

PCI Update

Qesaria 2009

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Interventional Cardiology

Chaim Sheba Medical Center

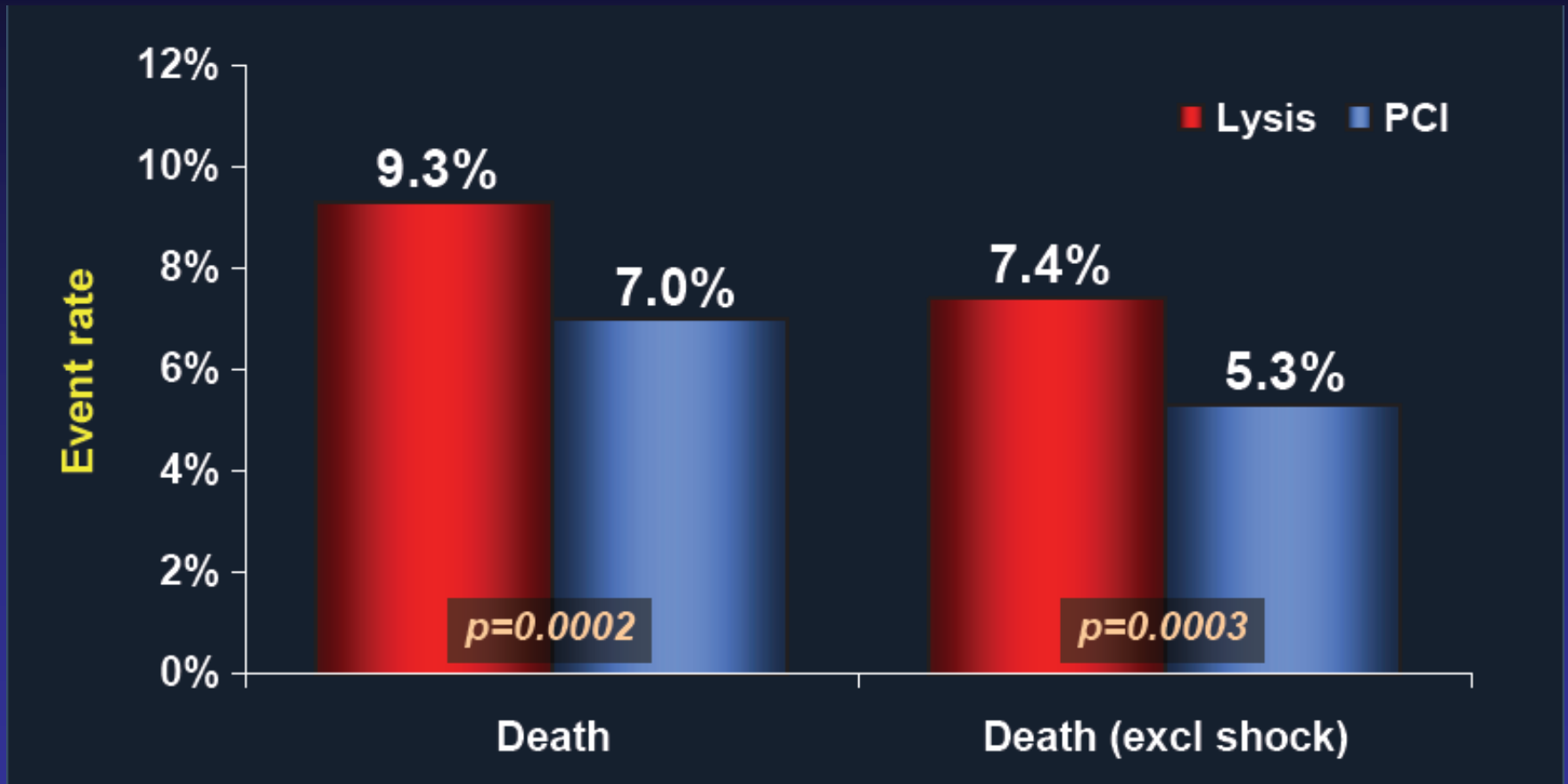


Outline

- **Primary PCI**
- **Non-ST elevation ACS**
- **Multi-vessel disease**
- **Hemodynamic assessment of borderline lesions - FFR**
- **Stable AP**
- **Non-coronary interventions - TAVI**



23 Randomized Studies of Primary PCI vs. Lysis n=7739

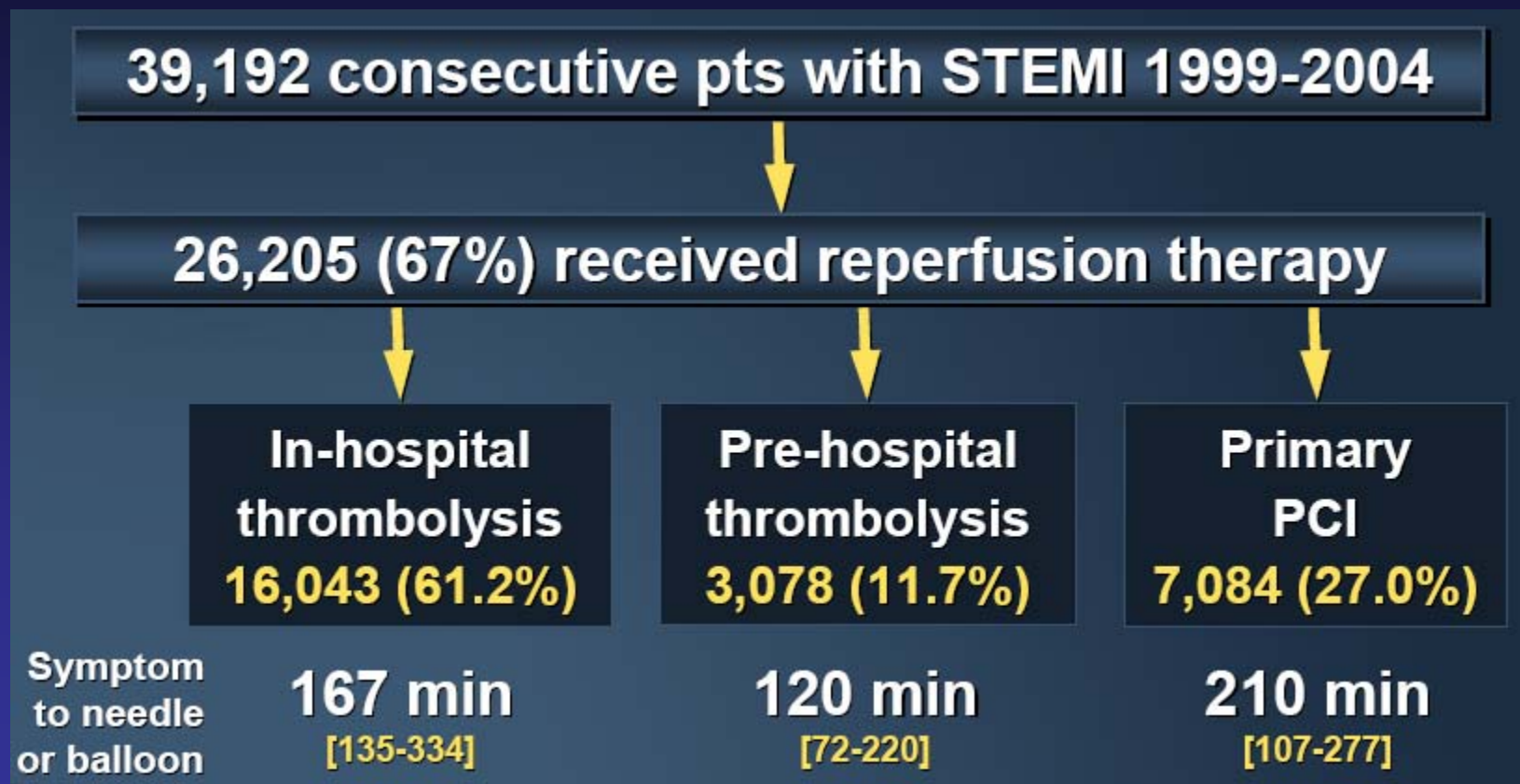


Keeley et al, Lancet 2003



The RIKS The RIKS-HIA Registry

Consecutive pts admitted in 75 of 78 hospitals with CCUs in Sweden

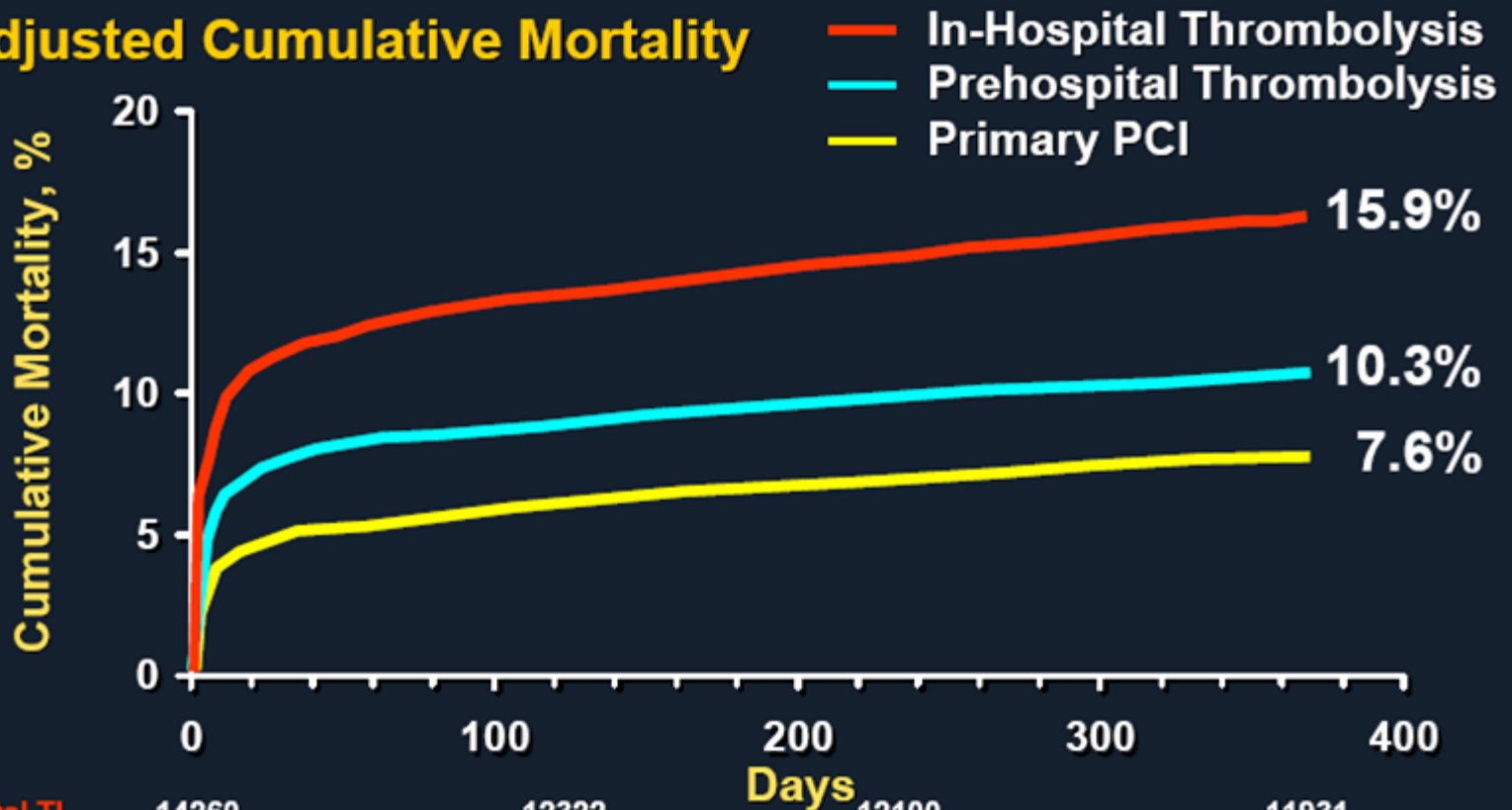


Stenestrand U et al. *JAMA* 2006



The RIKS-HIA Registry

Unadjusted Cumulative Mortality



at Risk

In Hospital TL
Prehospital TL
Primary PCI

14260
2736
6030

12322
2491
5661

Days

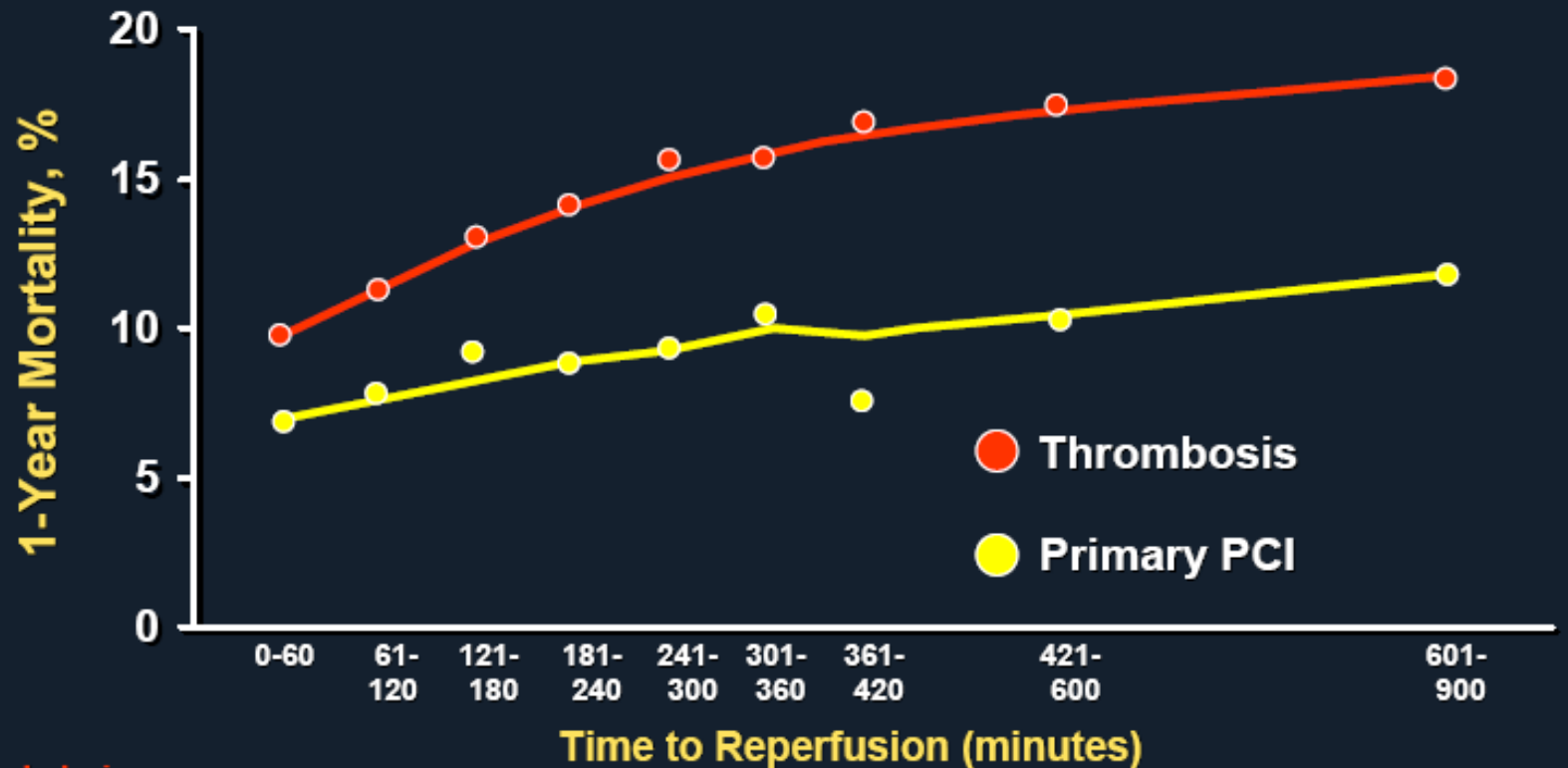
12100
2460
5607

11931
2442
5555

Stenestrand U et al. *JAMA* 2006



The RIKS-HIA Registry



Thrombolysis

No. of Deaths	122	503	503	332	239	159	121	196	139
Total No. of Pts	1248	4375	3659	2199	1438	946	658	1061	703

Primary PCI

No. of Deaths	7	61	81	50	43	37	17	41	31
Total No. of Pts	125	895	1126	776	567	453	282	458	332

Stenestrand U et al. *JAMA* 2006

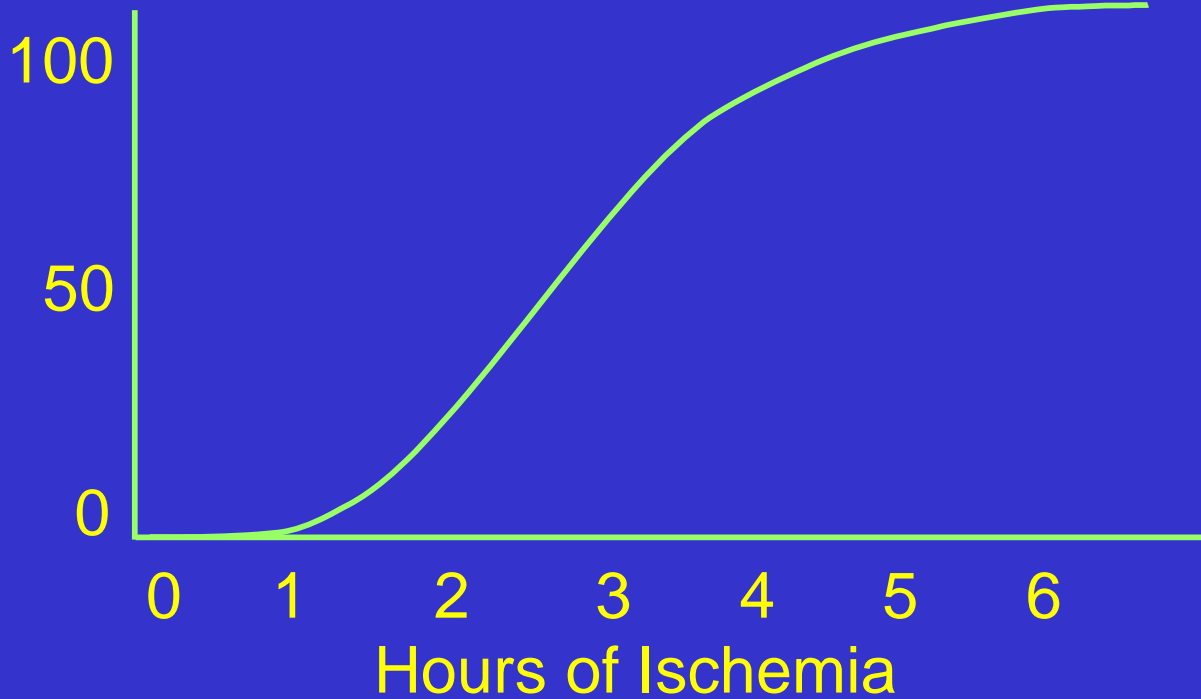


How Late After Symptom Onset Does Opening the Infarct Related Artery Still Provide Benefit?



Survival of Myocardium

Fraction of ischemic cells already dead



BRAVE II : Efficacy of Late Primary PCI

365 patients with MI presenting >12 - <48 hours after symptom onset (mean 22.5 hours)
Without ongoing chest pain or Killip class 3/4

Invasive

Angiography, then PCI if necessary
Median randomization time to PCI: 1.7 hrs

Conservative

Conventional medical therapy

PCI 94.6%, CABG 3.8%, Med Rx 1.6%

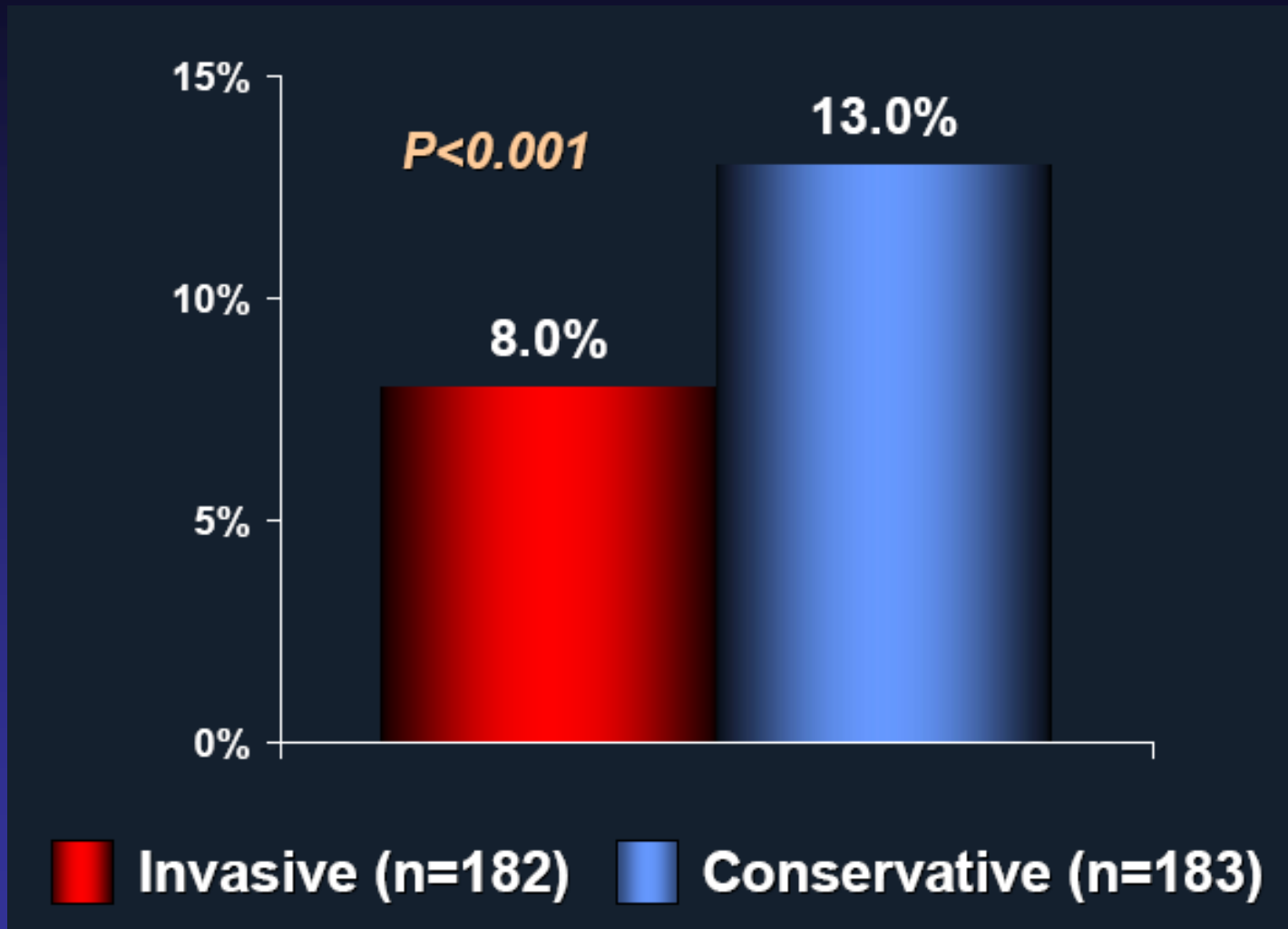
Endpoints:

- Primary – Infarct size determined by SPECT at 5-10 days
- Secondary – Death, MI, stroke, at 30 days

Schomig A et al. *JAMA* 2005



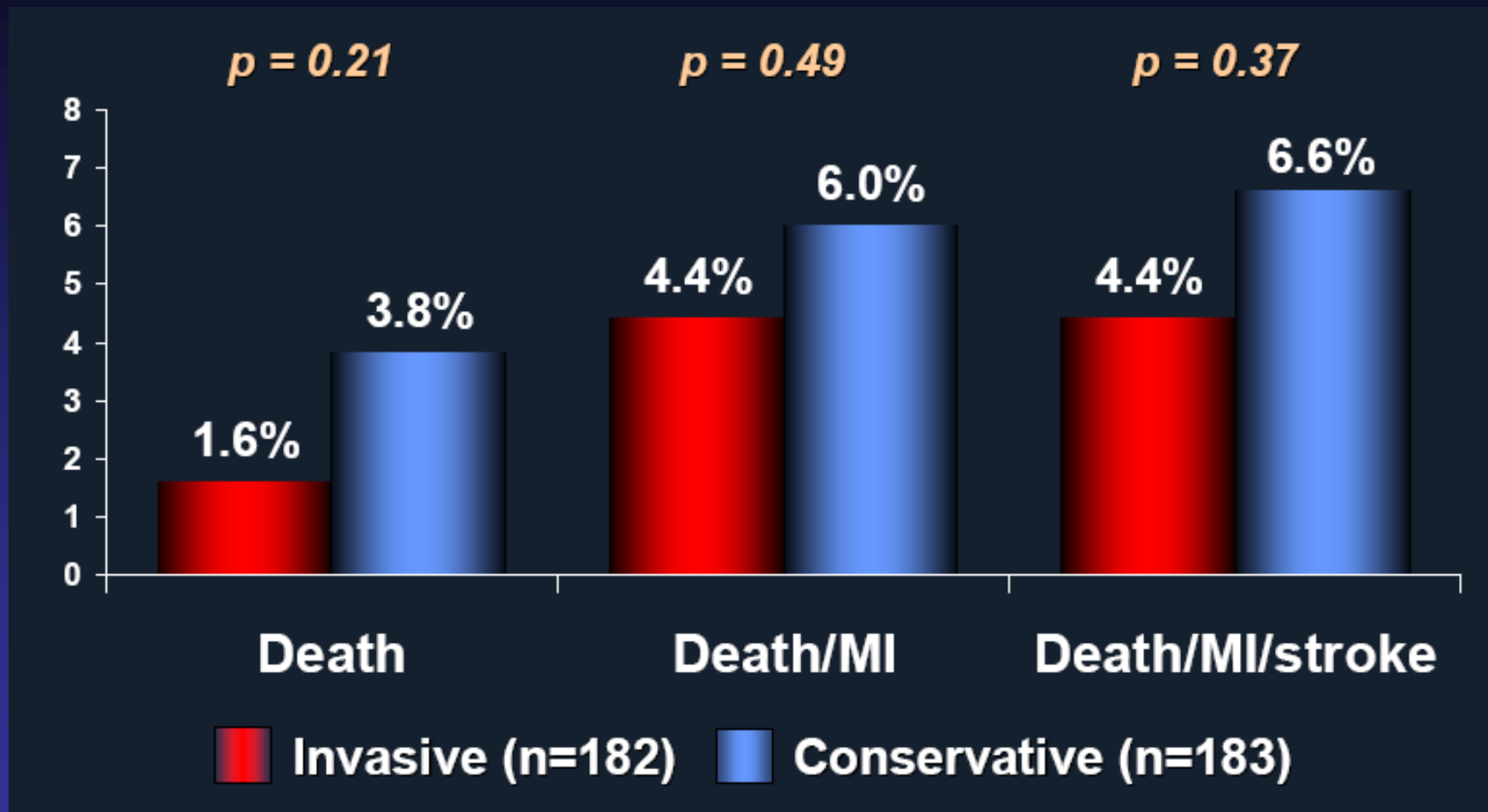
BRAVE 2 – Infarct Size at 7 days



Schomig A et al. *JAMA* 2005



BRAVE 2 – 30 day End-points



Schomig A et al. *JAMA* 2005



What is the optimal device / drug for primary PCI?



