitalization for MI or of stent thrombosis at 30 days
 - no reduction of other important clinical endpoints during hospitalization
- little role for manual thrombus aspiration as a routine adjunct to PCI in STEMI

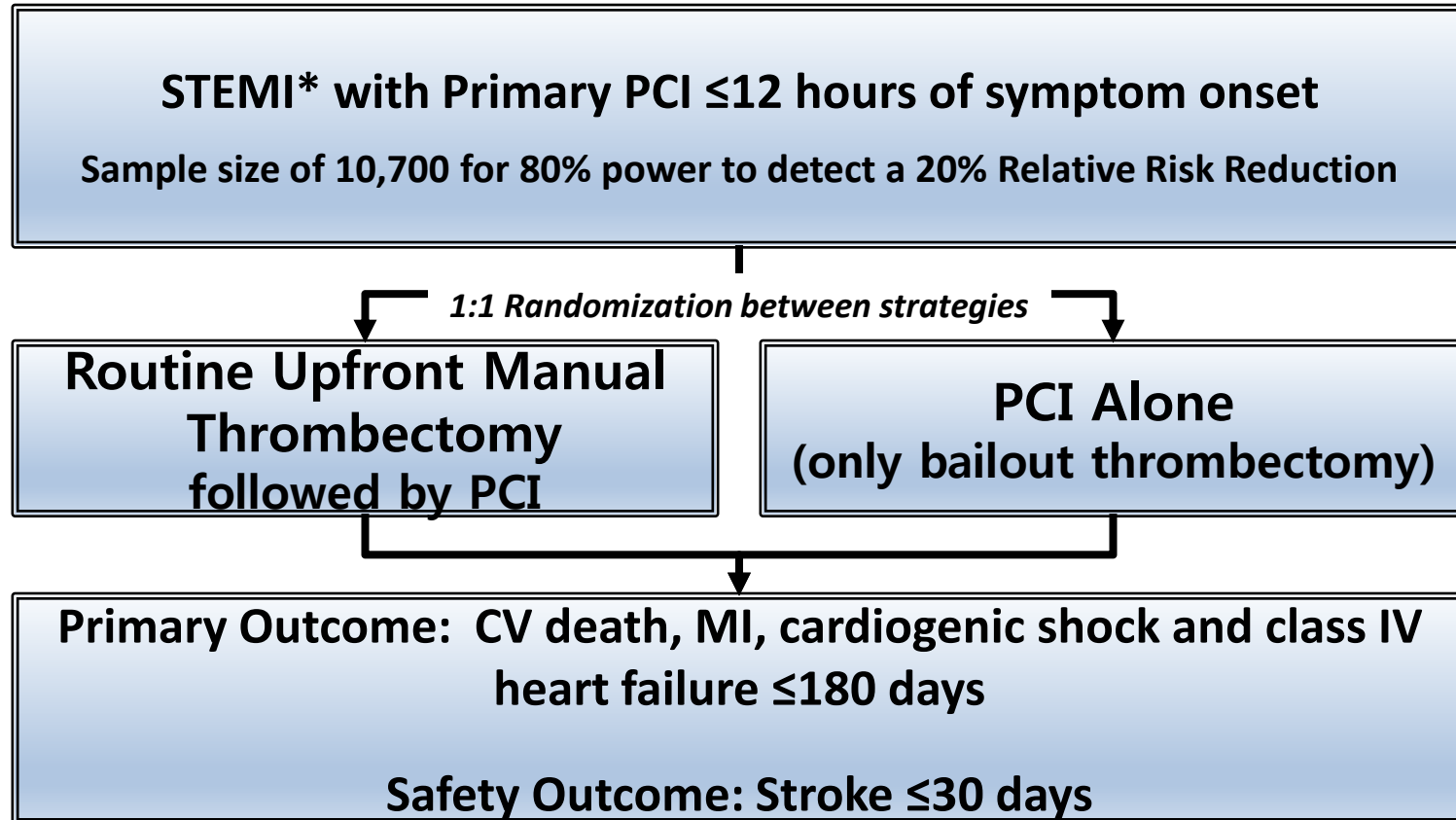
TOTAL

2015

North America



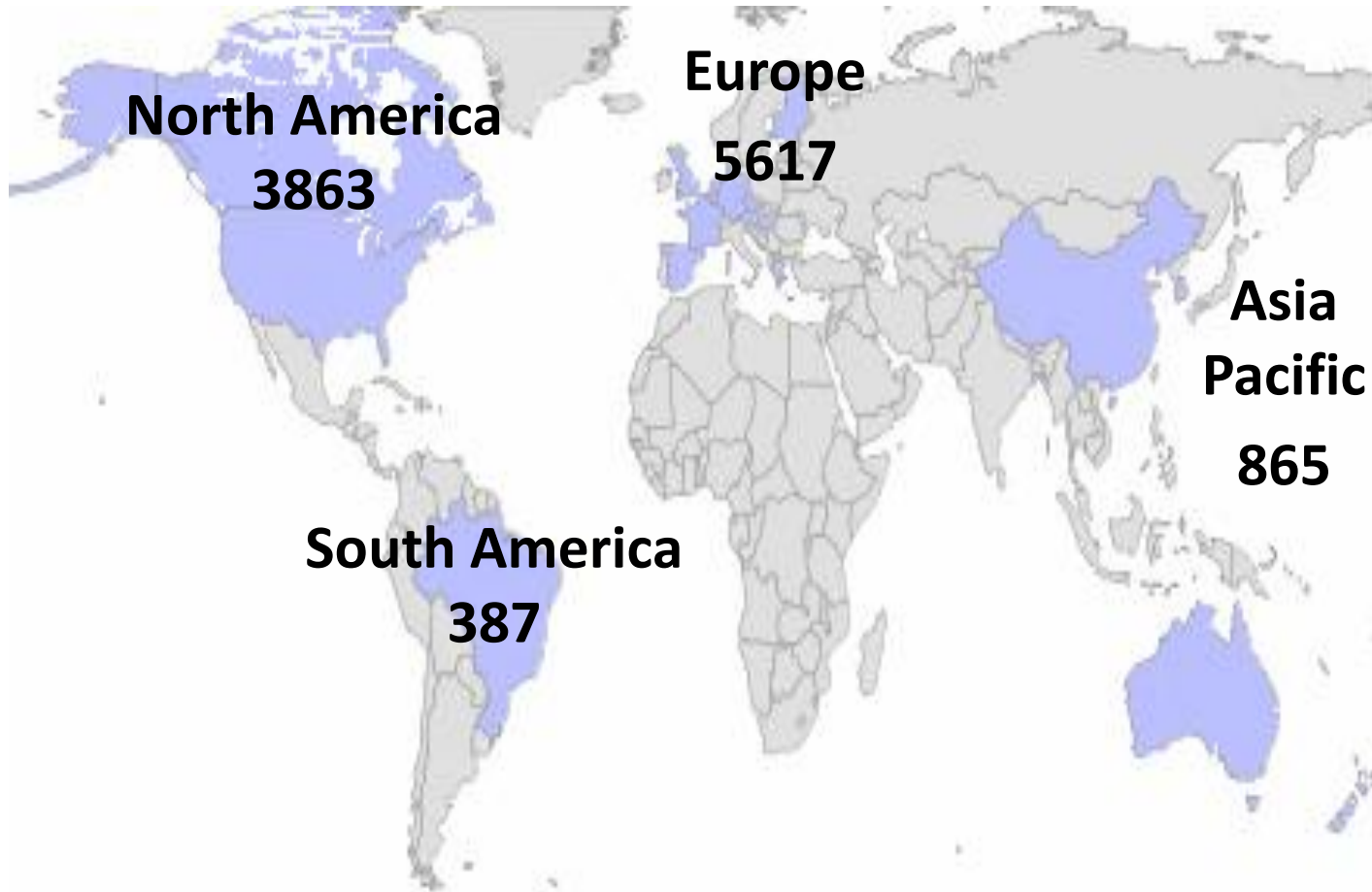
The TOTAL Trial Study Design



Bailout Thrombectomy allowed if PCI alone strategy fails:

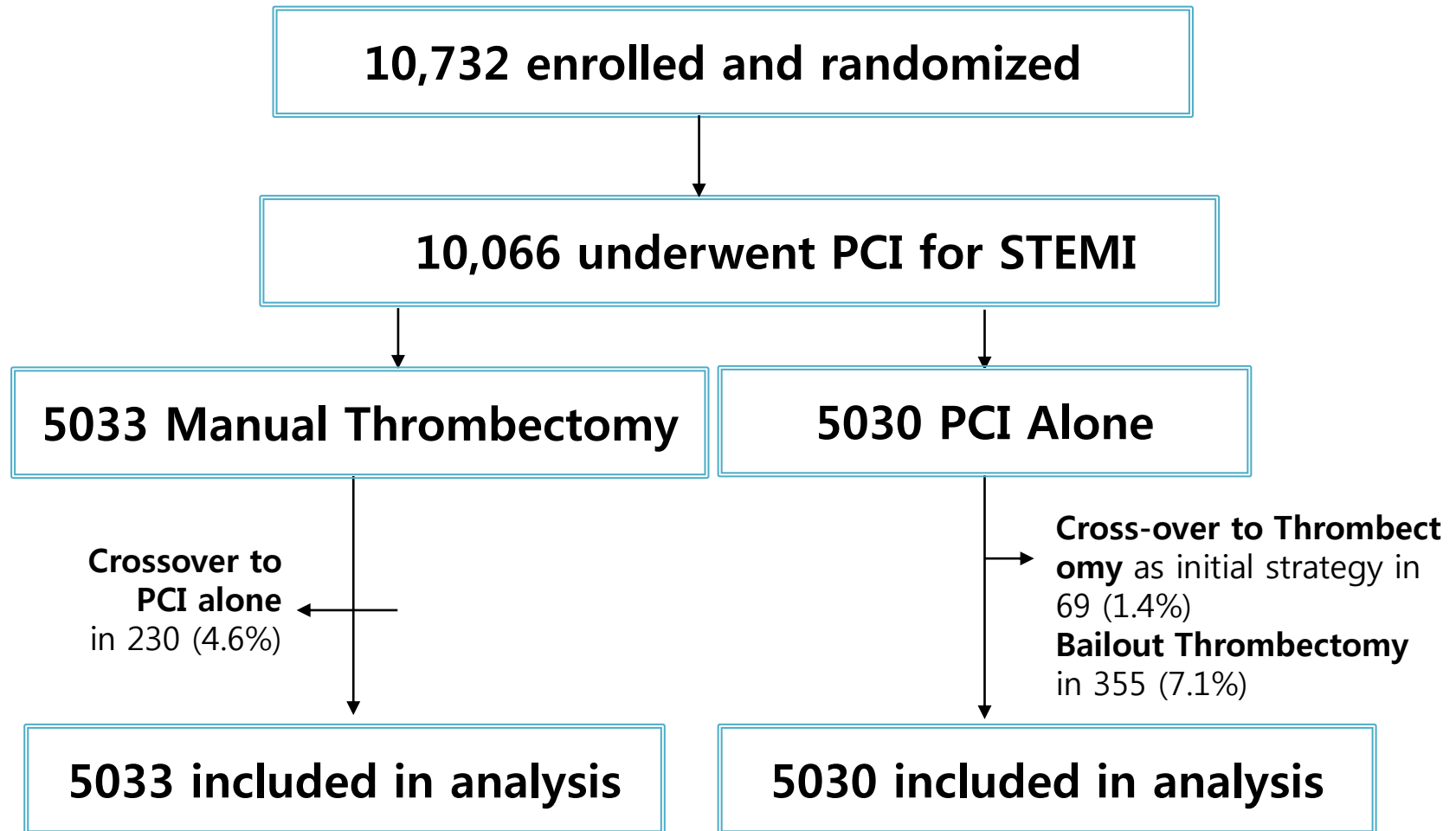
- Persistent TIMI 0 or 1 flow with large thrombus after balloon pre-dilatation
- Persistent large thrombus after stent deployment at target lesion

TOTAL Recruitment



10,732 patients randomized between August 2010 and July 2014

TOTAL Trial Flow



PCI Procedural Details

	Thrombectomy	PCI alone
	N=5033	N=5030
Pre PCI TIMI 0 flow	66.3%	67.8%
TIMI thrombus grade ≥ 3	90.8%	89.1%
Unfractionated Heparin	80.8%	81.6%
Bivalirudin	18.7%	17.3%
Upfront Glycoprotein IIb/IIIa**	22.7%	25.4%
Drug Eluting Stents	44.7%	45.0%
Radial Access	68.3%	68.2%

**P=0.0002



PCI Variables and Surrogate Outcomes

	Thrombecto my N=5033	PCI alone N=5030	P
PCI Procedure time (median)	39 min	35 min	<0.001
Direct Stenting	38.3%	21.3%	<0.001
Final TIMI 3 flow*	93.1%	93.1%	0.12
Distal Embolization*	1.6%	3.0%	<0.001
ST segment Resolution <70%*	27.0%	30.2%	<0.001

* Investigator Reported Outcomes. Core laboratory analysis is ongoing.