9 DES vs. BMS RCTs in AMI

(N=3,728 patients)

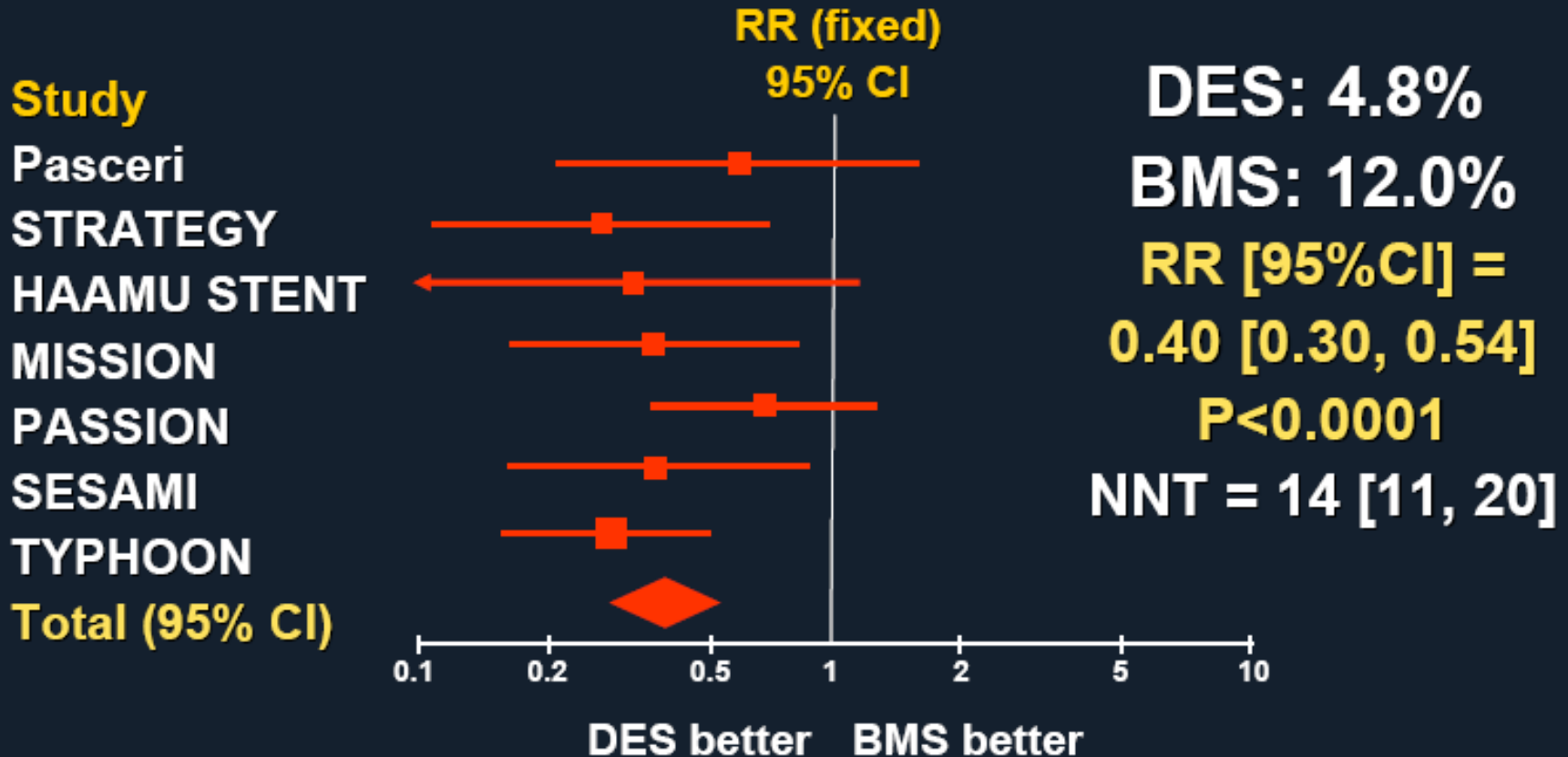
Trial	DES	N	Rescue PCI	Angio FU	Clinical FU
Pasceri	Cypher	65	18%	100%	12 mo
STRATEGY	Cypher	175	0%	90%	8 mo
PASSION	Taxus	605	0%	0%	12 mo
TYPHOON	Cypher	712	0%	26%	12 mo
SESAMI	Cypher	320	18%	52%	12 mo
Haamu-Stent	Taxus	164	45%	88%	12 mo
MISSION!	Cypher	316	0%	82%	12 mo
MultiStrategy	Cypher	745	0%	0%	8 mo
DEDICATION	Mixed	626	0%	87%	8 mo

Stone G. Fellows Course 2008



7 DES vs. BMS RCTs in AMI (n=2,357)

TLR at 8–12 Months

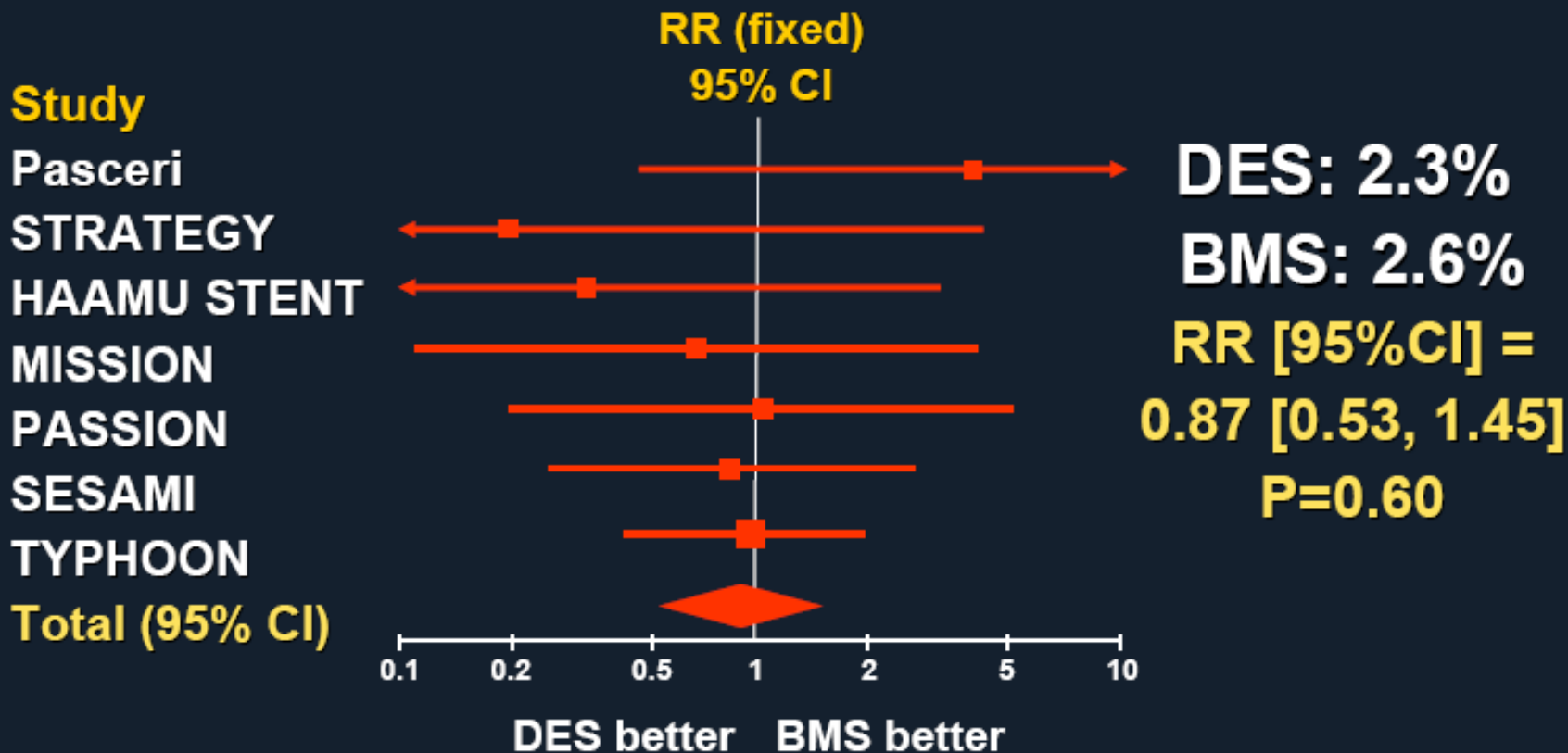


Pasceri V et al. AHJ 2007



7 DES vs. BMS RCTs in AMI (n=2,357)

Stent Thrombosis at 8–12 Months



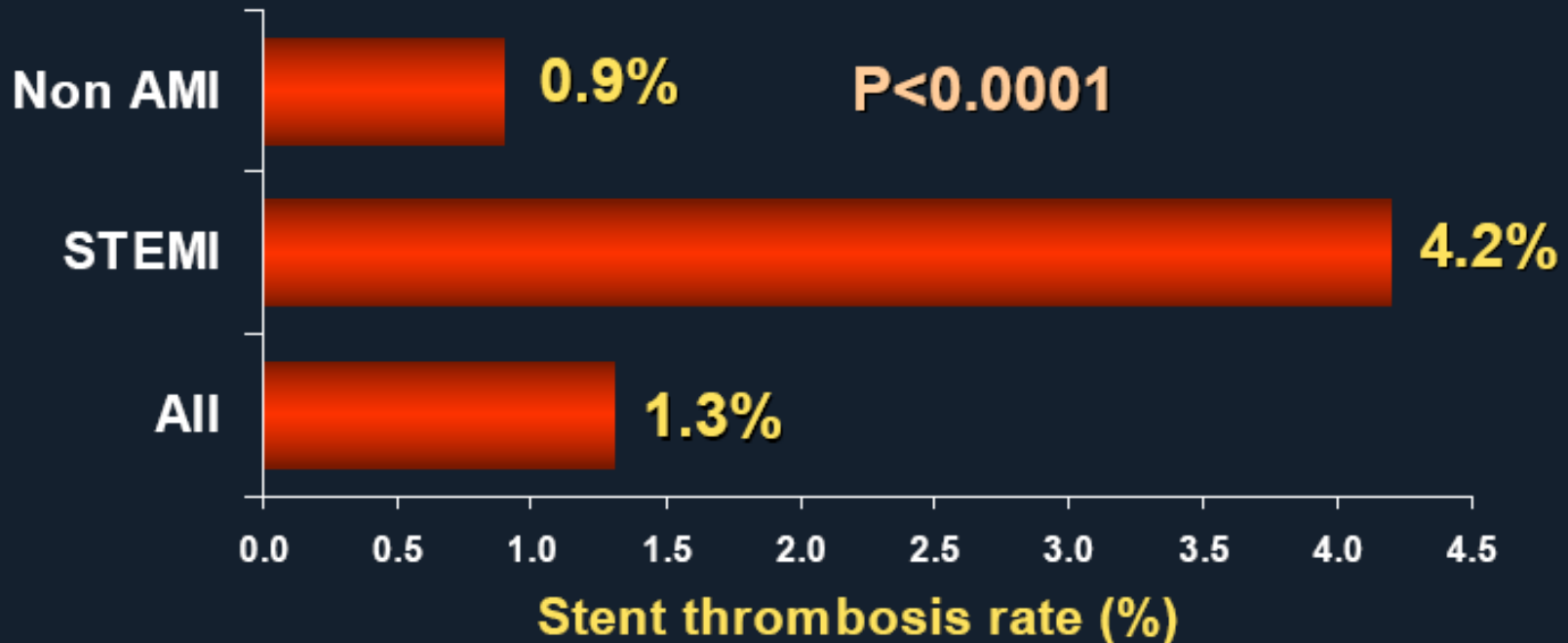
Pasceri V et al. AHJ 2007



The Spanish ESTROFA Registry

23,500 pts treated w/DES at 20 Spanish hospitals from 2002–06;
63% PES, 37% SES. Dual antiplatelet Rx for 8 ± 3 months.

1.3% ST rate at median FU 22 (11, 32) mos ; 2.0% ST at 3 yrs



De la Torre Hernandez J et al. JACC 2008



The Spanish ESTROFA Registry

Multivariate Predictors of Stent Thrombosis (n=14,120)

Early (≤ 30 days)	HR (95% CI)	P value
STEMI	6.9 (4.0-12.0)	<.0001
Stent length (per mm\uparrow)	1.08 (1.06–1.10)	0.0001
Diabetes	1.8 (1.0–3.0)	0.04
Renal insufficiency	3.1 (1.1–9.2)	0.04
ACS	2.6 (1.3–4.9)	0.003
LAD	2.2 (1.4–3.7)	0.001

De la Torre Hernandez J et al. JACC 2008



The Spanish ESTROFA Registry

Multivariate Predictors of Stent Thrombosis (n=14,120)

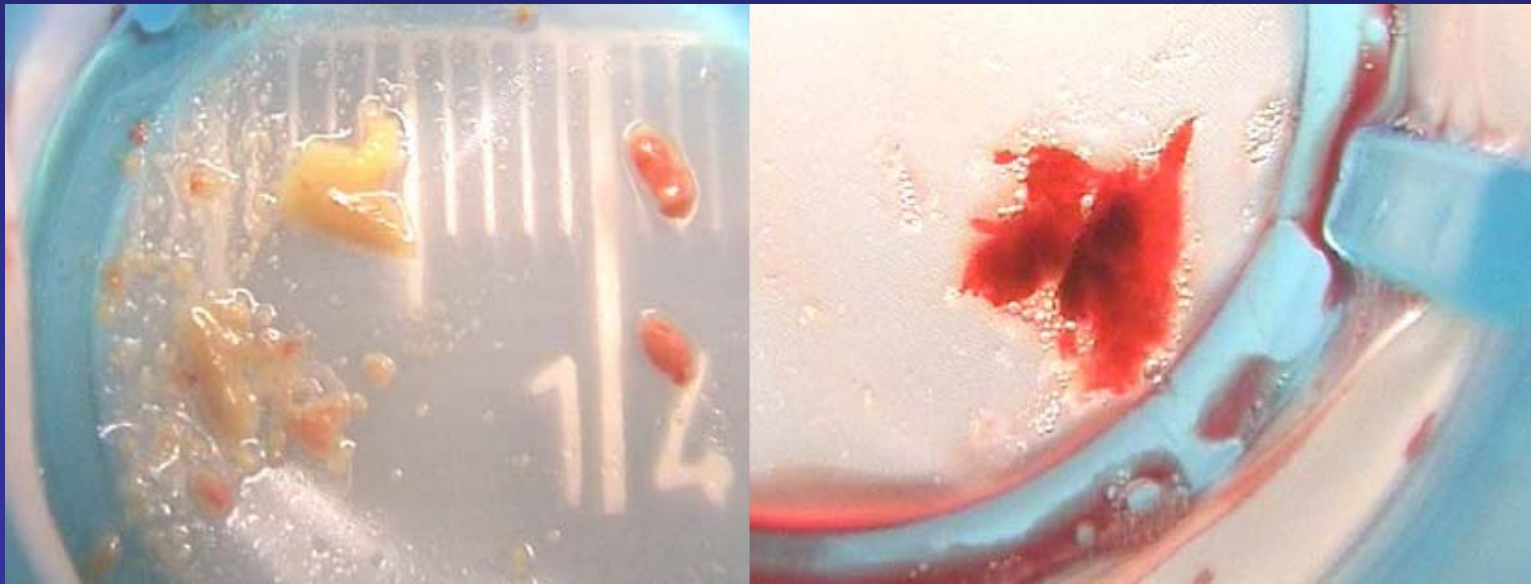
	HR (95% CI)	P value
Late		
STEMI	5.5 (3.5–7.6)	<0.0001
LAD	3.0 (2.0–4.4)	<0.0001
Stent length (per mm[↑])	1.07 (1.05–1.09)	<0.0001

De la Torre Hernandez J et al. JACC 2008

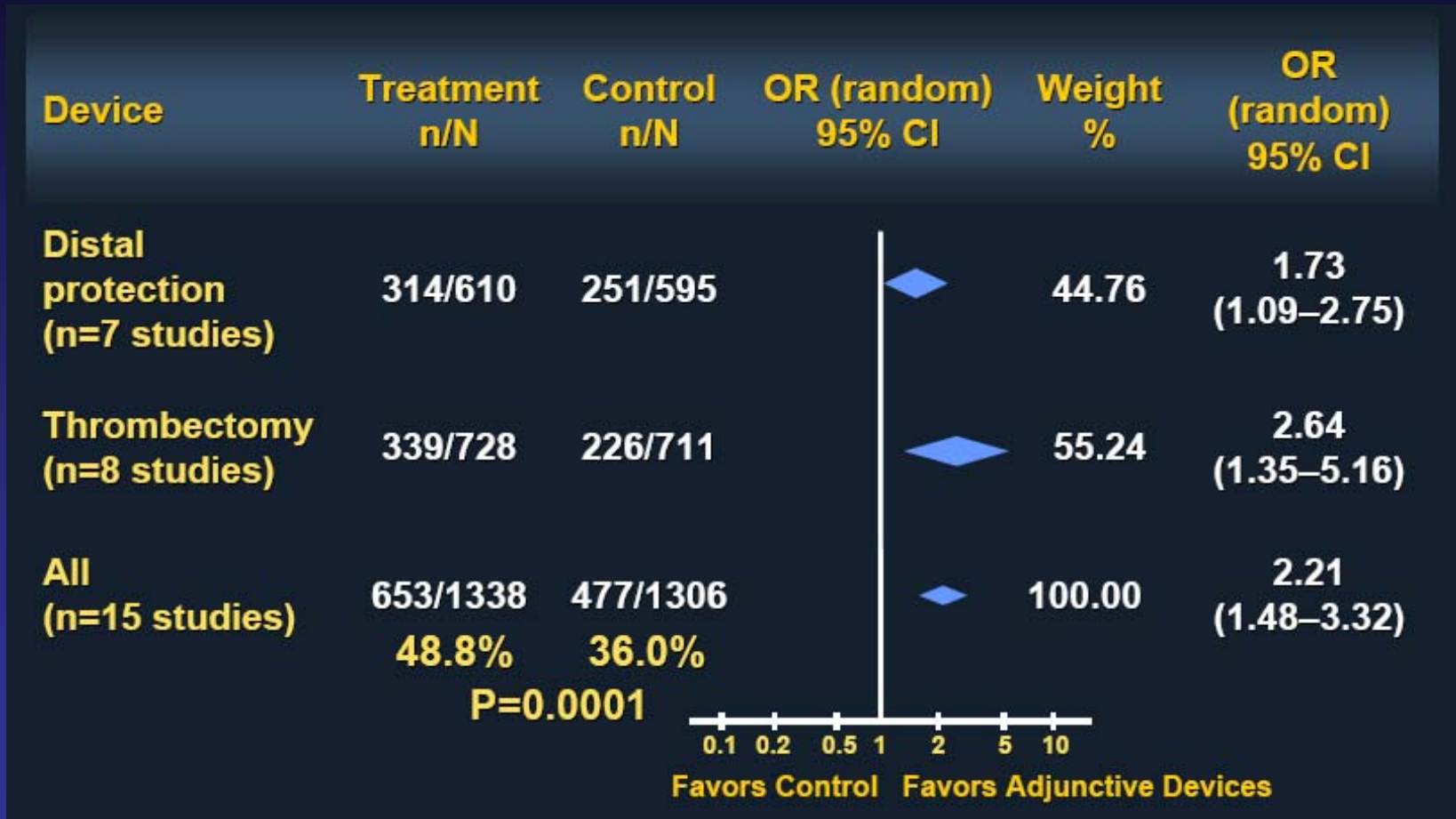


Is thrombus retrieval useful during primary PCI?

Distal Protection and Thrombectomy in AMI - Macroscopic embolic debris can be retrieved from >75% of cases



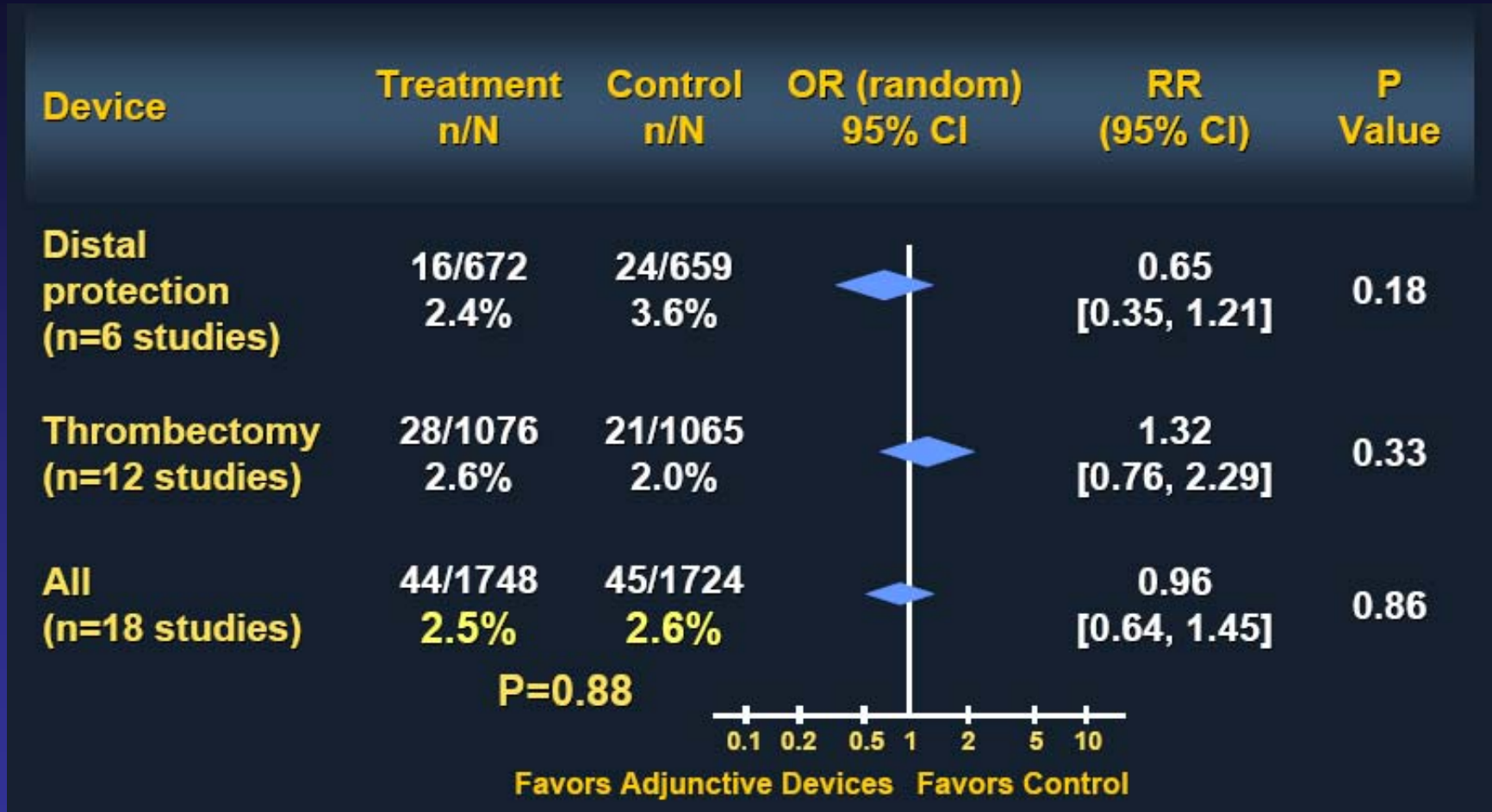
Myocardial Blush-3 Flow: 15 RCTs



De Luca G et al. AHJ 2007



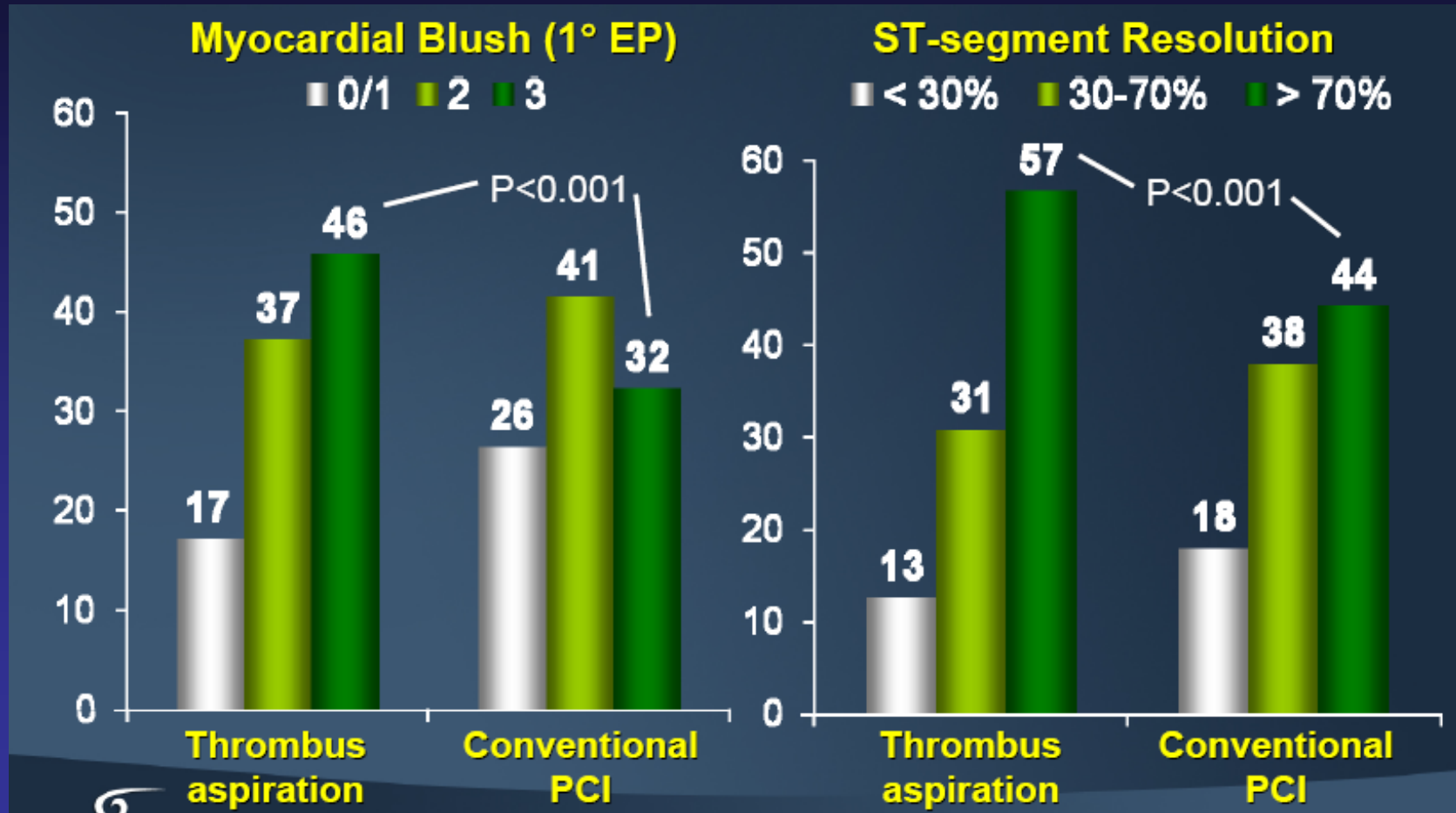
Mortality at 30 Days: 18 RCTs



De Luca G et al. AHJ 2007



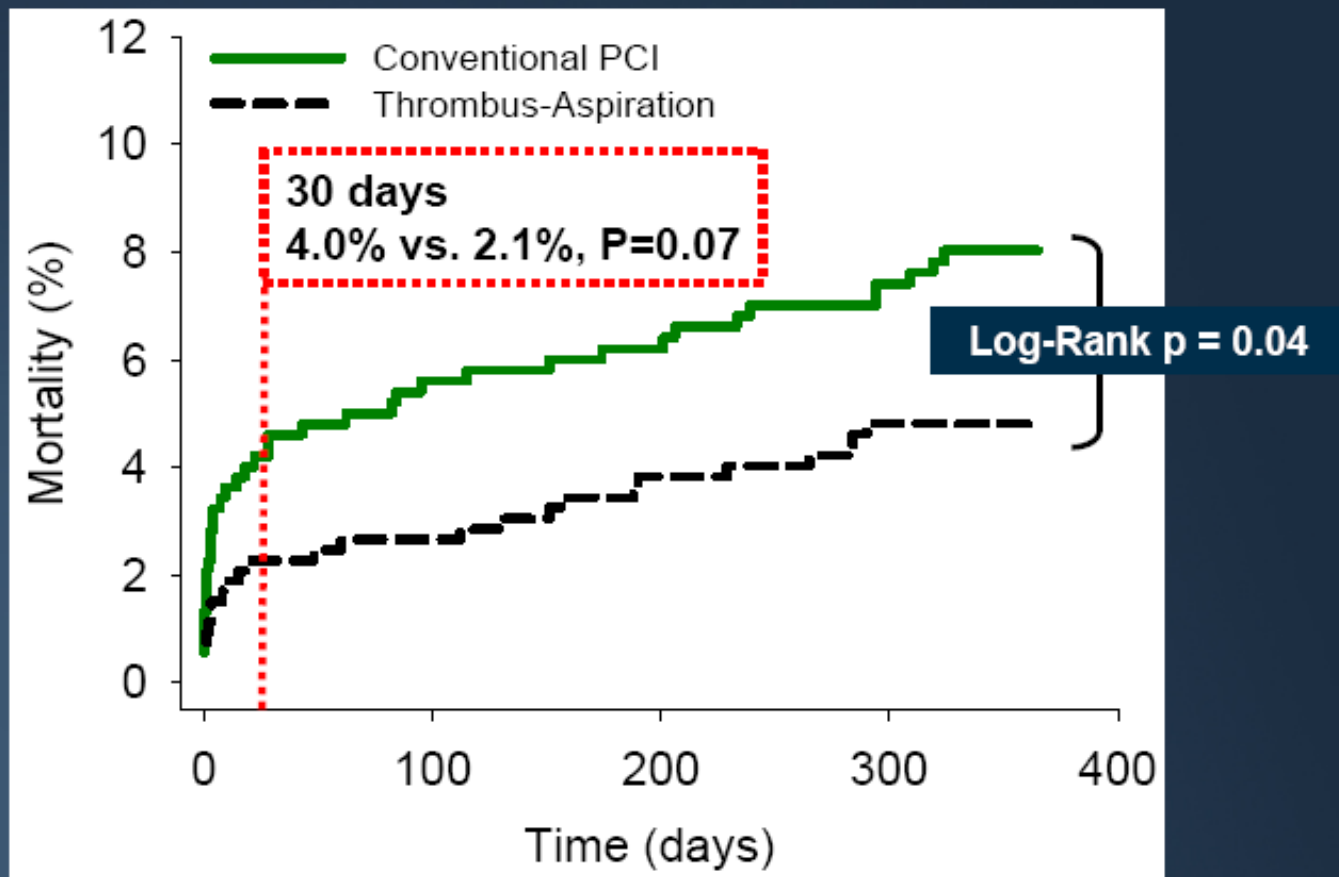
TAPAS: 1,071 pts with STEMI undergoing primary PCI at a single center were randomized in the ER to manual aspiration (Export) vs. control



Svilaas T et al. N Engl J Med 2008



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Svilaas T et al. N Engl J Med 2008

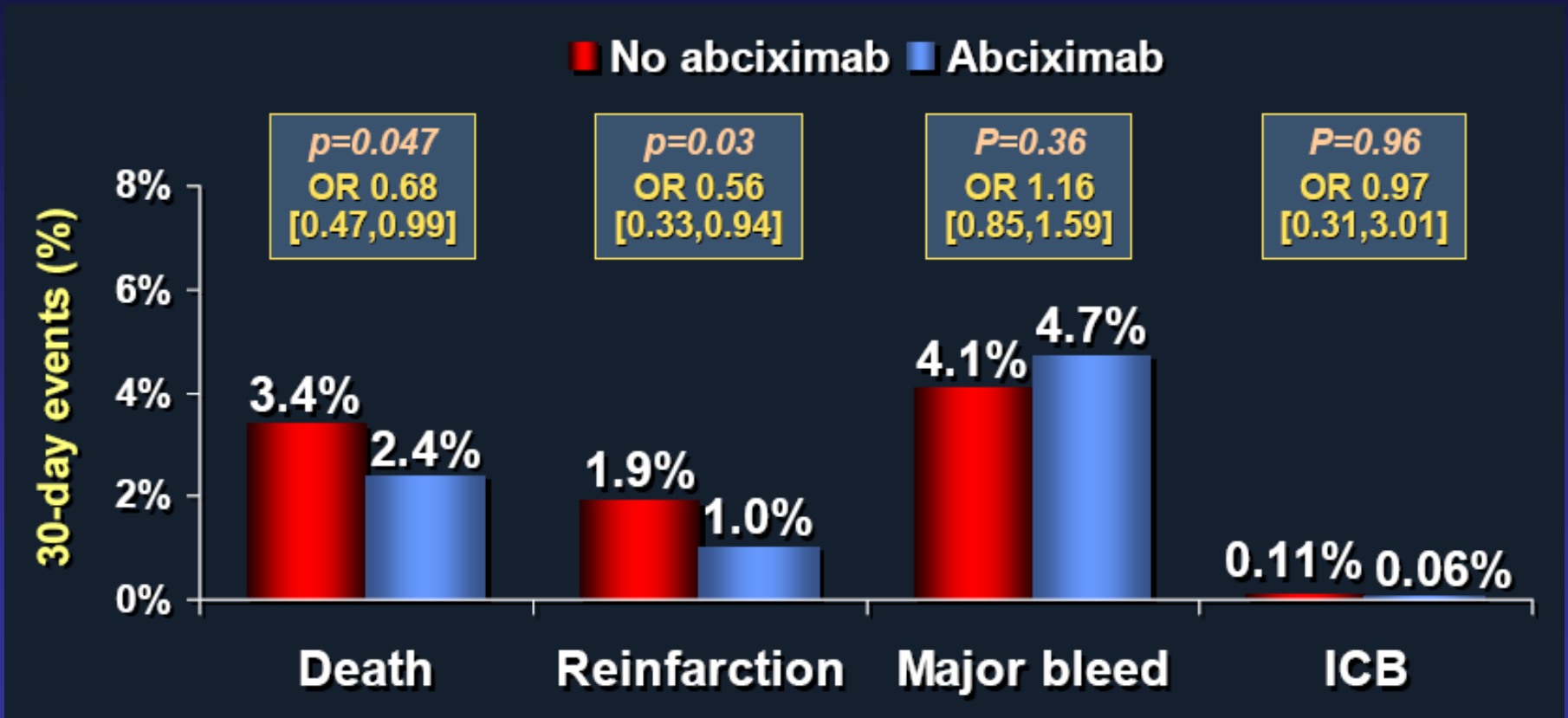


What is the Optimal anti-Thrombotic Regimen in Primary PCI?



Abciximab in Primary PCI Meta-analysis

8 RCTs 3,949 pts with AMI w/i 12^o undergoing primary (7) or rescue (1) PCI rand to abciximab vs. placebo



De Luca G et al. JAMA 2005



HORIZONS-AMI

3,602 pts with STEMI with symptom onset ≤ 12 hours

Aspirin, thienopyridine

R
1:1

UFH + GP IIb/IIIa inhibitor
(abciximab or eptifibatide)

Bivalirudin monotherapy
(\pm provisional GP IIb/IIIa)

Emergent angiography, followed by triage to...

CABG – Primary PCI – Medical Rx

3000 pts eligible for stent randomization

R
1:3

Bare metal stent

TAXUS paclitaxel-eluting stent

Clinical FU at 30 days, 6 months,
1 year, and then yearly through 5 years

HORIZONSAMI

Stone G et al. N Engl J Med 2008



HORIZONS-AMI – Primary End-points

1) Net Adverse Clinical Events

and

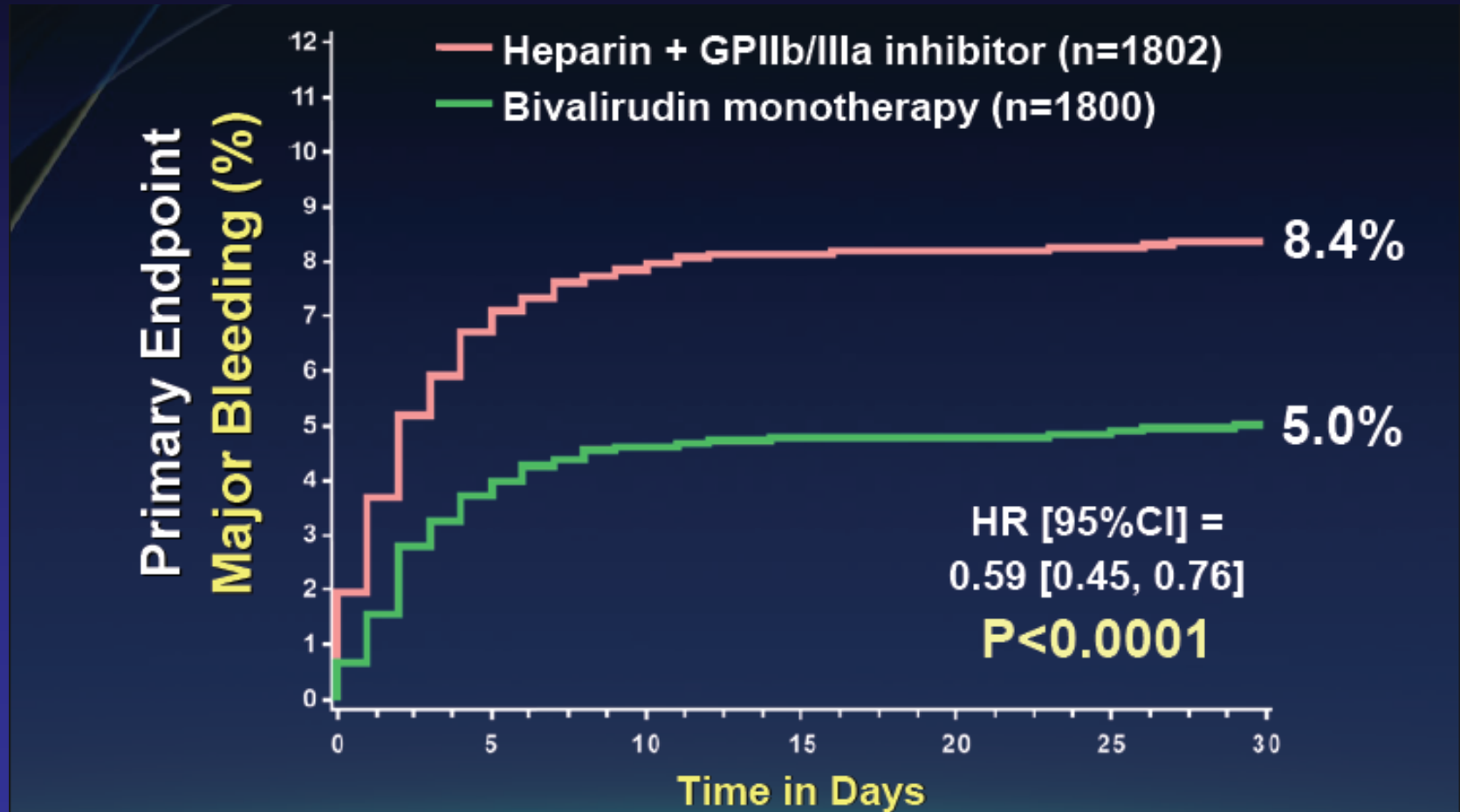
2) Major Bleeding (non CABG)

- Intracranial bleeding
- Intraocular bleeding
- Retroperitoneal bleeding
- Access site bleed requiring intervention/surgery
- Hematoma ≥ 5 cm
- Hgb $\downarrow \geq 3$ g/dL with an overt source
- Hgb $\downarrow \geq 4$ g/dL w/o overt source
- Reoperation for bleeding
- Blood product transfusion

Stone G et al. N Engl J Med 2008



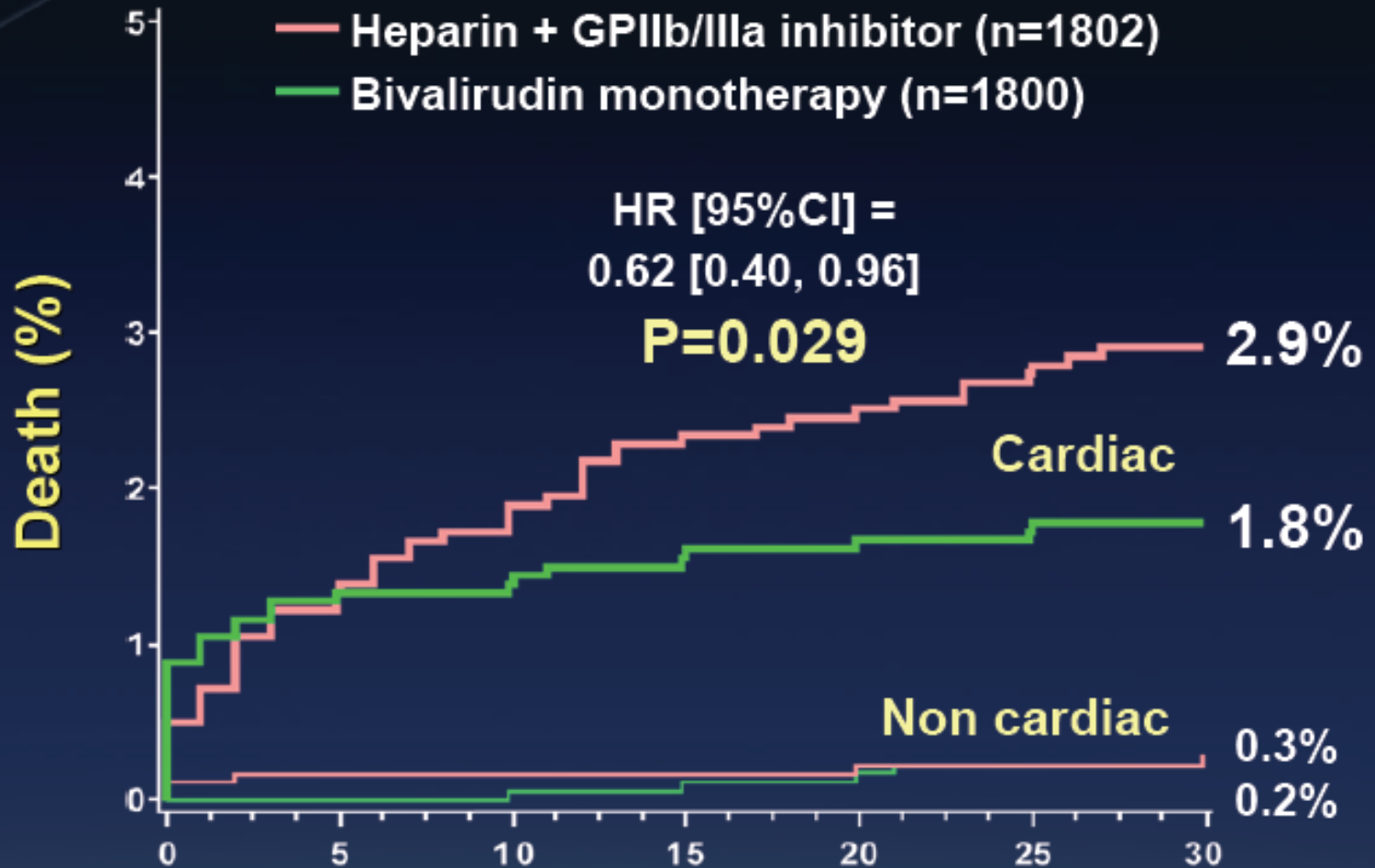
HORIZONS-AMI – Major bleeding (non-CABG)



Stone G et al. N Engl J Med 2008



HORIZONS-AMI – Mortality



Stone G et al. N Engl J Med 2008



HORIZONS-AMI – Stent Thrombosis

	UFH + GP IIb/IIIa (N=1553)	Bivalirudin (N=1571)	P Value
ARC 30d definite or probable stent thrombosis*	1.9%	2.5%	0.30
- definite	1.4%	2.2%	0.09
- probable	0.5%	0.3%	0.24
- acute (≤ 24 hrs)	0.3%	1.3%	0.0007
- subacute (>24 hrs – 30d)	1.7%	1.2%	0.28

Stone G et al. N Engl J Med 2008



Clinical events in the HORIZONS-AMI pharmacology arm at two years

End point	Bivalirudin, n=1800 (%)	Heparin plus GP IIb/IIIa inhibitor, n=1802 (%)	Hazard ratio (95% CI)
Major bleeding, non-CABG	6.4	9.6	0.64 (0.51–0.81)
All-cause mortality	4.6	6.1	0.75 (0.56–1.00)
Cardiac mortality	2.5	4.2	0.59 (0.41–0.86)
Reinfarction	5.1	6.9	0.75 (0.56–0.98)
ARC definite or probable stent thrombosis	4.3	4.6	0.94 (0.67–1.32)

Stone G. TCT 2009; September 21-25, 2009; San Francisco, CA.