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

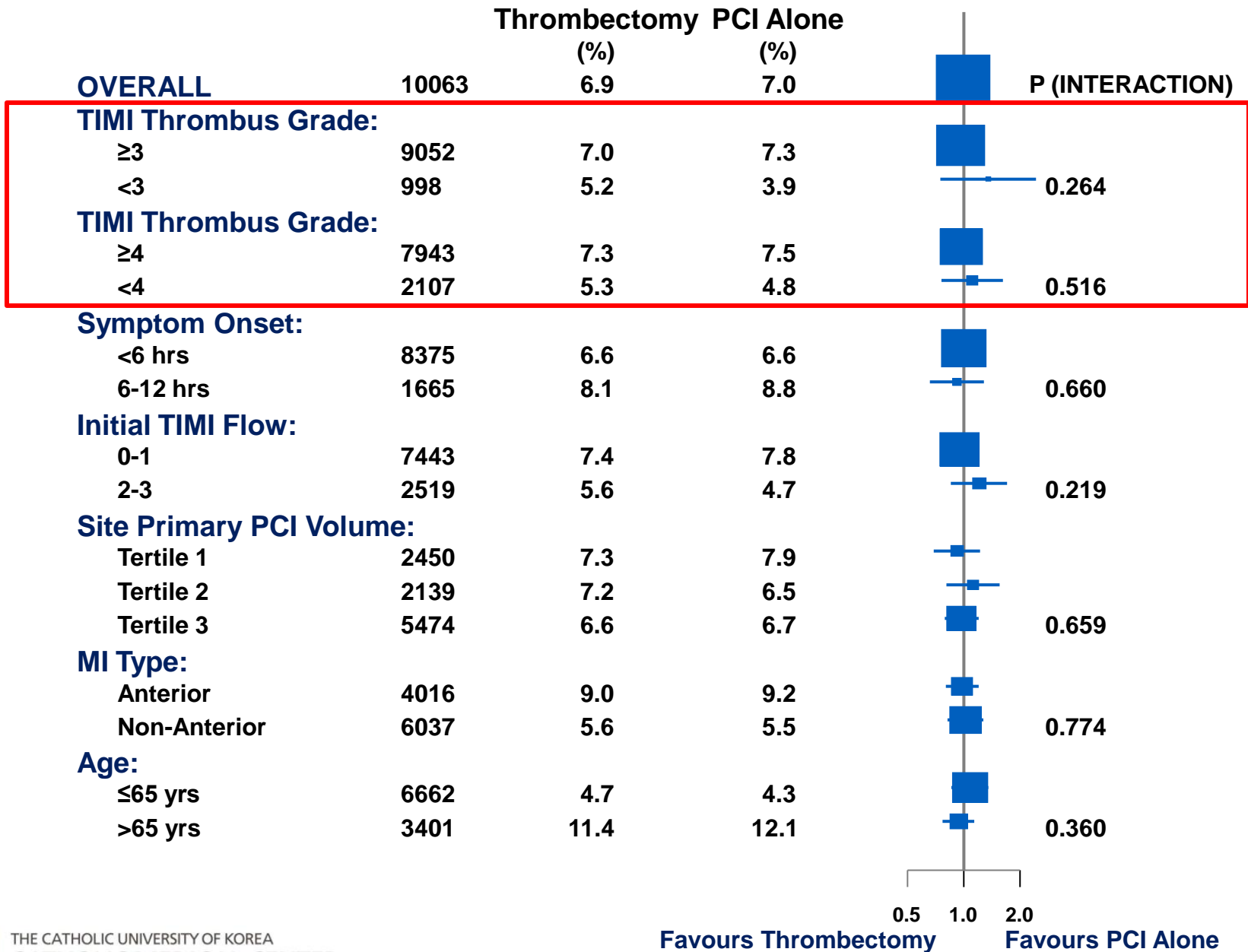
Safety Outcomes

	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

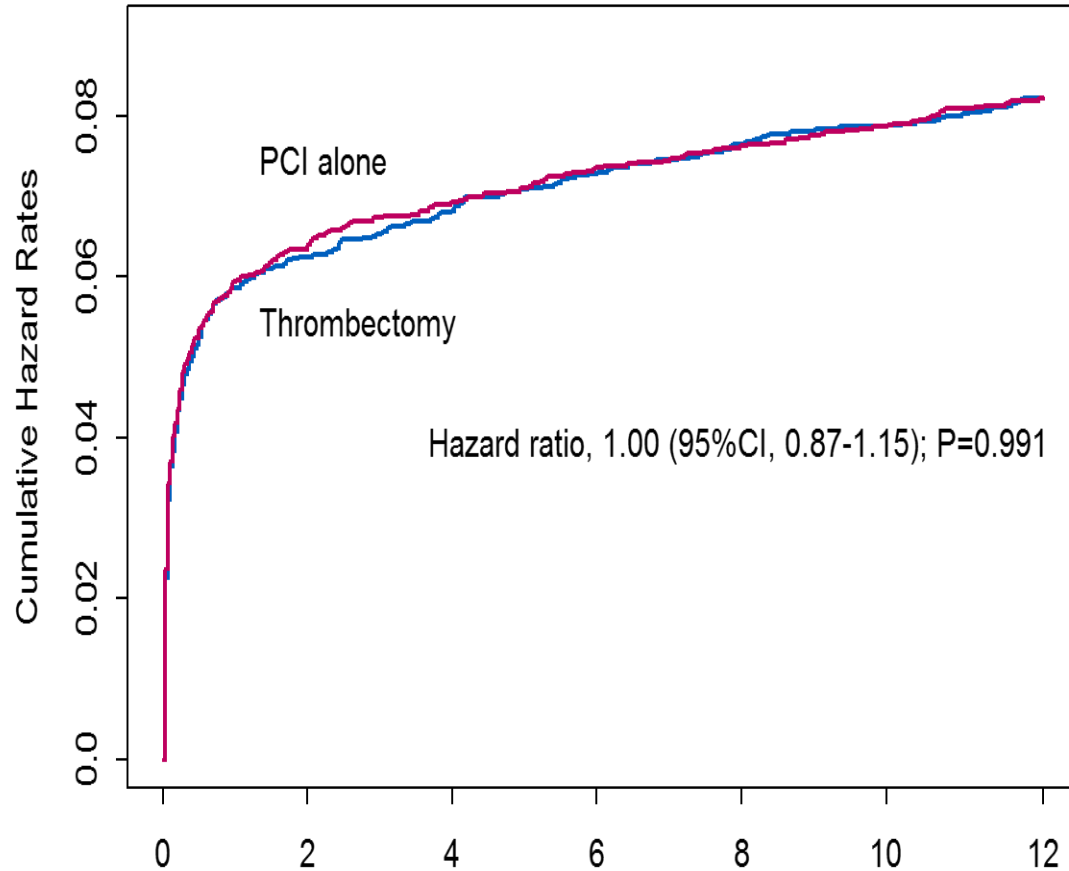
Outcomes at 30 days

	Thrombectomy (N=5033) (%)	PCI alone (N=5030) (%)	HR	95% CI	p
CV Death, MI, shock or class IV heart failure	281 (5.6%)	287 (5.7%)	0.98	0.83-1.15	0.79
Stent Thrombosis	59 (1.2%)	69 (1.4%)	0.85	0.60-1.21	0.37
Target Vessel Revascularization	126 (2.5%)	132 (2.6%)	0.95	0.75-1.22	0.69

Subgroup Analysis Primary Outcome



Primary Outcome at 1 year



	Months of Follow-up						
No. at Risk							
Thrombectomy	5035	4681	4646	4621	4580	4562	4508
PCI Alone	5029	4662	4625	4600	4555	4536	4474

Primary Outcome at 1 year

1 year	Thrombectomy (N=5033) (%)	PCI alone (N=5030) (%)	HR	95% CI	p
CV death, MI, shock or class IV heart failure	395 (7.8)	394 (7.8)	1.00	(0.87 – 1.15)	0.99
CV death	179 (3.6)	192 (3.8)	0.93	(0.76 – 1.14)	0.48
Recurrent MI	125 (2.5)	118 (2.3)	1.05	(0.82 -1.36)	0.68
Cardiogenic Shock	95 (1.9)	105 (2.1)	0.90	(0.68 – 1.19)	0.47
Class IV heart failure	106 (2.1)	96 (1.9)	1.01	(0.83 – 1.45)	0.50



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



Discussion



Thrombus aspiration

- Theoretically right
- Routine aspiration in RCT 18,000 Pts.
 - Not reduced Infarct size, MI, stent thrombus, heart failure, mortality
 - Not beneficial in subgroup
 - Associated with higher rate of stroke



2014 ESC guideline

Stenting is recommended (over balloon angioplasty) for primary PCI.	I	A	241,242
New-generation DES are recommended over BMS in primary PCI.	I	A	128,247,248,268,269
Radial access should be preferred over femoral access if performed by an experienced radial operator.	IIa	A	237,238,270
Thrombus aspiration may be considered in selected patients.	IIb	A	250–256,259

Role of thrombus aspiration?



STEVEN SENNE/HP

I HAVE TO ABANDON THROMBUS ASPIRATION

with present device and technique



Future of thrombus aspiration

**We need development of
New device and new technique**



Thank you