Clinical and safety events in the HORIZONS-AMI stent arm at two years

End point	Taxus, n=2257 (%)	Express bare-metal stent, n=749 (%)	Hazard ratio (95% CI)
Ischemic target lesion revascularization	6.8	11.6	0.58 (0.44–0.76)
MACE (death, reinfarction, stroke, stent thrombosis)	11.0	11.2	0.98 (0.77–1.26)
All-cause mortality	4.3	5.2	0.83 (0.57–1.20)
ARC definite or probable stent thrombosis	4.1	4.1	1.00 (0.66–1.51)



NSTE-ACS

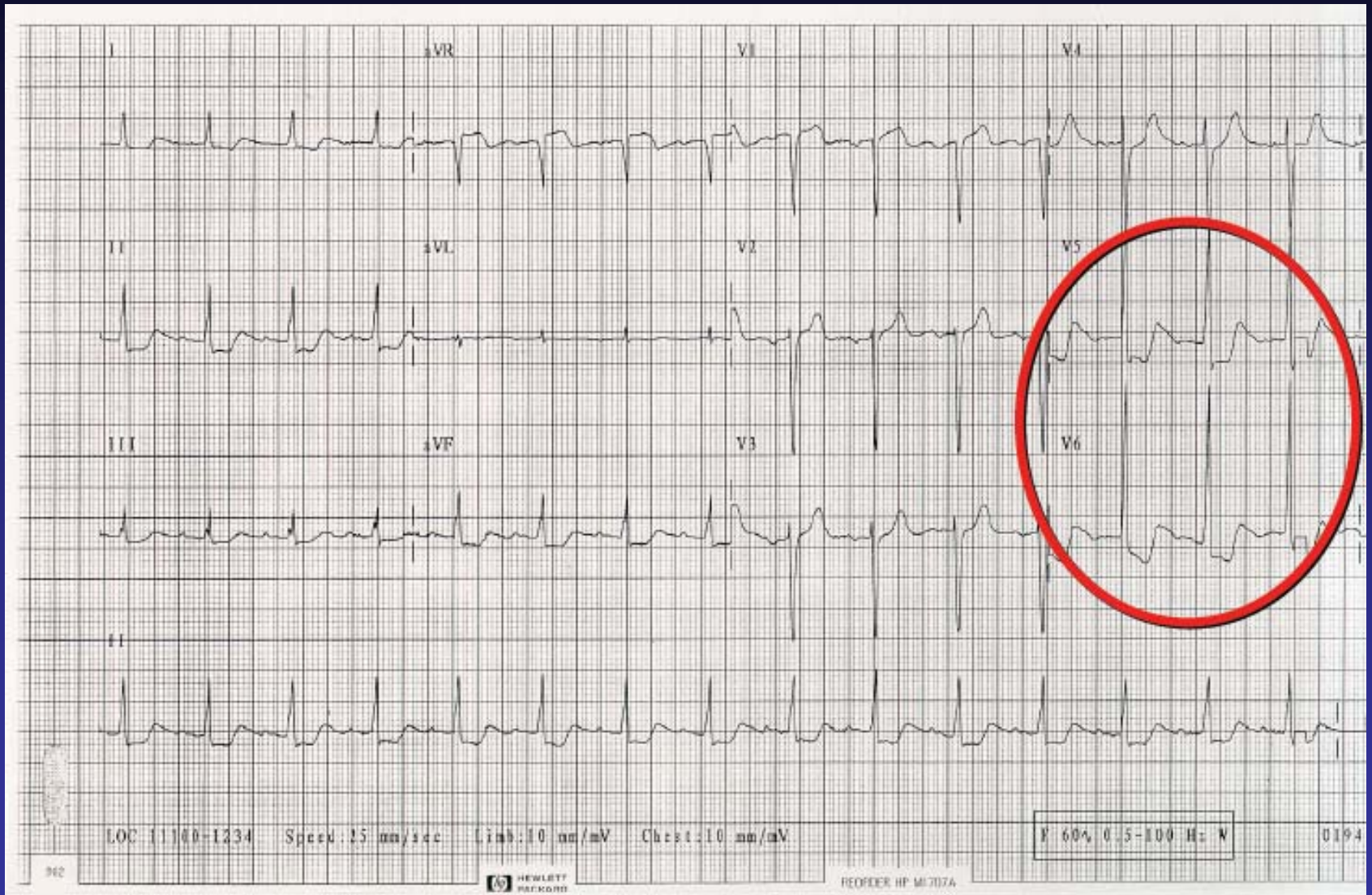


A case of ACS

- **76 year old woman presents to ER with shoulder discomfort**
- **Chronic risk factors: hyperlipidemia, type II diabetes, HTN, chronic renal insufficiency**
- **Left shoulder pain improved with movement, massage therapy. Similar symptoms on exercise bike, resolves after 10 minutes**
- **Exam: HR 90, BP 118/70; crackles at both lung bases**
- **Labs: creatinine 1.7 mg/dL, Troponin T 0.32**



A case of ACS



According to GRACE score, what is her in-hospital and 6-month mortality rate?

- 2-3% and 5%
- 5% and 9%
- 10% and 15%
- 20% and 30%



GRACE Score

GRACE™ ACS Risk Model 0.36

Age ▼ Years **HR** ▼ bpm
SBP ▼ mmHg **Creat.** ▼ mg/dL
CHF ▼ Killip Class

Cardiac arrest at admission
 ST-segment deviation
 Elevated cardiac enzymes

Probability of	Death	Death or MI
In-hospital	<input data-bbox="513 1079 697 1158" type="text" value="%"/>	<input data-bbox="813 1079 996 1158" type="text" value="%"/>
To 6 months	<input data-bbox="513 1168 697 1246" type="text" value="%"/>	<input data-bbox="813 1168 996 1246" type="text" value="%"/>

Variables

- Age (continuous)
- Killip class
- Blood pressure
- ST deviation
- Cardiac arrest
- Creatinine
- Elevated CK-MB or Tn
- Heart rate

GRACE Score

Variables

- Age (continuous) 76
- Killip class II
- Blood pressure 118/70
- ST deviation yes
- Cardiac arrest no
- Creatinine 1.7
- Elevated CK-MB/Tn yes
- Heart rate 90



	In-hosp	6 mo
Death	20%	30%
Death/MI	30%	50%

Selection of Initial Treatment Strategy: Invasive Versus Conservative Strategy

Preferred Strategy	Patient Characteristics
Invasive	<ul style="list-style-type: none">Recurrent angina or ischemia at rest or with low-level activities despite intensive medical therapyElevated cardiac biomarkers (TnT or Tnl)New or presumably new ST-segment depressionSigns or symptoms of HF or new or worsening mitral regurgitationHigh-risk findings from noninvasive testingHemodynamic instabilitySustained ventricular tachycardiaPCI within 6 monthsPrior CABGHigh risk score (e.g., TIMI, GRACE)Reduced left ventricular function (LVEF less than 40%)
Conservative	<ul style="list-style-type: none">Low risk score (e.g., TIMI, GRACE)Patient or physician preference in the absence of high-risk features

UA/NSTEMI ACC/AHA guidelines. Circulation 2007

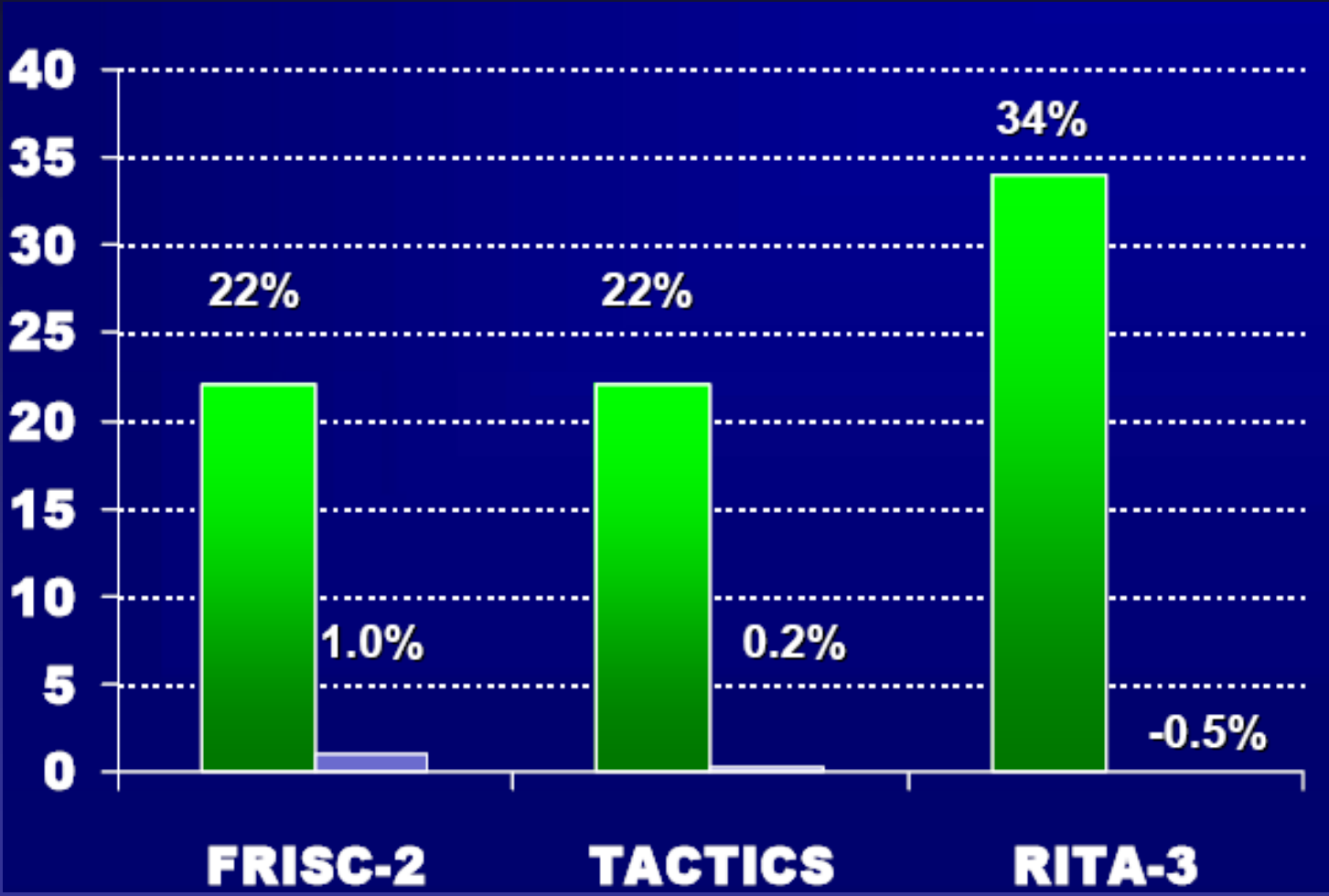


Non STE ACS

Early Versus Invasive
What's new?

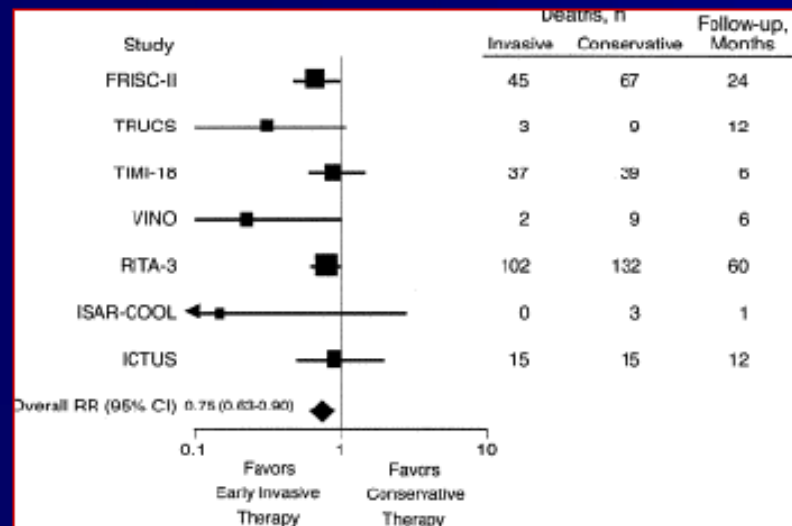


Randomized Trials in NonSTMI: Relative reduction in composite outcome and absolute difference in mortality

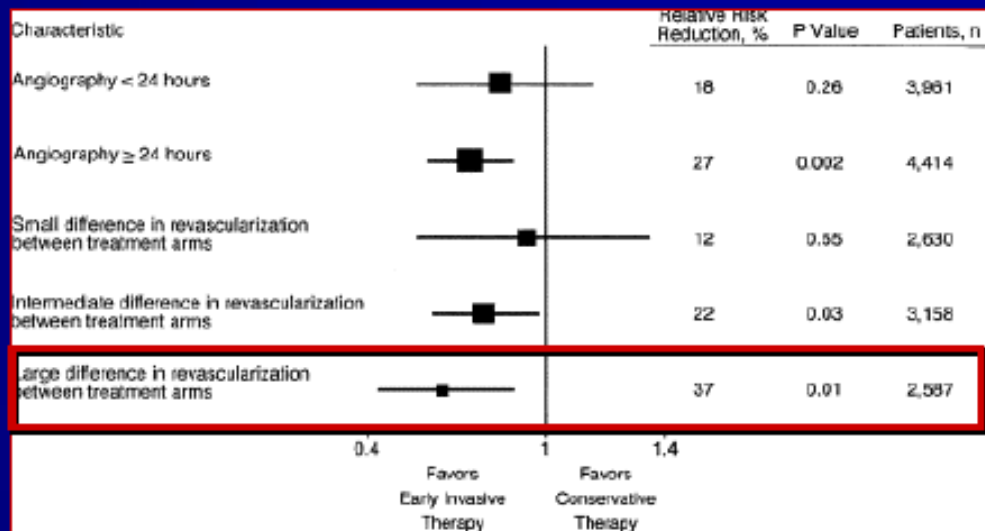


Bogarty et al. Lancet 2003

Early Invasive vs Selective Invasive Meta-analysis, average 2 year follow-up



**Death
(25% RRR, p=0.001)**

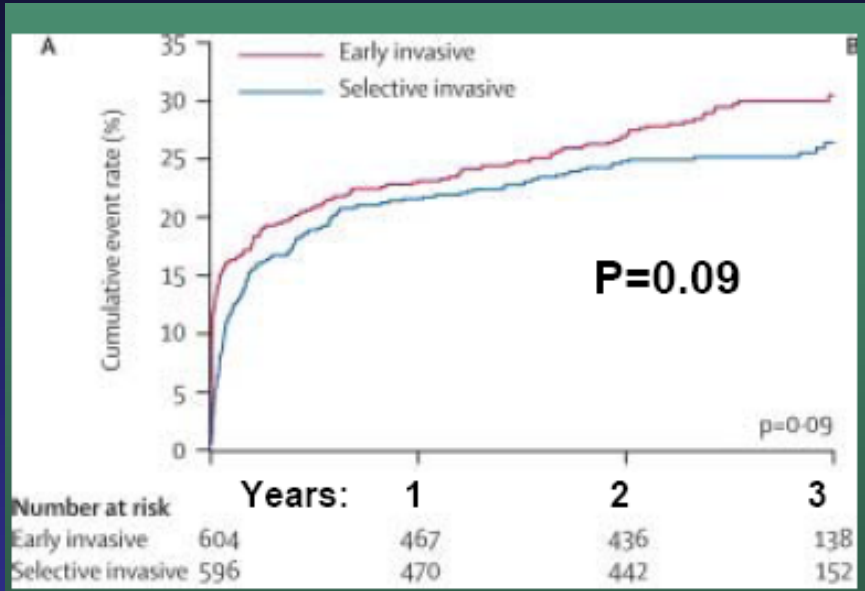


**Death, according to time to cath
and Δ revasc rates**

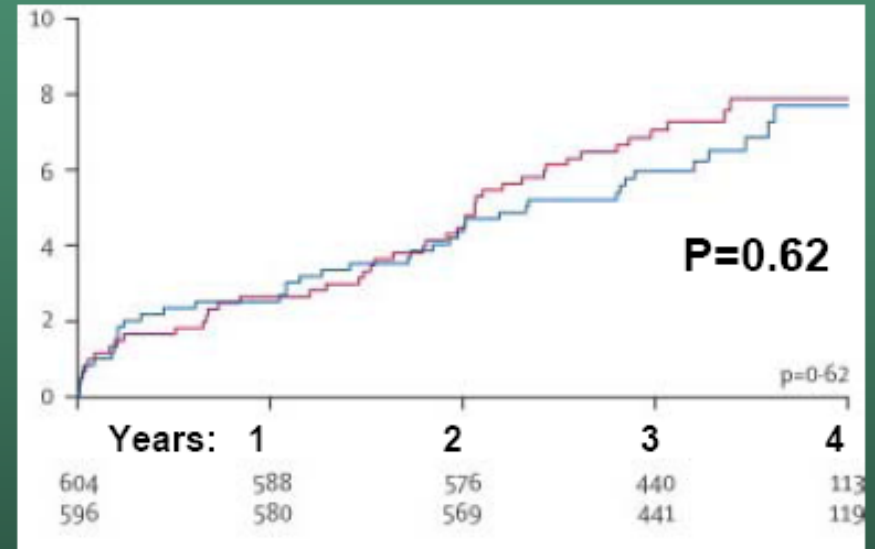
Bavry et al. JACC 2006



ICTUS – 4 year follow-up



Death, MI, Rehosp for angina

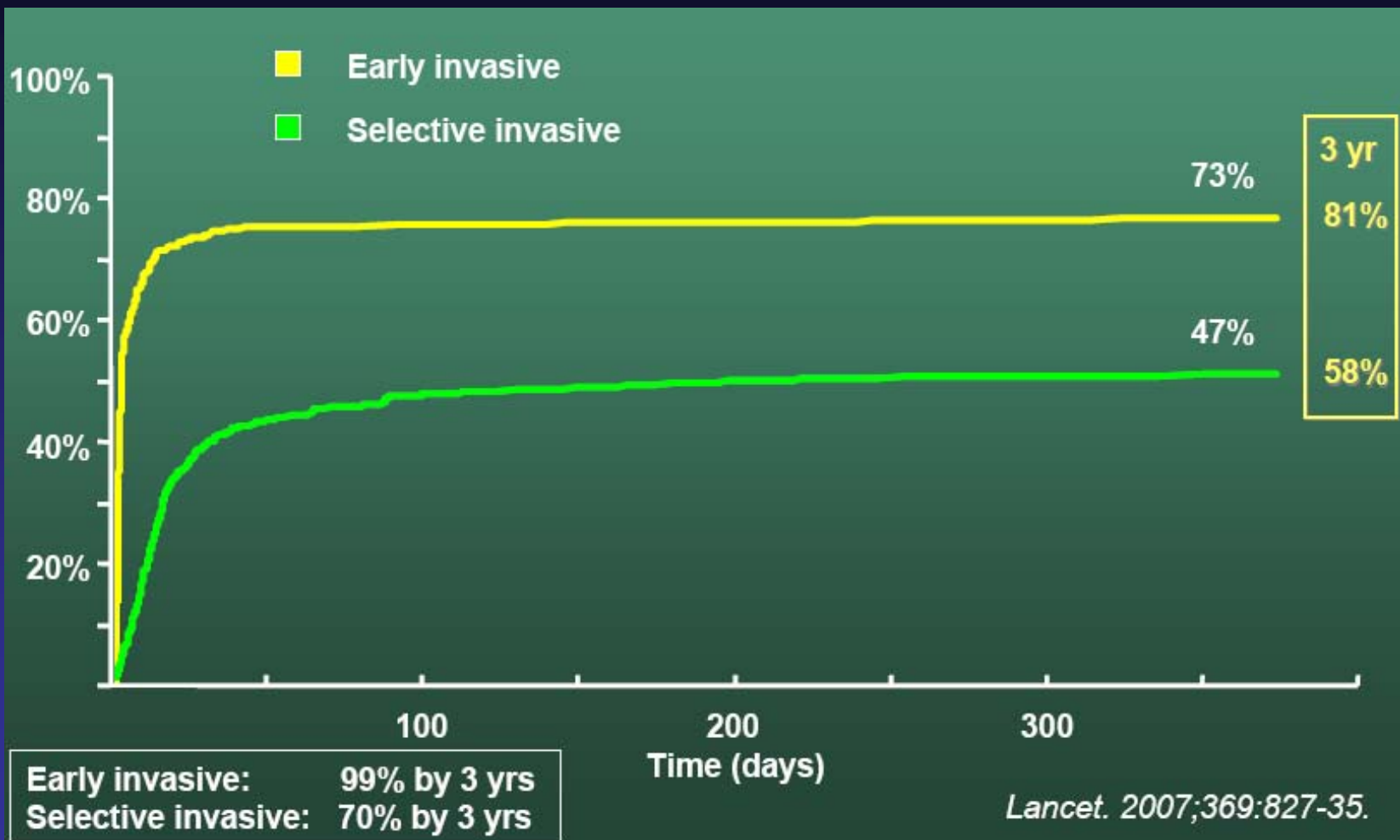


Death

Lancet 2007



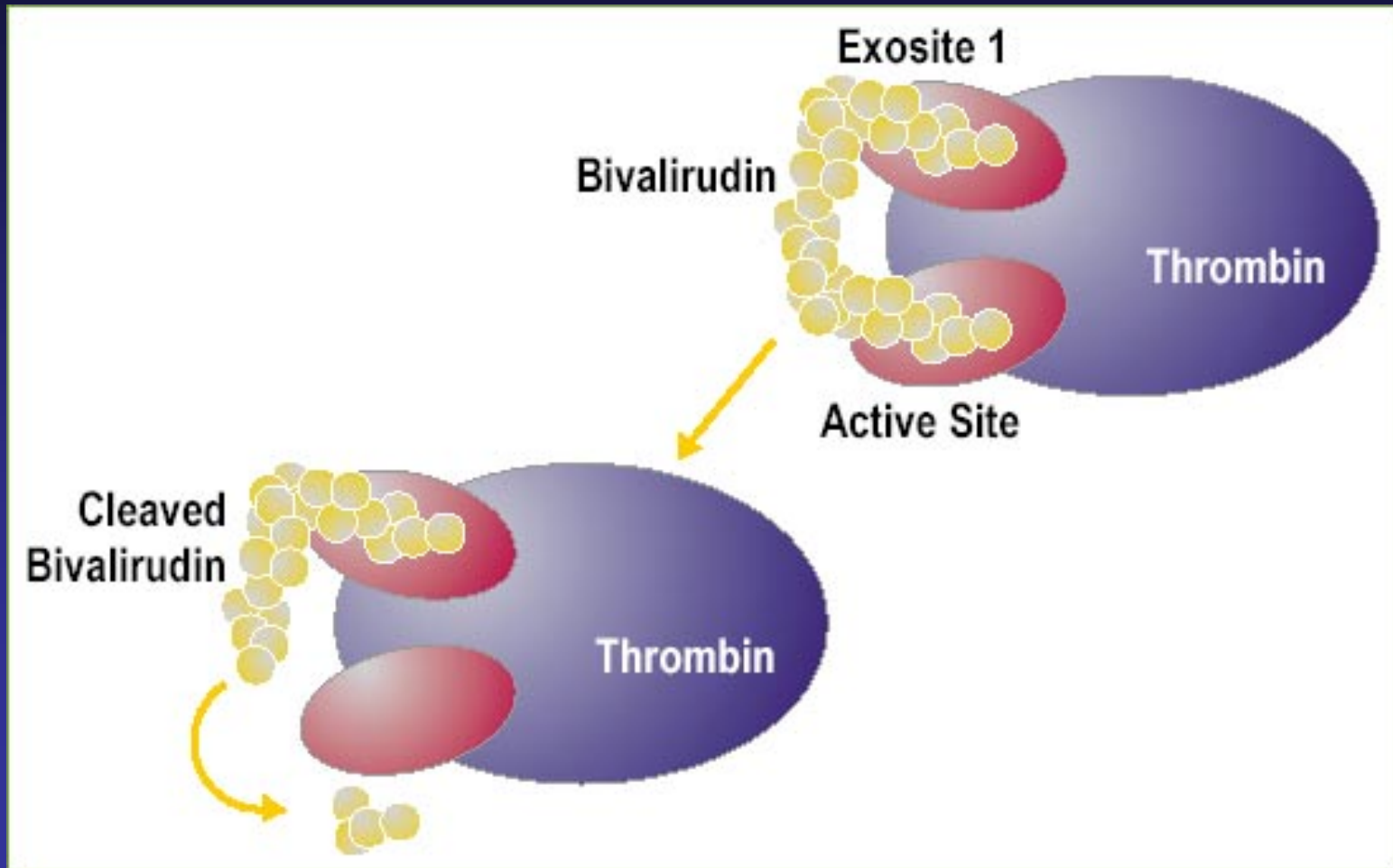
ICTUS – Revascularization



Lancet 2007



Bivalirudin



ACUITY Study

13,809 pts with mod-high risk ACS
undergoing early invasive therapy

Heparin + GPIIb/IIIa

Bivalirudin + GPIIb/IIIa

Bivalirudin alone

Stone G et al. N Engl J Med 2006



ACUITY: 30 day outcome

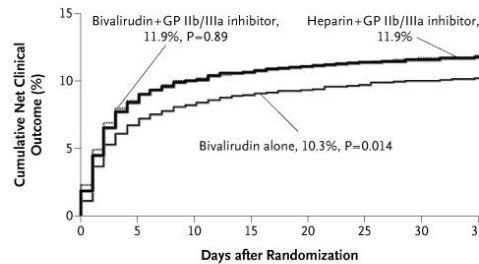
Outcome	Unfractionated Heparin or Enoxaparin plus Glycoprotein IIb/IIIa Inhibitors (N=4603)	Bivalirudin plus Glycoprotein IIb/IIIa Inhibitors (N=4604)	Risk Ratio (95% CI)	P Value	Bivalirudin Alone (N=4612)	Risk Ratio (95% CI) [†]	P Value [‡]
Net clinical outcome — no. (%)	538 (11.7)	541 (11.8)	1.01 (0.90–1.12)	<0.001 [‡] 0.93	466 (10.1)	0.86 (0.77–0.97)	<0.001 [‡] 0.015
Composite ischemia — no. (%)	334 (7.3)	356 (7.7)	1.07 (0.92–1.23)	0.007 [‡] 0.39	360 (7.8)	1.08 (0.93–1.24)	0.01 [‡] 0.32
Death from any cause	62 (1.3)	70 (1.5)		0.48	74 (1.6)		0.31
Myocardial infarction	227 (4.9)	229 (5.0)		0.93	248 (5.4)		0.33
Q wave	50 (1.1)	44 (1.0)		0.53	50 (1.1)		0.99
Non-Q wave	177 (3.8)	187 (4.1)		0.59	199 (4.3)		0.25
Unplanned revascularization for ischemia	105 (2.3)	123 (2.7)		0.23	110 (2.4)		0.74
Major bleeding (not related to CABG) — no. (%)	262 (5.7)	243 (5.3)	0.93 (0.78–1.10)	<0.001 [‡] 0.38	139 (3.0)	0.53 (0.43–0.65)	<0.001 [‡] <0.001
Intracranial	3 (<0.1)	3 (<0.1)		1.00	3 (<0.1)		1.00
Retroperitoneal	24 (0.5)	26 (0.6)		0.78	7 (0.2)		0.002
Access-site hemorrhage	117 (2.5)	117 (2.5)		1.00	38 (0.8)		<0.001
Requiring intervention or surgery	24 (0.5)	28 (0.6)		0.58	14 (0.3)		0.10
Hematoma ≥5 cm	102 (2.2)	101 (2.2)		0.94	32 (0.7)		<0.001
Hemoglobin decrease ≥3 g/dl with overt source	102 (2.2)	83 (1.8)		0.16	45 (1.0)		<0.001
Hemoglobin decrease ≥4 g/dl with no overt source	39 (0.8)	33 (0.7)		0.48	33 (0.7)		0.47
Blood transfusion	125 (2.7)	119 (2.6)		0.70	75 (1.6)		<0.001
Reoperation for bleeding	2 (<0.1)	5 (0.1)		0.45	4 (0.1)		0.69
All major bleeding — no. (%)	543 (11.8)	512 (11.1)		0.31	421 (9.1)		<0.001
Minor bleeding (not related to CABG) — no. (%) [§]	993 (21.6)	1001 (21.7)		0.84	592 (12.8)		<0.001
Bleeding according to the TIMI scale — no. (%)	306 (6.6)	297 (6.5)		0.70	183 (4.0)		<0.001
Major	86 (1.9)	76 (1.7)		0.43	43 (0.9)		<0.001
Minor	295 (6.4)	281 (6.1)		0.54	170 (3.7)		<0.001
Acquired thrombocytopenia — no. (%) [¶]	511 (11.1)	497 (10.8)		0.64	457 (9.9)		0.06

Stone G et al. N Engl J Med 2006



ACUITY - 30 day outcome

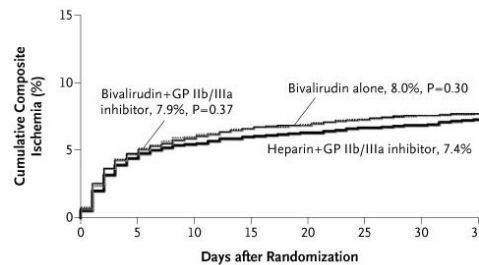
A Net Clinical Outcome



No. at Risk

Heparin + GP IIb/IIIa inhibitor	4603	4172	4091	4054	4030	3992	3529	2422
Bivalirudin + GP IIb/IIIa inhibitor	4604	4158	4084	4053	4030	3996	3550	2467
Bivalirudin alone	4612	4246	4173	4133	4112	4065	3614	2452

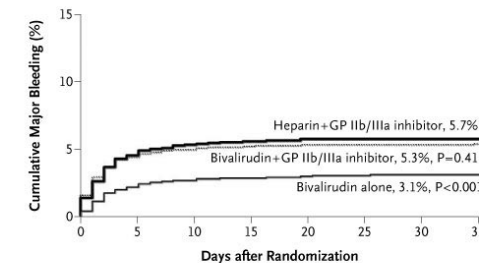
B Composite Ischemia



No. at Risk

Heparin + GP IIb/IIIa inhibitor	4603	4351	4296	4264	4245	4201	3708	2543
Bivalirudin + GP IIb/IIIa inhibitor	4604	4329	4265	4235	4215	4179	3719	2585
Bivalirudin alone	4612	4330	4276	4236	4218	4170	3708	2521

C Major Bleeding



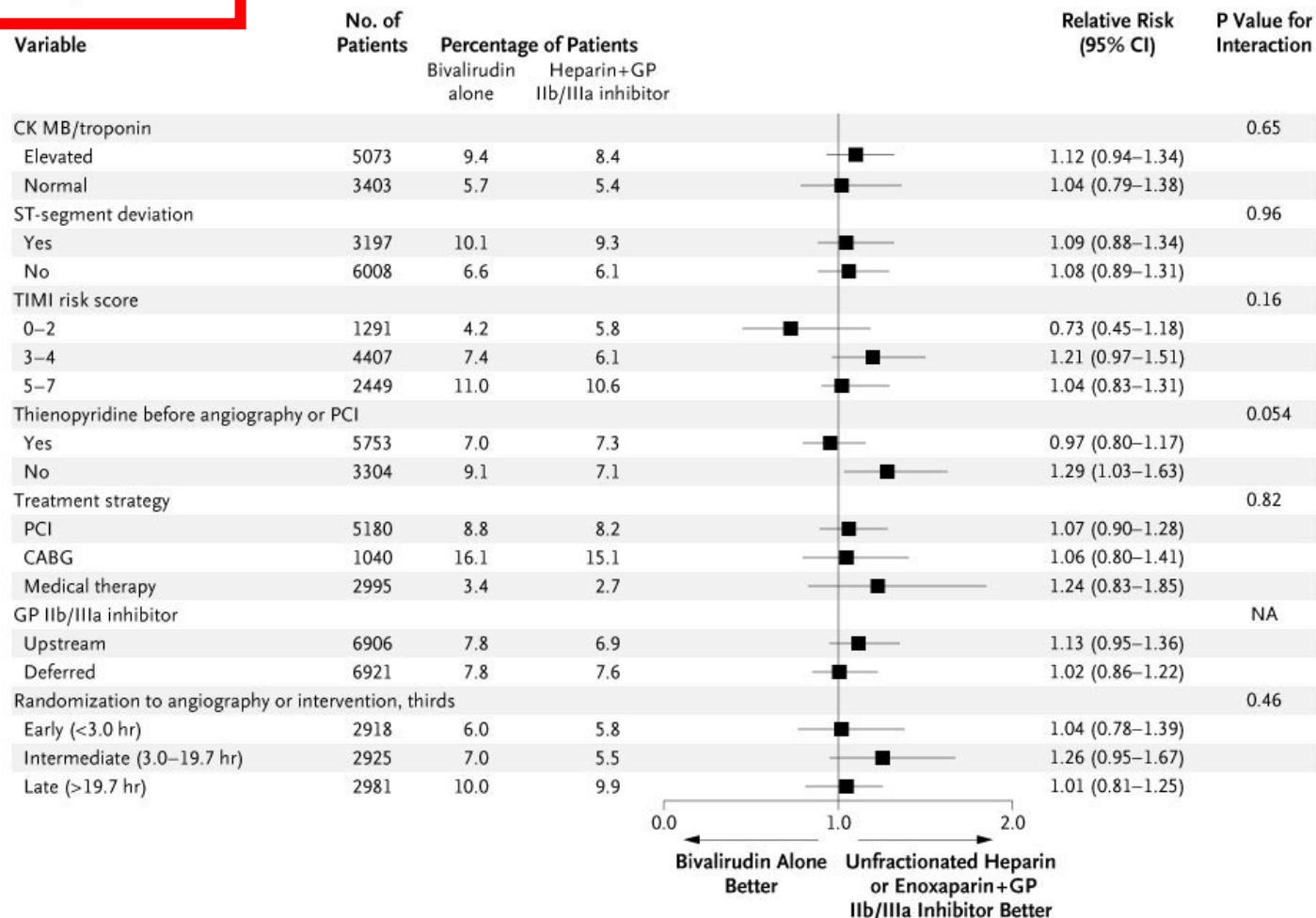
No. at Risk

Heparin + GP IIb/IIIa inhibitor	4603	4336	4282	4258	4240	4208	3729	2575
Bivalirudin + GP IIb/IIIa inhibitor	4604	4329	4286	4266	4250	4222	3761	2625
Bivalirudin alone	4612	4423	4389	4366	4352	4312	3846	2633



Acuity - Subgroup analysis

A Composite Ischemia

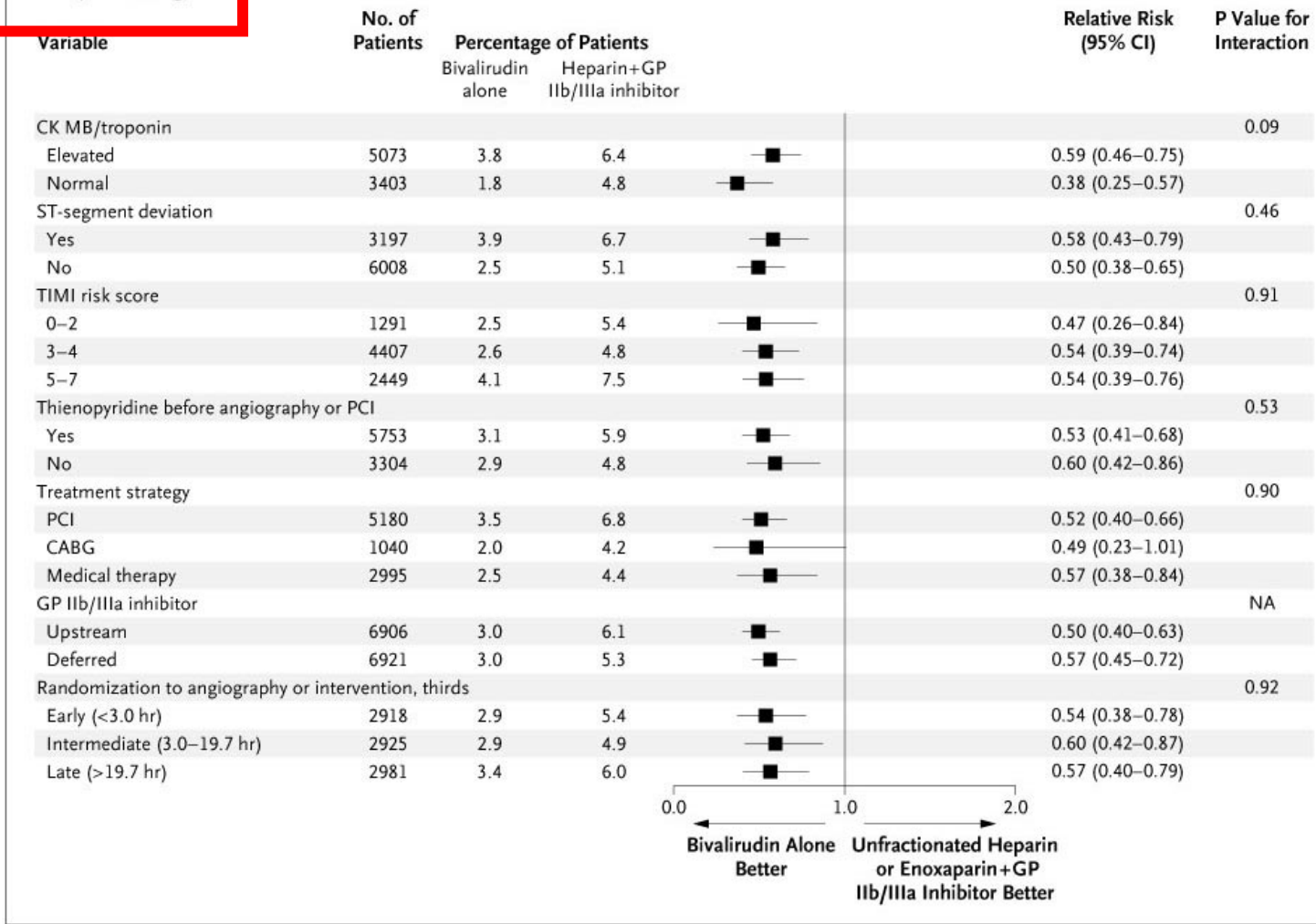


Stone G et al. N Engl J Med 2006



ACUITY - Subgroup analysis


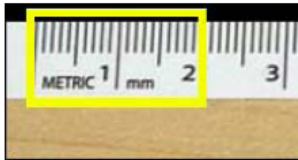
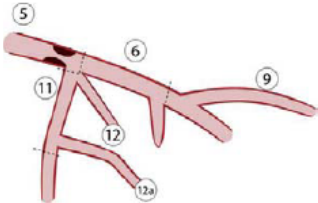
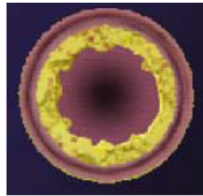
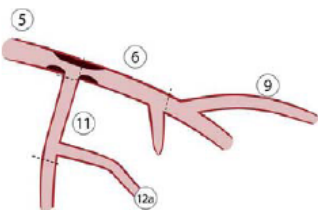
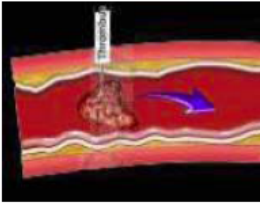
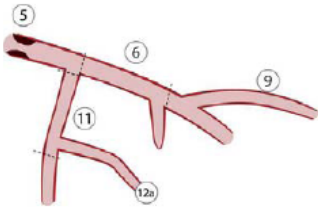

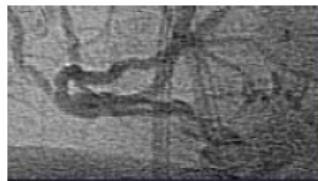
B Major Bleeding



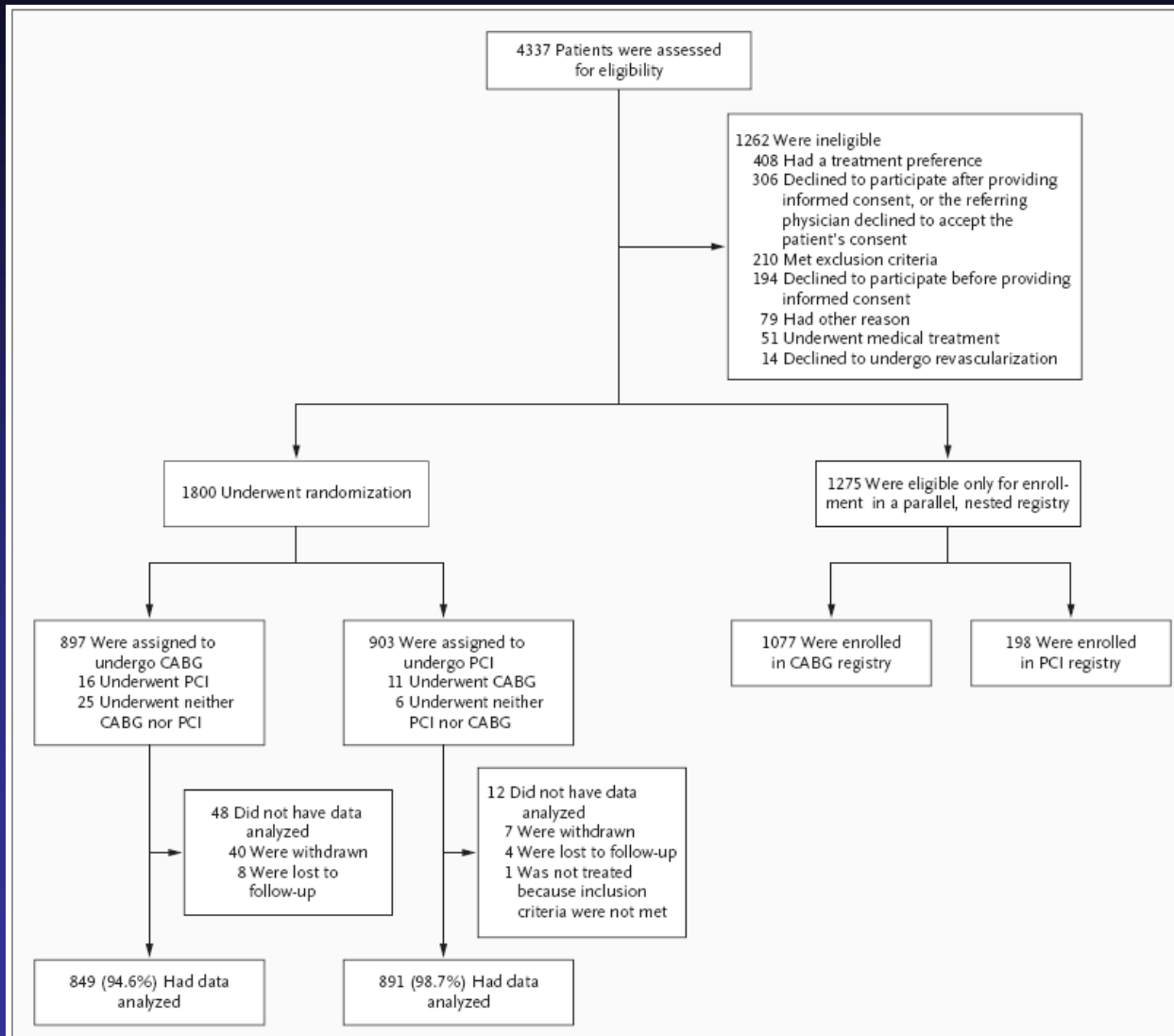
Multi-Vessel Disease



SYNTAX Score

<p>4. Total occlusion</p> 	<p>9. Length >20 mm</p> 
<p>5. Trifurcation</p> 	<p>10. Heavy calcification</p> 
<p>6. Bifurcation</p> 	<p>11. Thrombus</p> 
<p>7. Aorto Ostial lesion</p> 	<p>12. "Diffuse disease"/ small vessels</p> 
<p>8. Severe Tortuosity</p> 	

SYNTAX Trial

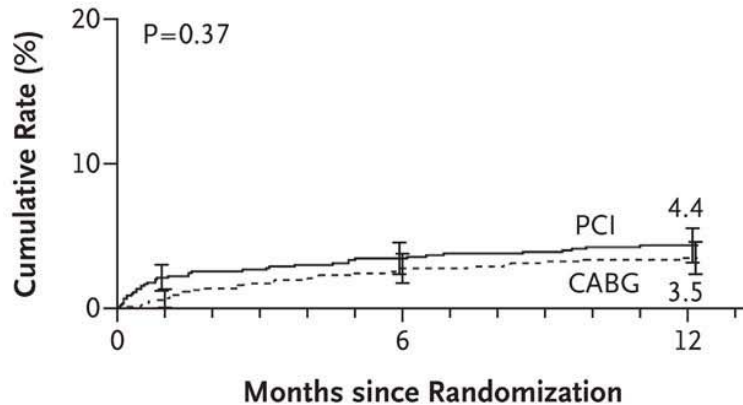


Serruys PW et al. N Engl J Med 2009

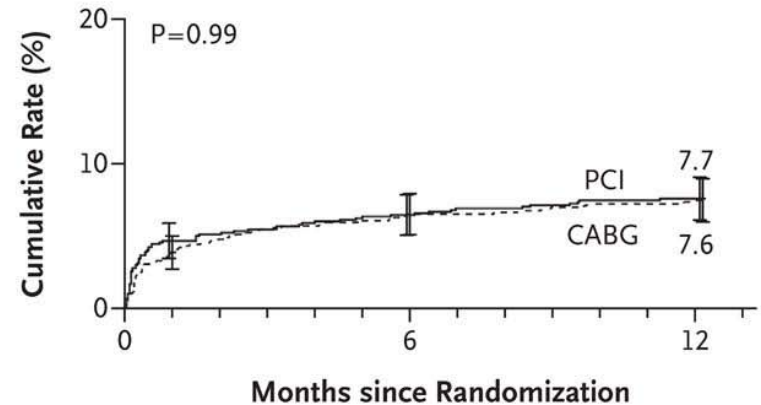


SYNTAX Trial

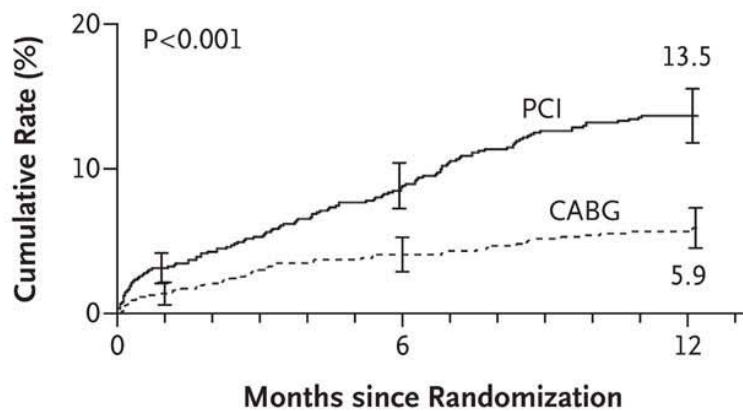
A Death from Any Cause



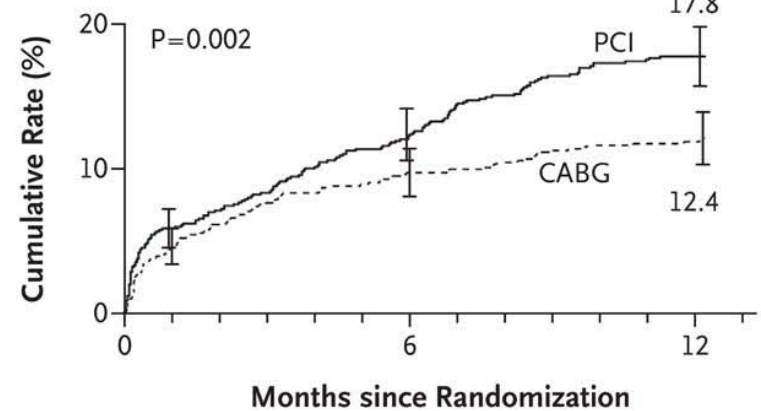
B Death from Any Cause, Stroke, or MI



C Repeat Revascularization



D Major Adverse Cardiac or Cerebrovascular Event



SYNTAX Trial

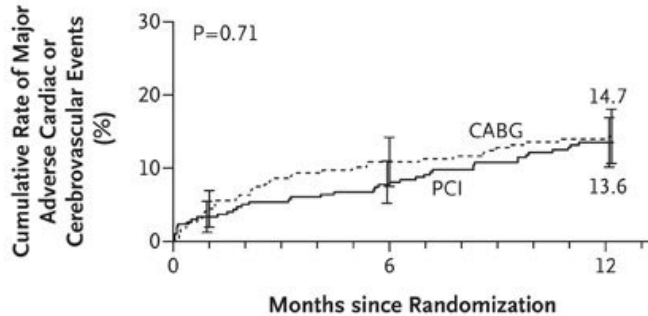
Table 3. Clinical End Points Occurring in the Hospital or after Discharge, According to Study Group.*

Variable	PCI	CABG	P Value	Relative Risk with PCI (95% CI)
	no./total no. (%)			
Major adverse cardiac or cerebrovascular event				
In hospital	39/896 (4.4)	47/870 (5.4)	0.31	0.81 (0.53–1.22)
30 Days after procedure	54/895 (6.0)	45/866 (5.2)	0.45	1.16 (0.79–1.71)
6 Mo after randomization	111/893 (12.4)	85/860 (9.9)	0.09	1.26 (0.96–1.64)
12 Mo after randomization	159/891 (17.8)	105/849 (12.4)	0.002	1.44 (1.15–1.81)
Death, stroke, or MI	68/891 (7.6)	65/849 (7.7)	0.98	1.00 (0.72–1.38)
Death	39/891 (4.4)	30/849 (3.5)	0.37	1.24 (0.78–1.98)
From cardiac causes	33/891 (3.7)	18/849 (2.1)	0.05	1.75 (0.99–3.08)
From cardiovascular causes	1/891 (0.1)	3/849 (0.4)	0.36†	0.32 (0.03–3.05)
From noncardiovascular causes	5/891 (0.6)	9/849 (1.1)	0.24	0.53 (0.18–1.57)
Stroke	5/891 (0.6)	19/849 (2.2)	0.003	0.25 (0.09–0.67)
MI	43/891 (4.8)	28/849 (3.3)	0.11	1.46 (0.92–2.33)
Repeat revascularization‡	120/891 (13.5)	50/849 (5.9)	<0.001	2.29 (1.67–3.14)
CABG	25/891 (2.8)	11/849 (1.3)	0.03	2.17 (1.07–4.37)
PCI	102/891 (11.4)	40/849 (4.7)	<0.001	2.43 (1.71–3.46)
Graft occlusion or stent thrombosis§	28/848 (3.3)	27/784 (3.4)	0.89	0.96 (0.57–1.62)
Acute (at ≤1 day)	2/896 (0.2)	3/870 (0.3)	0.68†	0.65 (0.11–3.86)
Early (within 2–30 days)	18/893 (2.0)	3/868 (0.3)	0.001	5.83 (1.72–19.73)
Late (within 31–365 days)	9/874 (1.0)	21/854 (2.5)	0.02	0.42 (0.19–0.91)

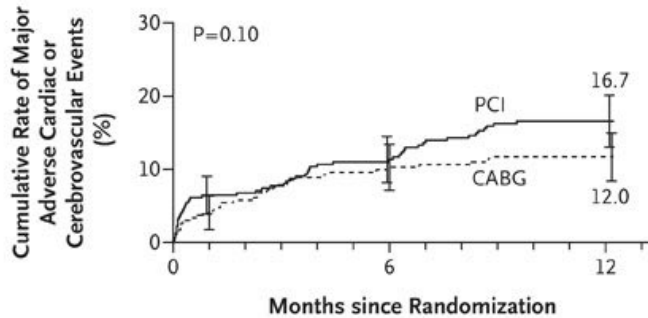


SYNTAX Trial

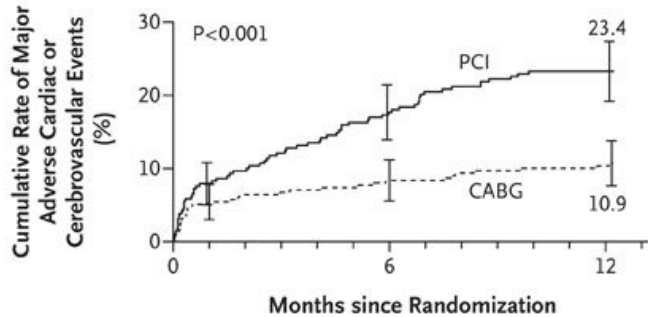
A Low SYNTAX Score



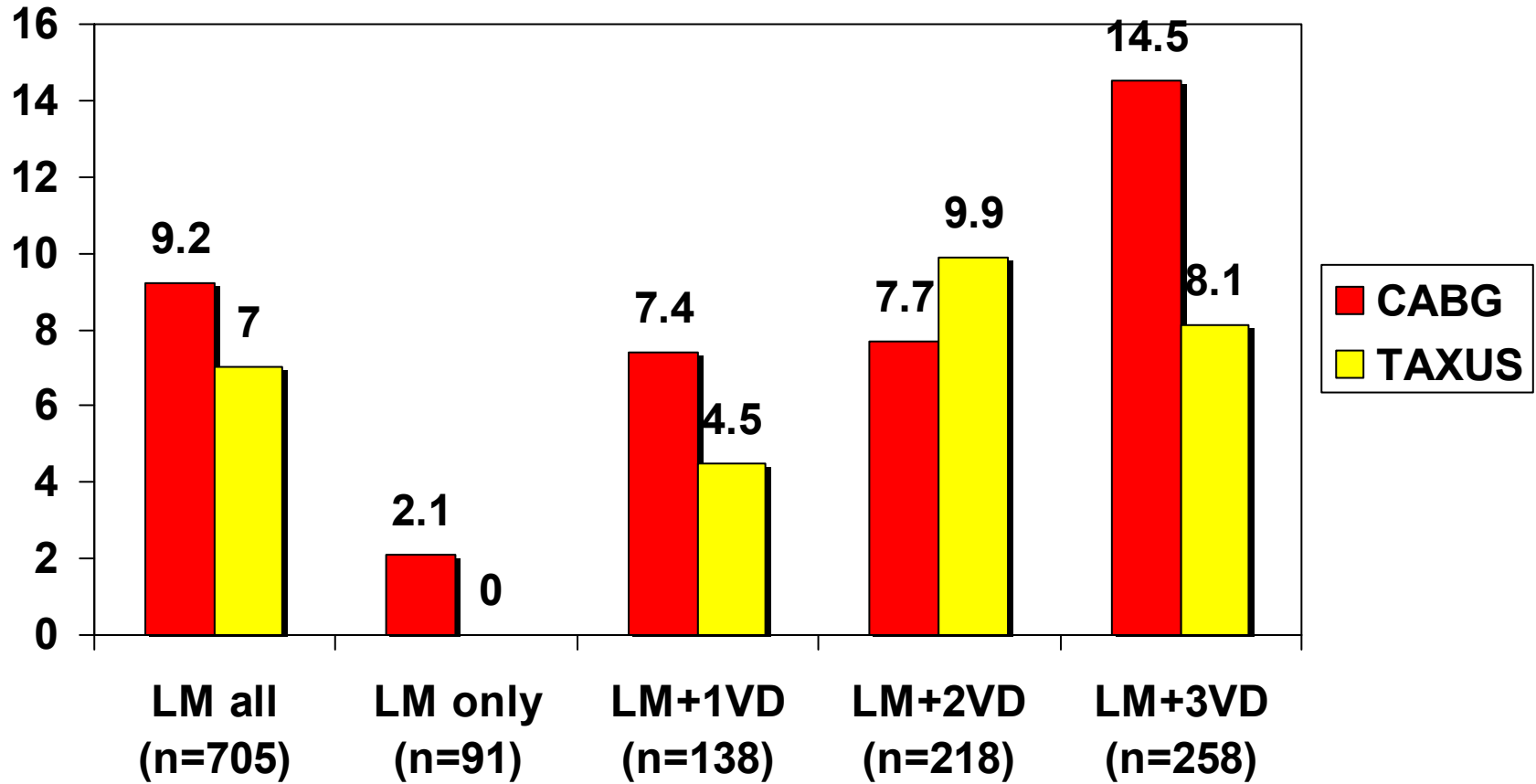
B Intermediate SYNTAX Score



C High SYNTAX Score



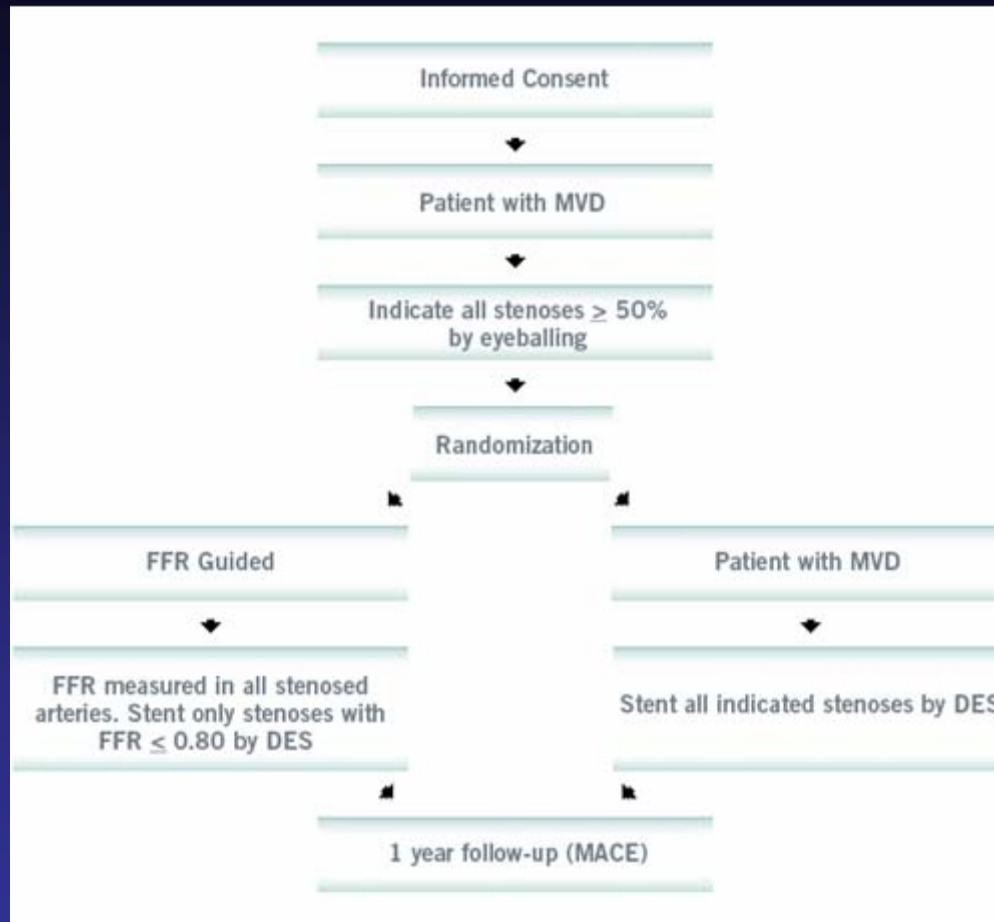
SYNTAX – Safety @ 12 Mo. Death / CVA / MI in LM Subset



The Revival of FFR



FAME Study



- **Primary EP - Composite of death, myocardial infarction, or repeat revascularization (“MACE”) at 1 year**

FAME Study

	ANGIO-group N=496	FFR-group N=509	P-value
# indicated lesions per patient	2.7 ± 0.9	2.8 ± 1.0	0.34
FFR results			
Lesions successfully measured, No (%)	-	1329 (98%)	-
Lesions with FFR ≤ 0.80 ,No (%)	-	874 (63%)	-
Lesions with FFR > 0.80 ,No (%)	-	513 (37%)	-
stents per patient	2.7 ± 1.2	1.9 ± 1.3	<0.001
Lesions successfully stented (%)	92%	94%	-
DES, total, No	1359	980	-



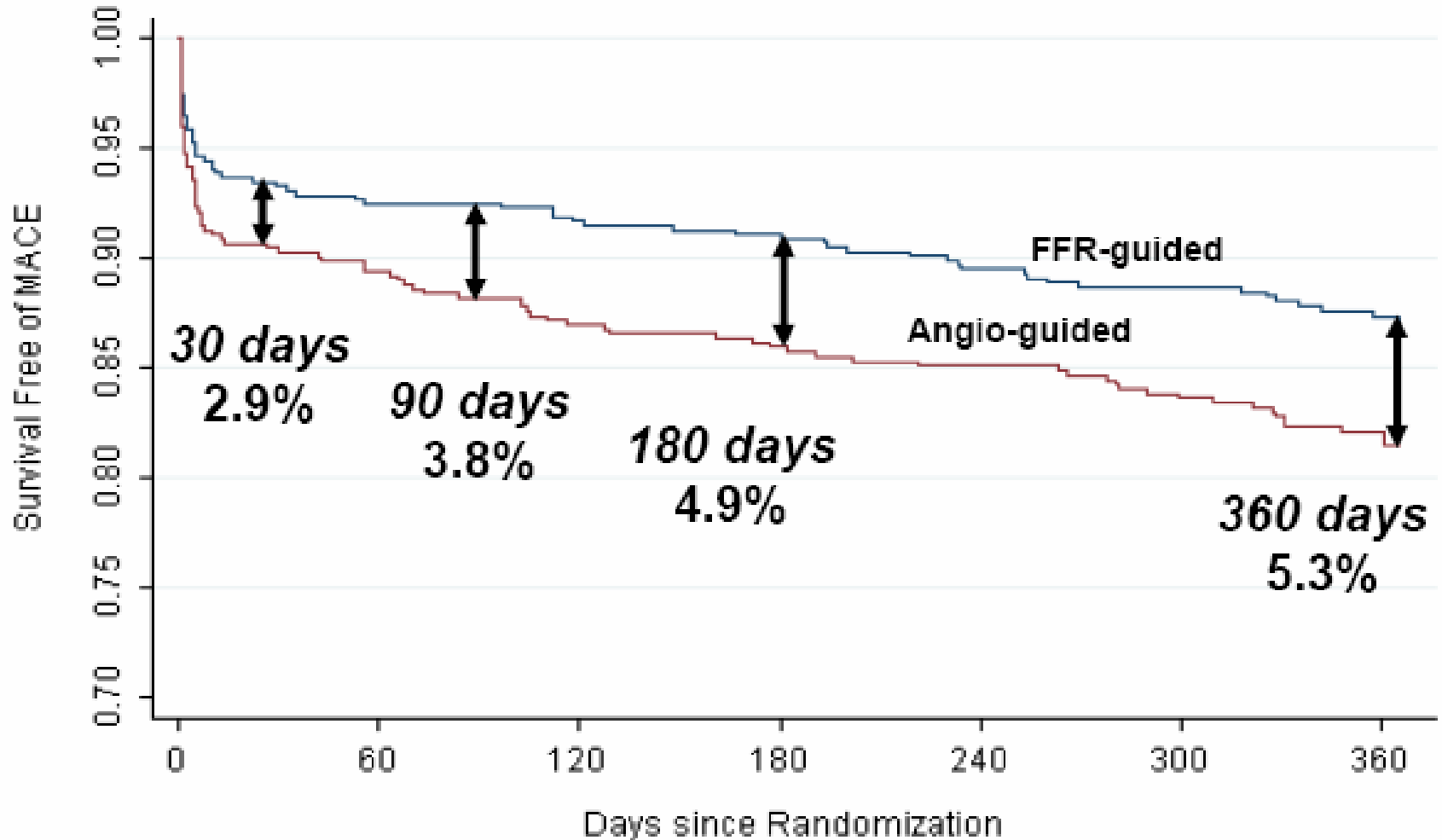
FAME Study

	ANGIO-group N=496	FFR-group N=509	P-value
<i>Events at 1 year, No (%)</i>			
Death, MI, CABG, or repeat-PCI	91 (18.4)	67 (13.2)	0.02
Death	15 (3.0)	9 (1.8)	0.19
Death or myocardial infarction	55 (11.1)	37 (7.3)	0.04
CABG or repeat PCI	47 (9.5)	33 (6.5)	0.08
Total no. of MACE	113	76	0.02
<i>Myocardial infarction, specified</i>			
All myocardial infarctions	43 (8.7)	29 (5.7)	0.07
Small periprocedural CK-MB 3-5 x N	16	12	
Other infarctions ("late or large")	27	17	

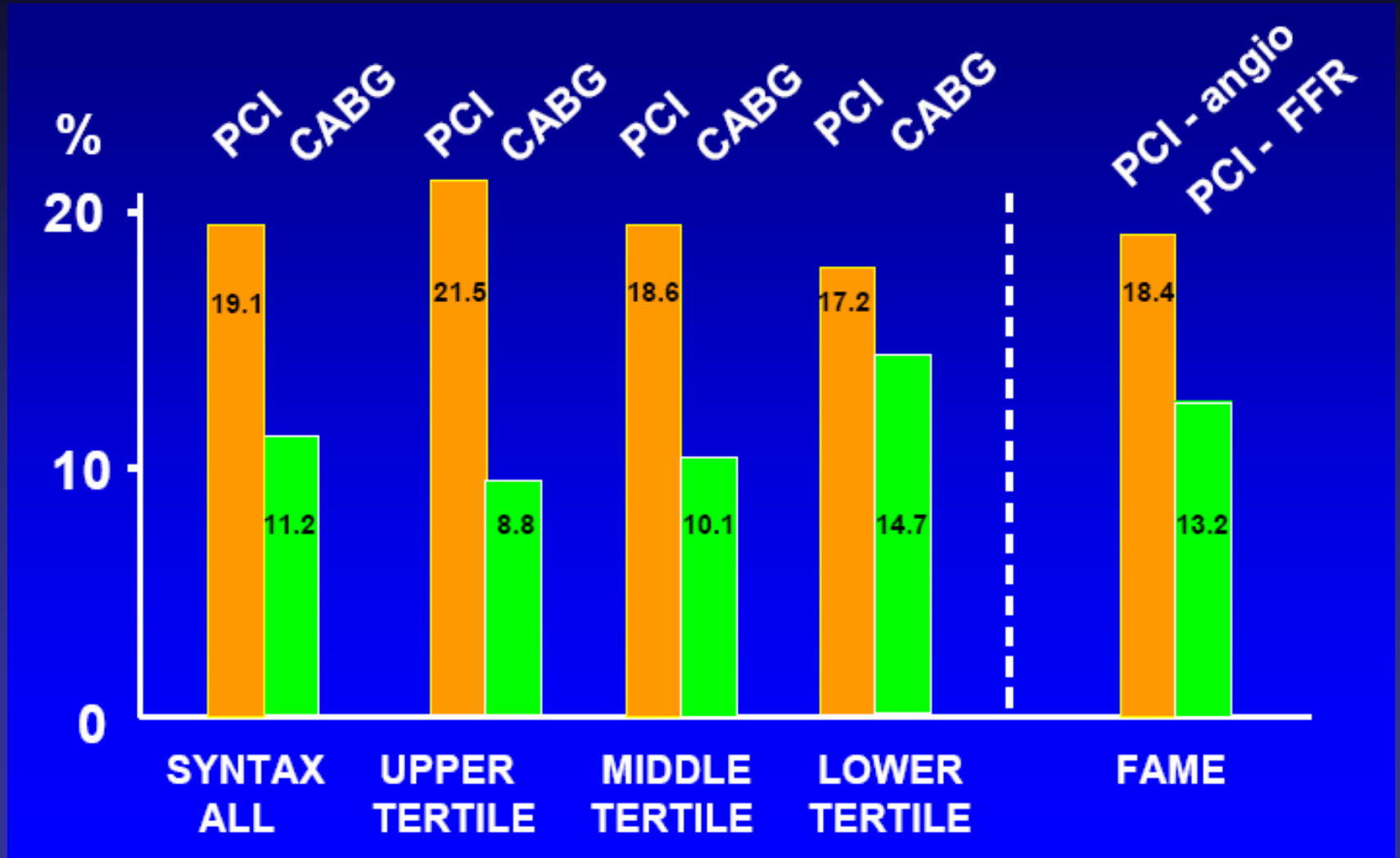


FAME Study

absolute difference in MACE-free survival



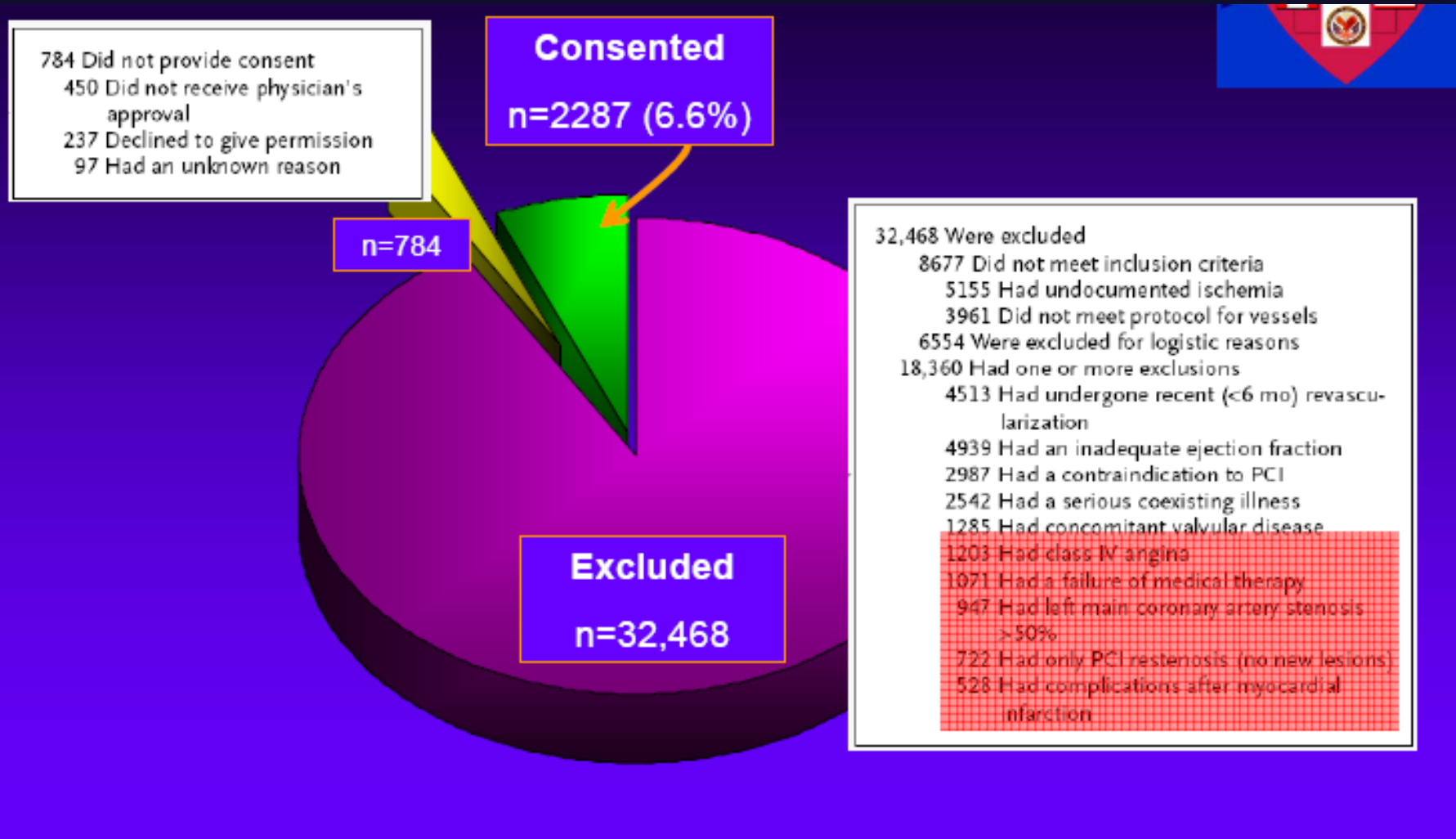
SYNTAX Vs. FAME



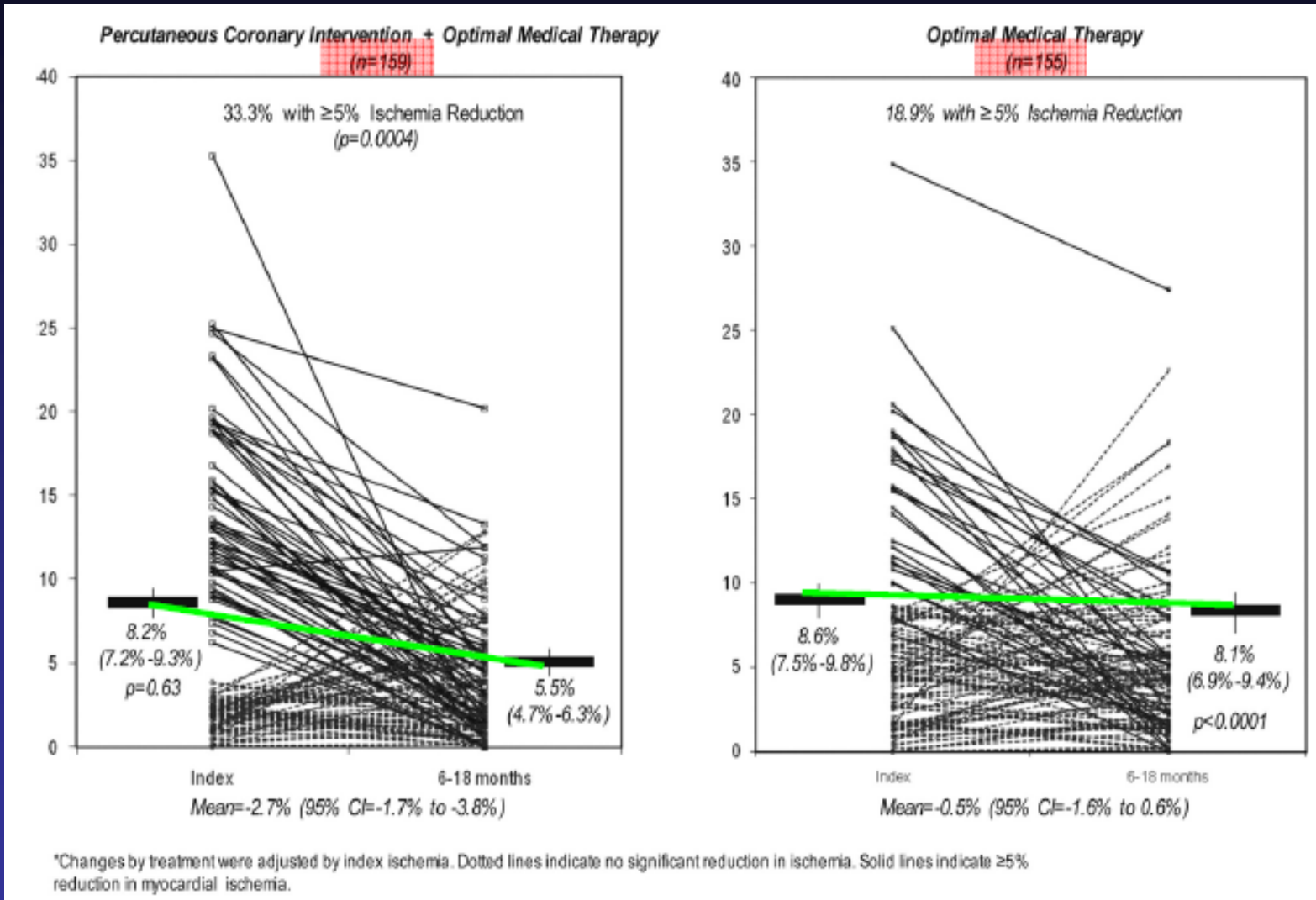
PCI in Stable Angina



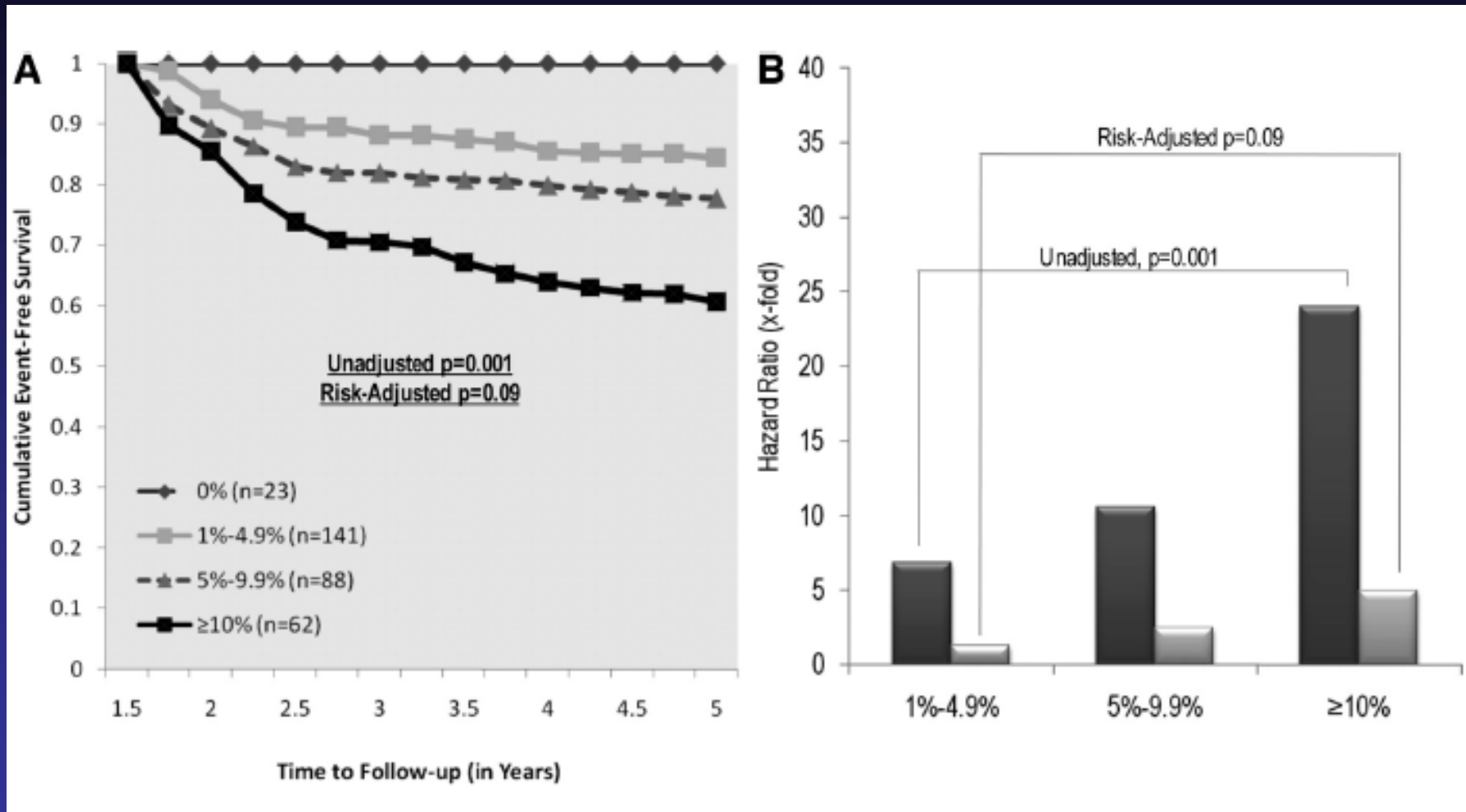
COURAGE – Patients Screening



COURAGE – Nuclear Substudy



COURAGE – Outcome by residual ischemia



The NEW ENGLAND JOURNAL of MEDICINE

ORIGINAL ARTICLE

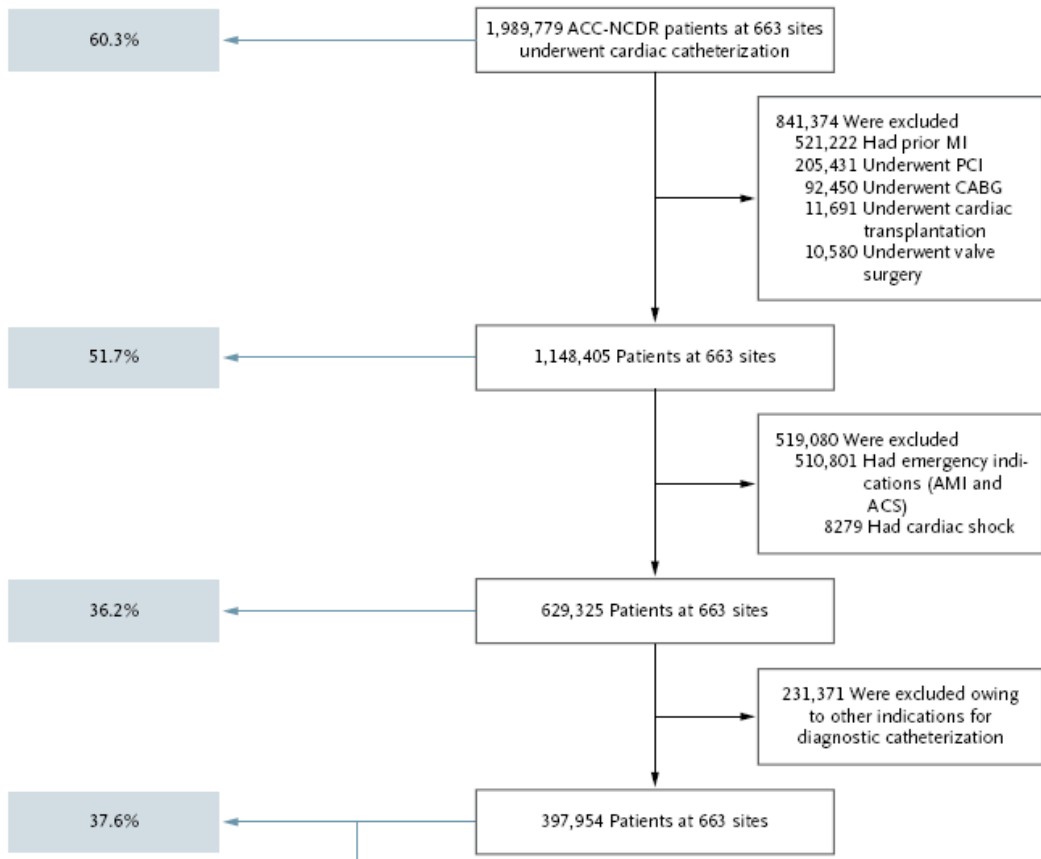
Low Diagnostic Yield of Elective Coronary Angiography

Manesh R. Patel, M.D., Eric D. Peterson, M.D., M.P.H., David Dai, M.S.,
J. Matthew Brennan, M.D., Rita F. Redberg, M.D., H. Vernon Anderson, M.D.,
Ralph G. Brindis, M.D., and Pamela S. Douglas, M.D.

N Engl J Med 2010;362:886-95.



Rate of Obstructive CAD



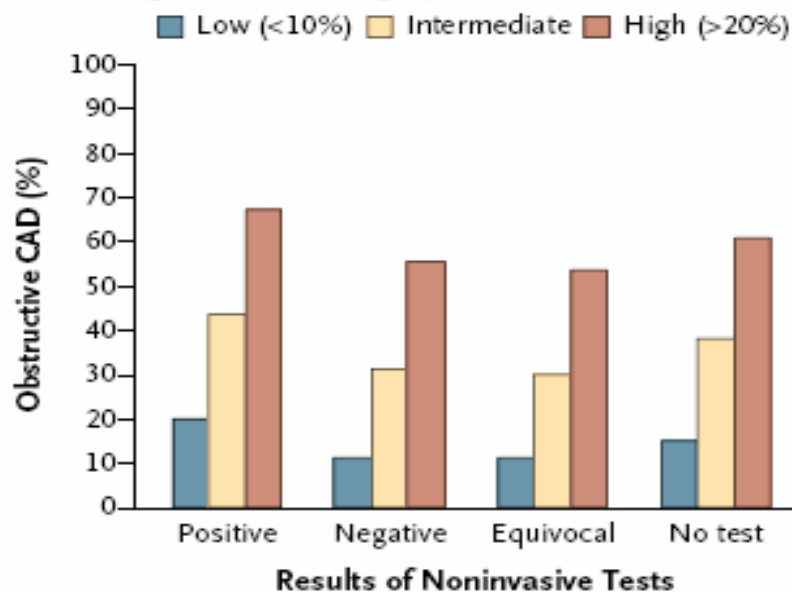
Obstructive CAD (N=149,739)

Multivessel CAD	53.0%
1-vessel CAD	46.7%
2-vessel CAD	30.5%
3-vessel CAD	22.5%



Patients with Obstructive Coronary Artery Disease, According to Noninvasive Test Result

A Framingham Risk Category



B Symptom Characteristic

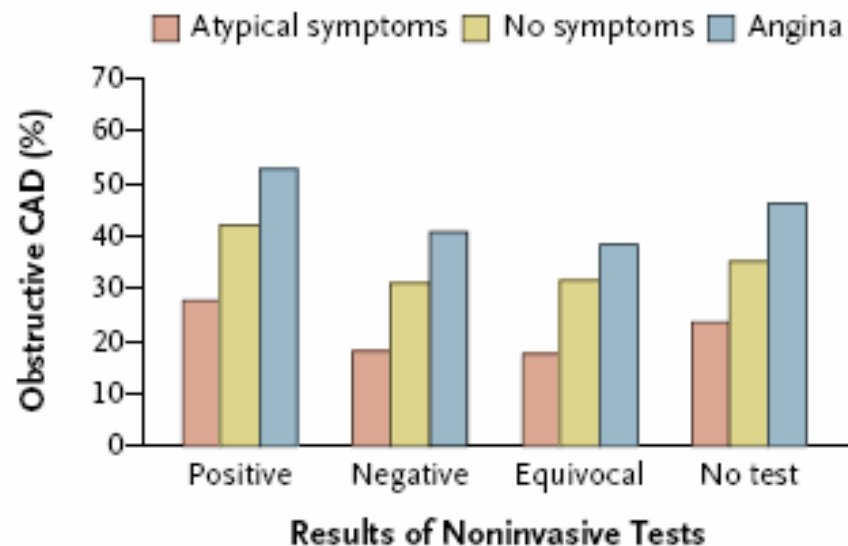


Table 2. Predictors of Obstructive Coronary Artery Disease.

Variable	Wald Chi-Square Statistic	Adjusted Odds Ratio (95% CI)
Age, per 5-yr increase	6146.2	1.29 (1.28–1.30)
Body-mass index, per 5-unit increase*	550.3	0.92 (0.91–0.92)
Male sex	8632.9	2.70 (2.64–2.76)
White race†	50.2	1.21 (1.15–1.28)
Diabetes‡		
Insulin-dependent	1932.3	2.14 (2.07–2.21)
Non-insulin-dependent	1187.8	1.45 (1.42–1.48)
Dyslipidemia	972.8	1.62 (1.57–1.67)
Use of tobacco		
Current	790.4	1.50 (1.45–1.54)
Former	34.3	1.09 (1.06–1.12)
Hypertension	561.4	1.29 (1.26–1.32)
Peripheral vascular disease	449.5	1.54 (1.48–1.61)
Cerebrovascular disease	197.8	1.26 (1.21–1.30)
Ejection fraction, per 5% increase	374.7	1.08 (1.07–1.09)
Congestive heart failure	83.1	0.80 (0.76–0.84)
Glomerular filtration rate, per 5-unit increase§	31.3	1.01 (1.00–1.01)
Renal failure¶		
Requiring dialysis	26.9	1.30 (1.18–1.43)
Not requiring dialysis	14.1	1.15 (1.07–1.23)
Chronic lung disease	298.6	0.78 (0.76–0.80)
Presence of symptoms		
Typical	353.6	1.91 (1.78–2.05)
Atypical	84.2	0.76 (0.71–0.80)
Noninvasive testing**		
Positive result	48.9	1.28 (1.19–1.37)
Equivocal result	25.3	0.79 (0.71–0.86)
Negative result	19.4	0.82 (0.74–0.89)



Trans-Catheter Aortic Valve Implantation (TAVI)

Edwards

Trans-femoral

Trans-apical

CoreValve

Trans-femoral



“High Risk” AS Patients

- **Octogenarians with multiple co-morbidities**
 - COPD
 - Diabetes
 - PVD
 - Reduced LVEF
 - Renal failure
 - Previous cardiac surgery
- **Euroscore >20% (~10% mortality@30 days)**
- **STS >10%**



Inoperable AS Patients

- Radiation chest wall / heart disease
- Severe chest wall deformities
- End-stage COPD
- Cirrhosis with portal hypertension
- Porcelain aorta (CT proven)
- Degenerative neurocognitive dysfunction
- High “frailty” index (qualitative assessment)
- >50% chance of mortality or never leaving a chronic care facility

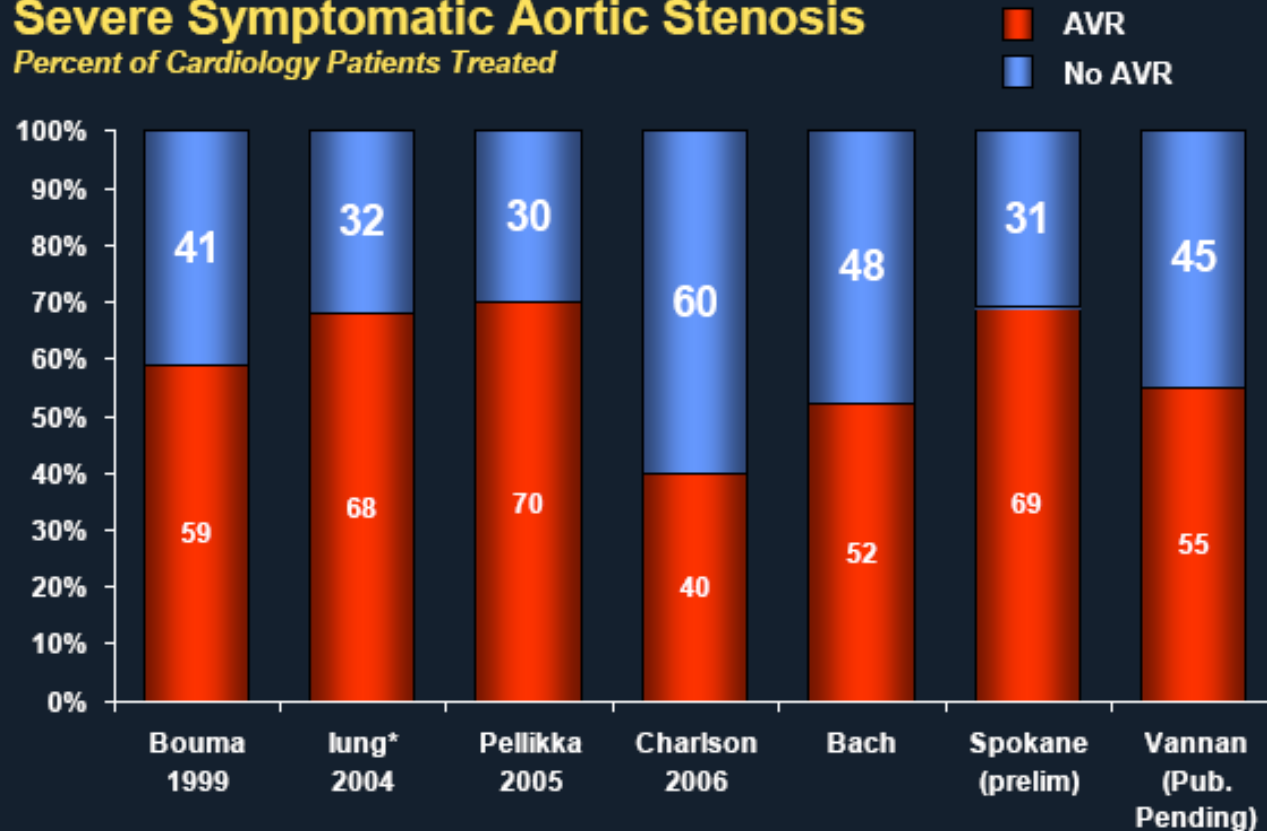
Surgeons are gatekeepers !!!



At least 30% of severe AS pts. are untreated

Severe Symptomatic Aortic Stenosis

Percent of Cardiology Patients Treated



Under-treatment especially prevalent among patients managed by *Primary Care physicians*

1. Bouma B J et al. To operate or not on elderly patients with aortic stenosis: the decision and its consequences. *Heart* 1999;82:143-148
2. lung B et al. A prospective survey of patients with valvular heart disease in Europe: The Euro Heart Survey on Valvular Heart Disease. *European Heart Journal* 2003;24:1231-1243 (*includes both Aortic Stenosis and Mitral Regurgitation patients)
3. Pellikka, Sarano et al. Outcome of 622 Adults with Asymptomatic, Hemodynamically Significant Aortic Stenosis During Prolonged Follow-Up. *Circulation* 2005
4. Charlson E et al. Decision-making and outcomes in severe symptomatic aortic stenosis. *J Heart Valve Dis* 2006;15:312-321



“First” Generation Devices



Edwards
>2500 patients



CoreValve
>2500 patients

Pre-procedural Assessment

- **Clinical – cardiologist and surgeon**
- **Echocardiography – Measurements**
- **Confirmatory TEE if necessary**
- **Angiography**
 - Do any PCI before
 - Aortic injection
 - Iliac / femoral angiography
- **CTA if needed**
- **Any PCI should be done before!**

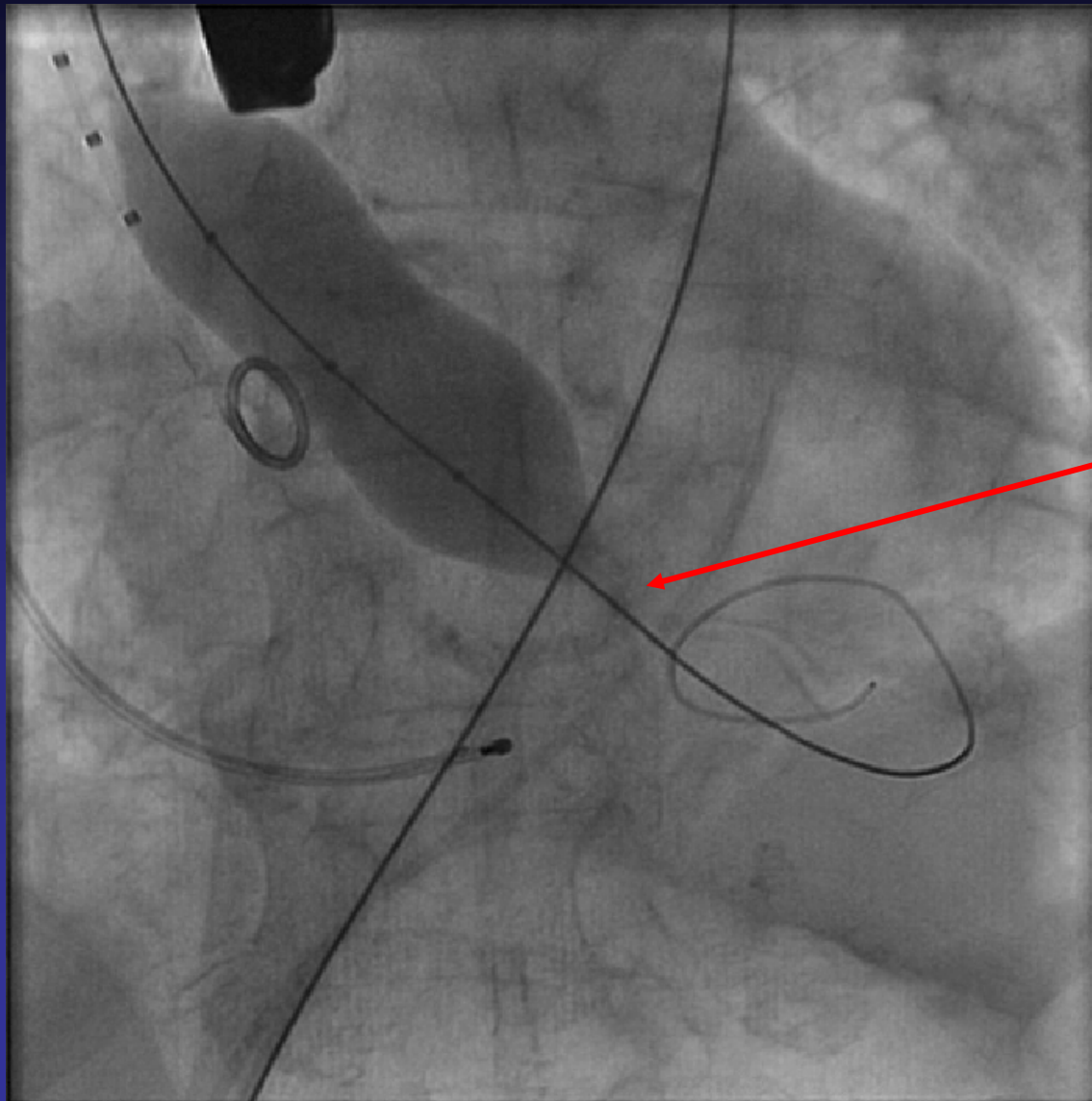


Deployment of ProStar® Closure Device Over 9Fr sheath



Balloon Valvuloplasty

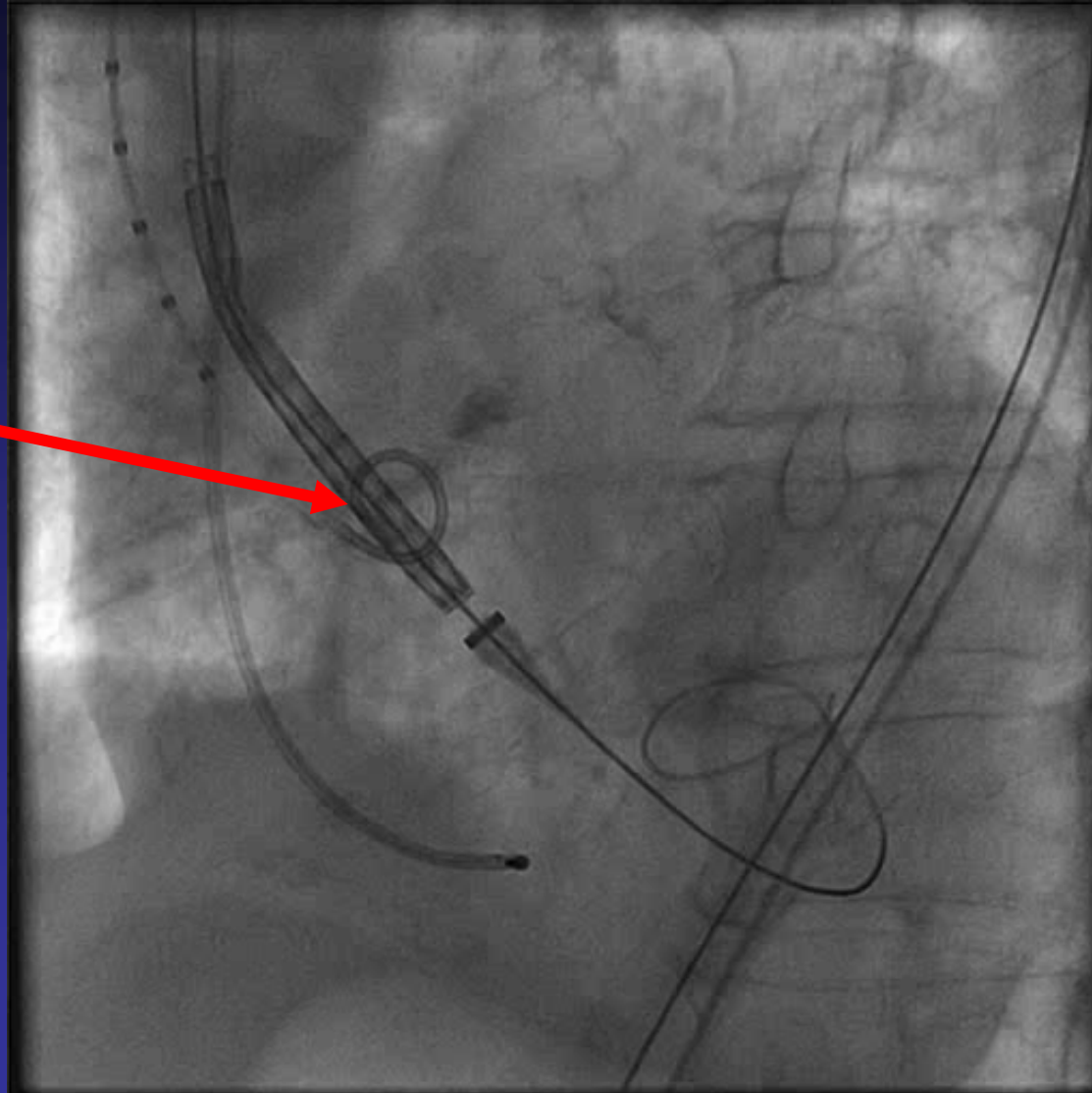
During rapid pacing (170/min)



Extra-stiff
guide-wire

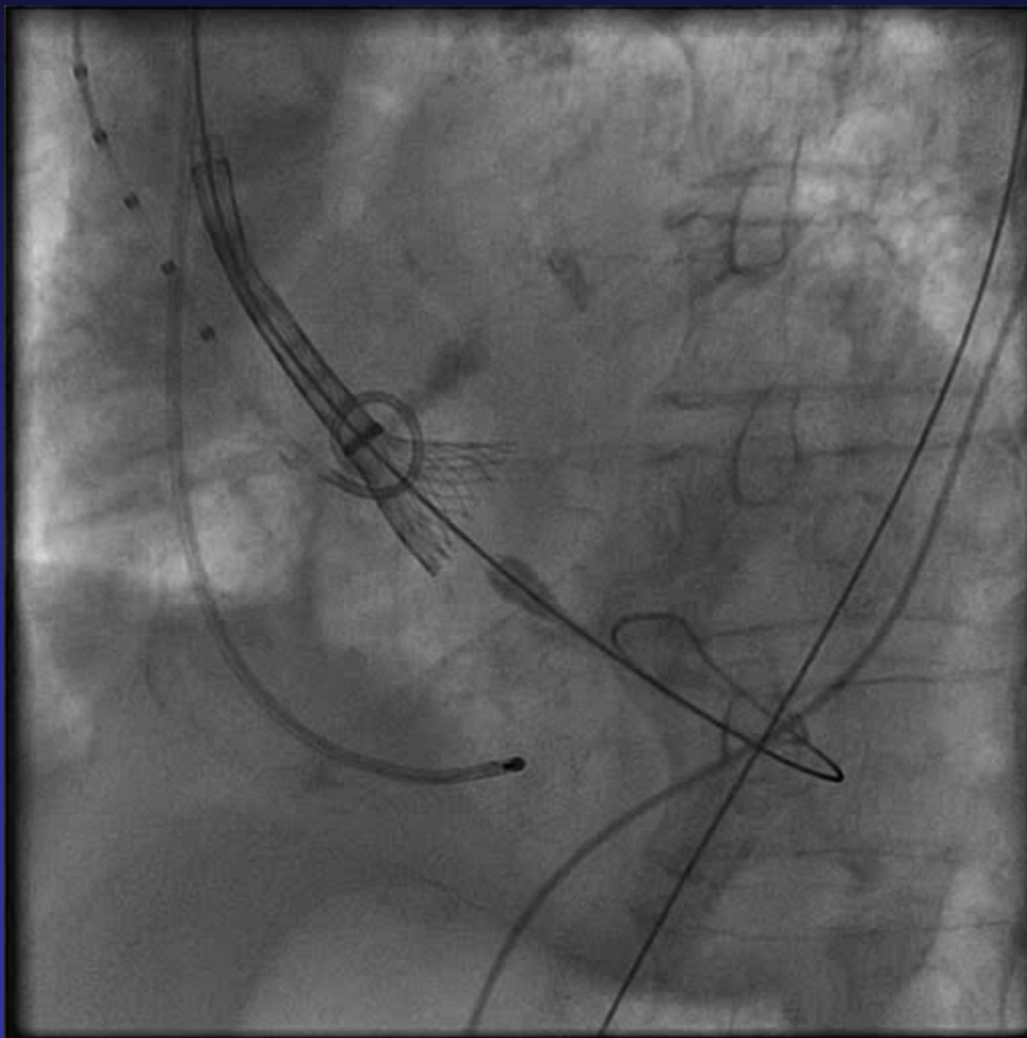


Positioning of CoreValve®

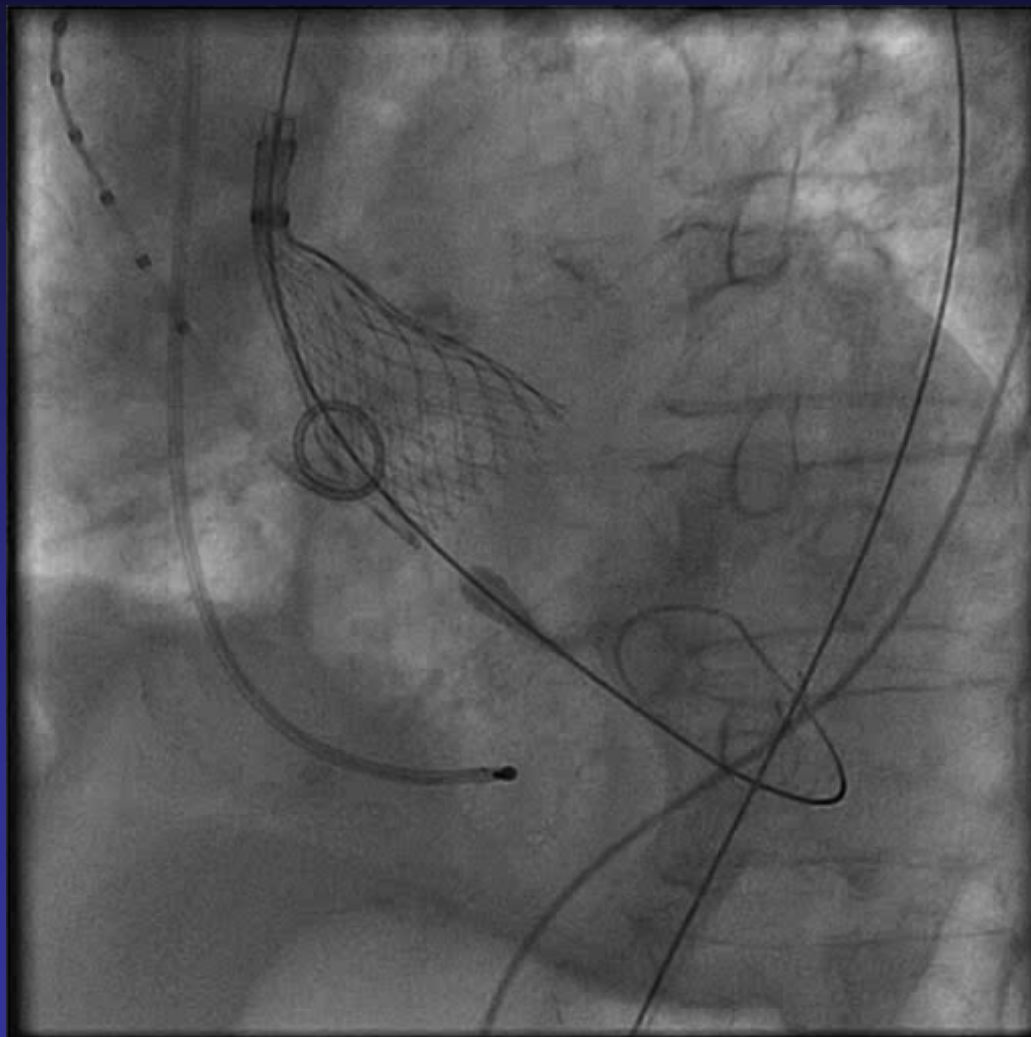


Line #2 at annulus

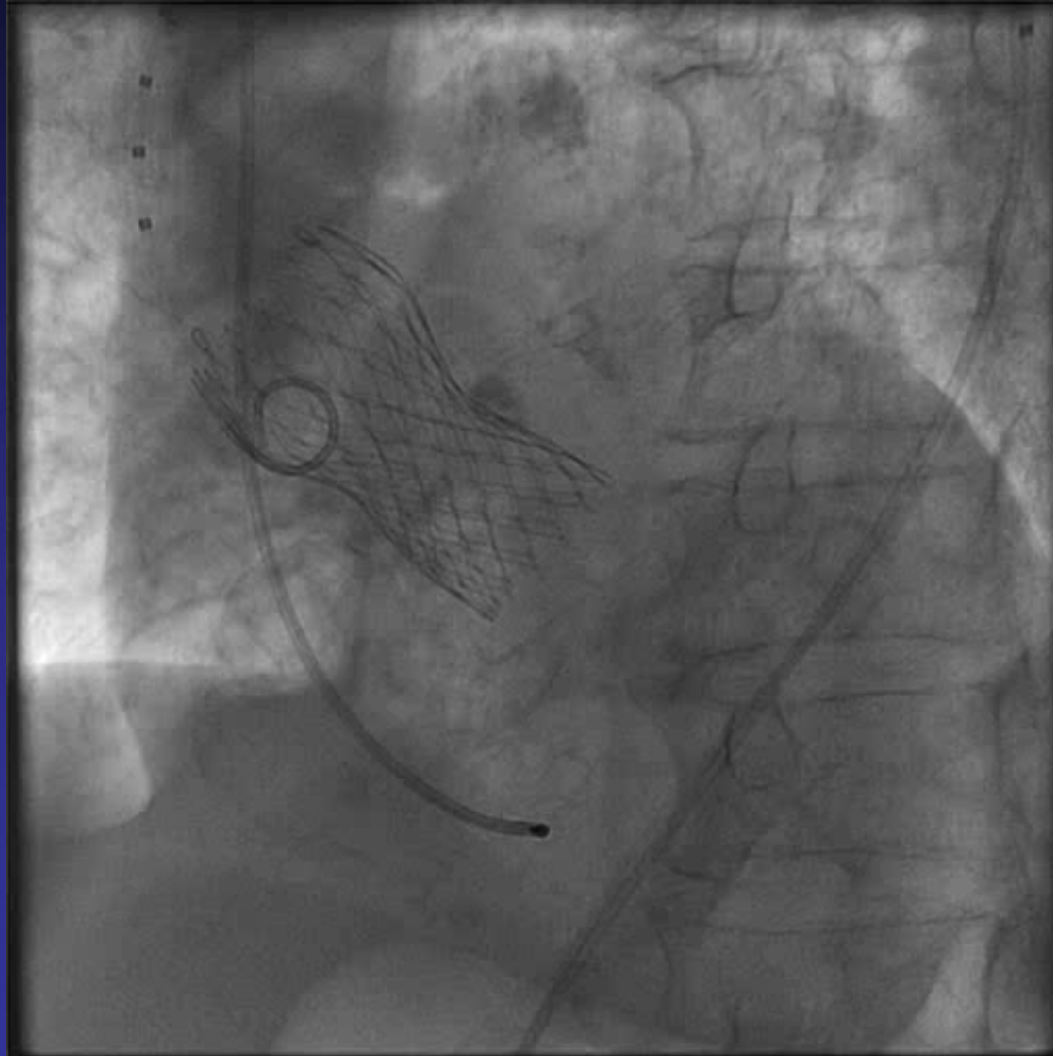
Opening of Ventricular Segment of CoreValve®



Opening of Aortic Segment of CoreValve® - still retrievable!!



CoreValve® Fully Deployed Mild AR



PARTNER Study

The NEW ENGLAND JOURNAL *of* MEDICINE

Transcatheter Aortic-Valve Implantation for Aortic Stenosis in Patients Who Cannot Undergo Surgery

Martin B. Leon, M.D., Craig R. Smith, M.D., Michael Mack, M.D., D. Craig Miller, M.D., Jeffrey W. Moses, M.D.,
Lars G. Svensson, M.D., Ph.D., E. Murat Tuzcu, M.D., John G. Webb, M.D., Gregory P. Fontana, M.D.,
Raj R. Makkar, M.D., David L. Brown, M.D., Peter C. Block, M.D., Robert A. Guyton, M.D.,
Augusto D. Pichard, M.D., Joseph E. Bavaria, M.D., Howard C. Herrmann, M.D., Pamela S. Douglas, M.D.,
John L. Petersen, M.D., Jodi J. Akin, M.S., William N. Anderson, Ph.D., Duolao Wang, Ph.D.,
and Stuart Pocock, Ph.D., for the PARTNER Trial Investigators*



Table 1. Baseline Characteristics of the Patients and Echocardiographic Findings.*

Characteristic	TAVI (N= 179)	Standard Therapy (N= 179)	P Value
Age — yr	83.1±8.6	83.2±8.3	0.95
Male sex — no. (%)	82 (45.8)	84 (46.9)	0.92
STS score†	11.2±5.8	12.1±6.1	0.14
Logistic EuroSCORE‡	26.4±17.2	30.4±19.1	0.04
NYHA class — no. (%)			0.68
II	14 (7.8)	11 (6.1)	
III or IV	165 (92.2)	168 (93.9)	
Coronary artery disease — no. (%)	121 (67.6)	133 (74.3)	0.20
Previous myocardial infarction — no./total no. (%)	33/177 (18.6)	47/178 (26.4)	0.10
Previous intervention — no./total no. (%)			
CABG	58/155 (37.4)	73/160 (45.6)	0.17
PCI	47/154 (30.5)	39/157 (24.8)	0.31
Balloon aortic valvuloplasty	25/154 (16.2)	39/160 (24.4)	0.09
Cerebral vascular disease — no./total no. (%)	48/175 (27.4)	46/167 (27.5)	1.00
Peripheral vascular disease — no./total no. (%)	54/178 (30.3)	45/179 (25.1)	0.29
COPD — no. (%)			
Any	74 (41.3)	94 (52.5)	0.04
Oxygen-dependent	38 (21.2)	46 (25.7)	0.38
Creatinine >2 mg/dl (177 μmol/liter) — no./total no. (%)	10/178 (5.6)	17/178 (9.6)	0.23
Atrial fibrillation — no./total no. (%)	28/85 (32.9)	39/80 (48.8)	0.04
Permanent pacemaker — no./total no. (%)	35/153 (22.9)	31/159 (19.5)	0.49
Pulmonary hypertension — no./total no. (%)	50/118 (42.4)	53/121 (43.8)	0.90
Frailty — no./total no. (%)§	21/116 (18.1)	33/118 (28.0)	0.09
Extensively calcified aorta — no. (%)	34 (19.0)	20 (11.2)	0.05
Deleterious effects of chest-wall irradiation — no. (%)	16 (8.9)	15 (8.4)	1.00
Chest-wall deformity — no. (%)	15 (8.4)	9 (5.0)	0.29
Liver disease — no./total no. (%)	6/177 (3.4)	6/178 (3.4)	1.00
Echocardiographic findings			
Aortic-valve area — cm ²	0.6±0.2	0.6±0.2	0.97
Mean aortic-valve gradient — mm Hg	44.5±15.7	43.0±15.3	0.39
Mean LVEF — %	53.9±13.1	51.1±14.3	0.06
Moderate or severe mitral regurgitation — no./total no. (%)¶	38/171 (22.2)	38/165 (23.0)	0.90



OUTCOMES

Outcome	30 Days			1 Year		
	TAVI (N=179)	Standard Therapy (N=179)	P Value†	TAVI (N=179)	Standard Therapy (N=179)	P Value†
	<i>no. of patients (%)</i>			<i>no. of patients (%)</i>		
Death						
From any cause	9 (5.0)	5 (2.8)	0.41	55 (30.7)	89 (49.7)	<0.001
From cardiovascular cause‡	8 (4.5)	3 (1.7)	0.22	35 (19.6)	75 (41.9)	<0.001
Stroke or TIA						
All	12 (6.7)	3 (1.7)	0.03	19 (10.6)	8 (4.5)	0.04
TIA	0	0	—	1 (0.6)	0	1.00
Stroke						
Minor	3 (1.7)	1 (0.6)	0.62	4 (2.2)	1 (0.6)	0.37
Major	9 (5.0)	2 (1.1)	0.06	14 (7.8)	7 (3.9)	0.18
Vascular complications						
All	55 (30.7)	9 (5.0)	<0.001	58 (32.4)	13 (7.3)	<0.001
Major	29 (16.2)	2 (1.1)	<0.001	30 (16.8)	4 (2.2)	<0.001
Major bleeding	30 (16.8)	7 (3.9)	<0.001	40 (22.3)	20 (11.2)	0.007



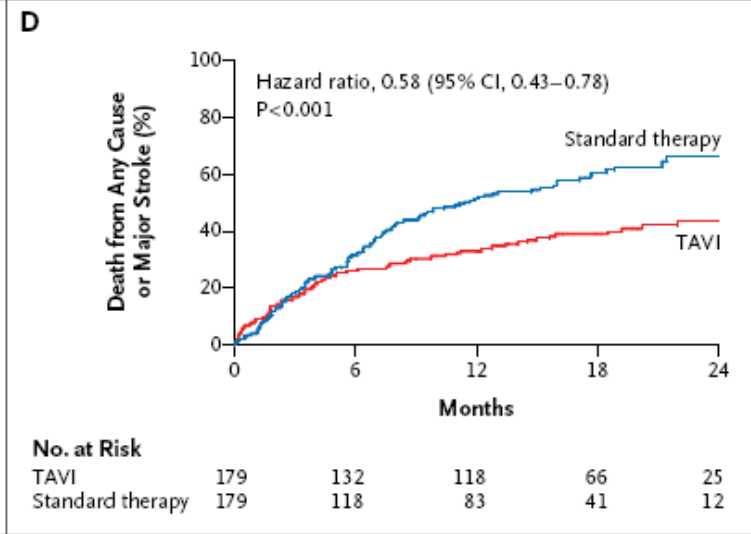
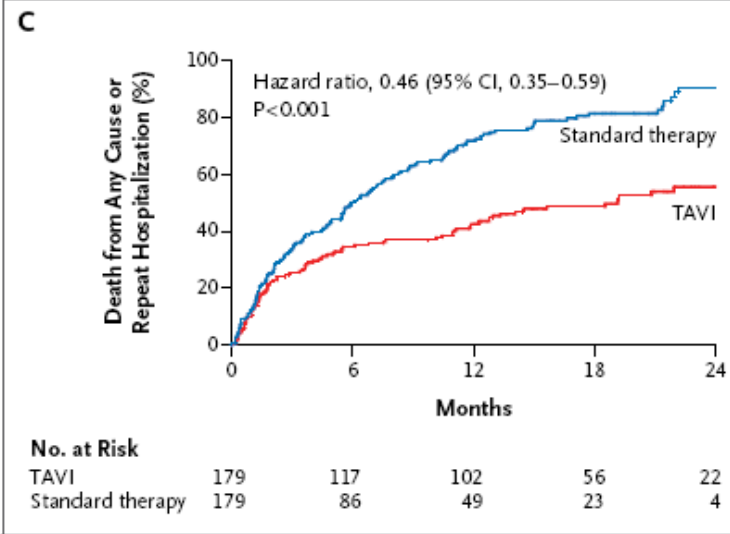
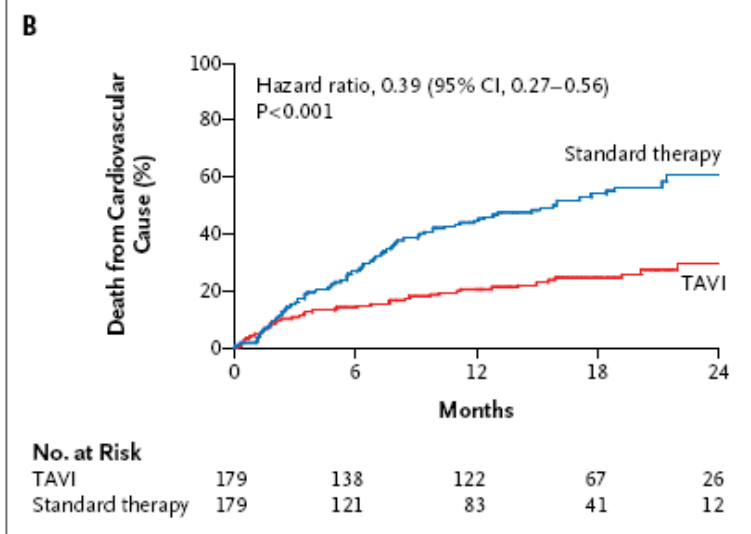
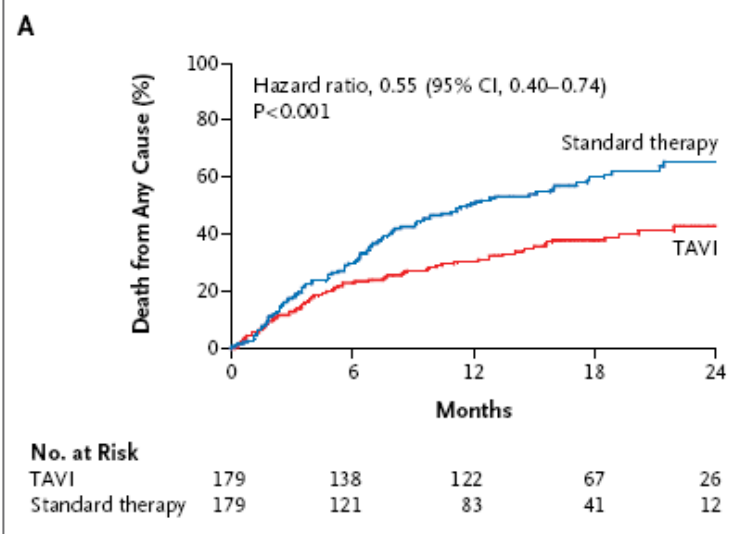


Figure 1. Time-to-Event Curves for the Primary End Point and Other Selected End Points.



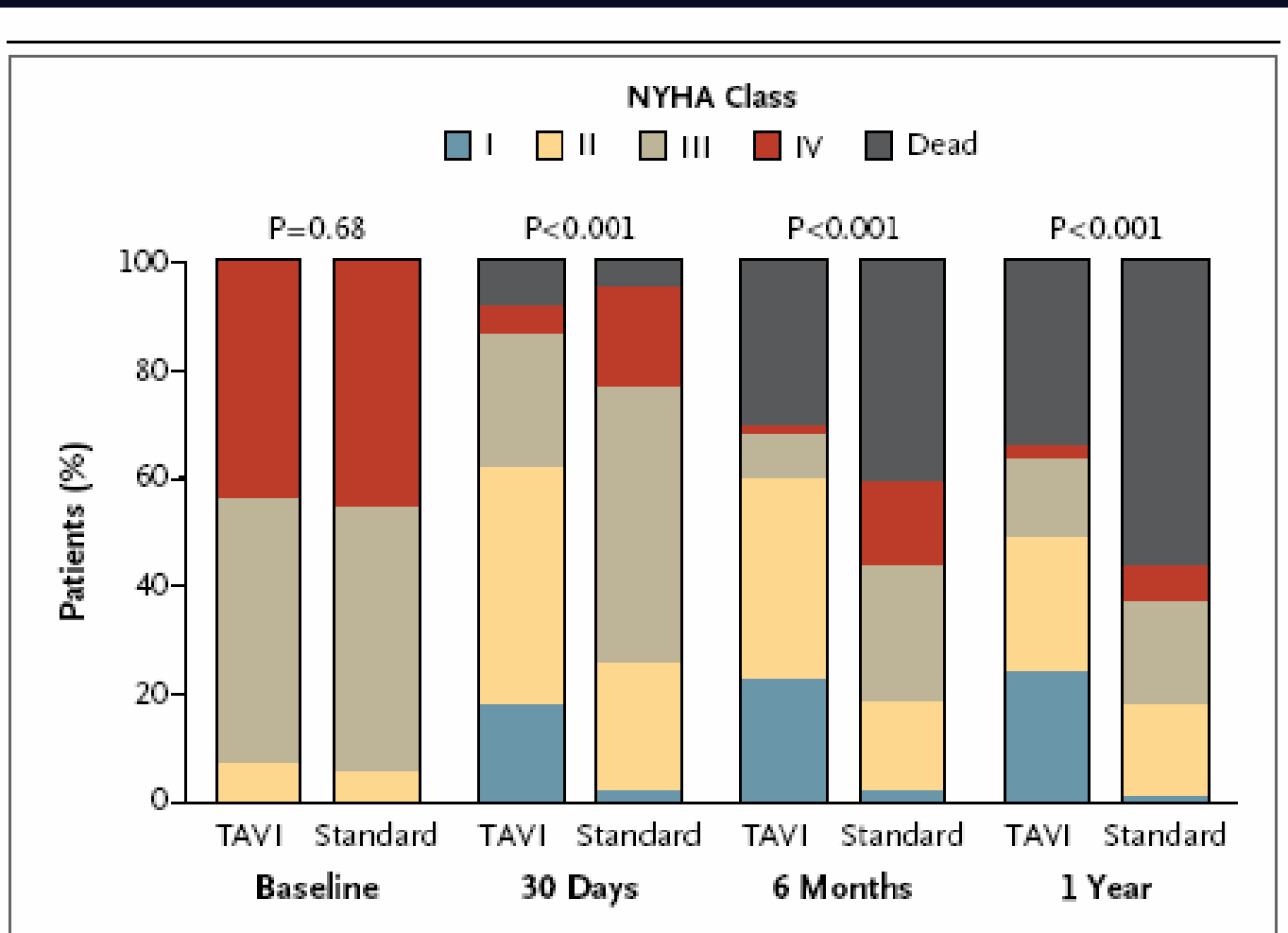


Figure 3. Symptom Status over Time.





European Heart Journal
doi:10.1093/eurheartj/ehq277

ESC/EACTS GUIDELINES



Guidelines on myocardial revascularization

The Task Force on Myocardial Revascularization of the European Society of Cardiology (ESC) and the European Association for Cardio-Thoracic Surgery (EACTS)

Developed with the special contribution of the European Association for Percutaneous Cardiovascular Interventions (EAPCI)[†]



תודה ובהצלחה!

