

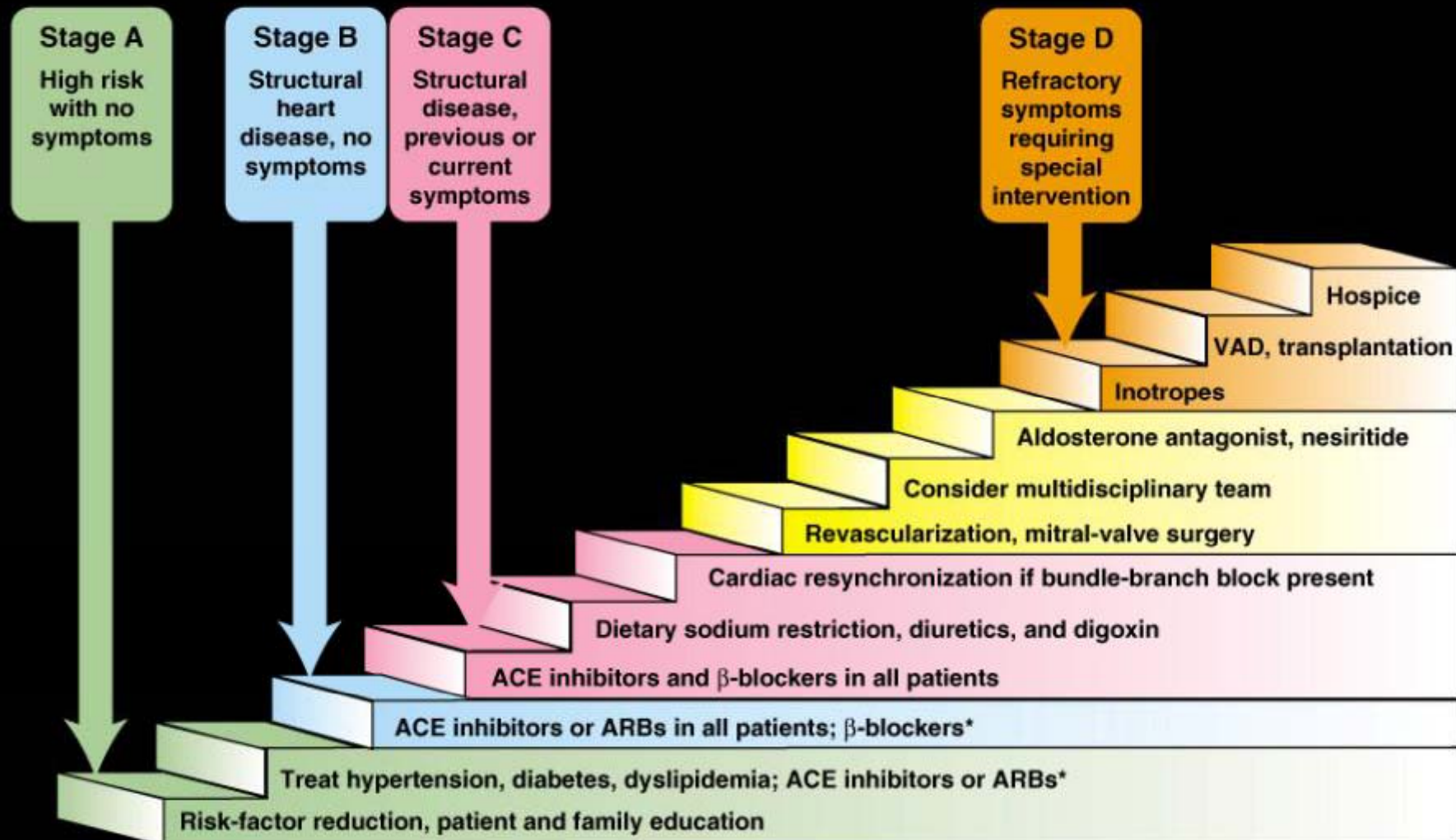
# **STICH – Surgeon's Perspective**

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**Disclosures: No relevant financial relationships  
to declare with commercial entities**

# ACC/AHA stages of systolic HF and treatment options



\*In appropriate patients

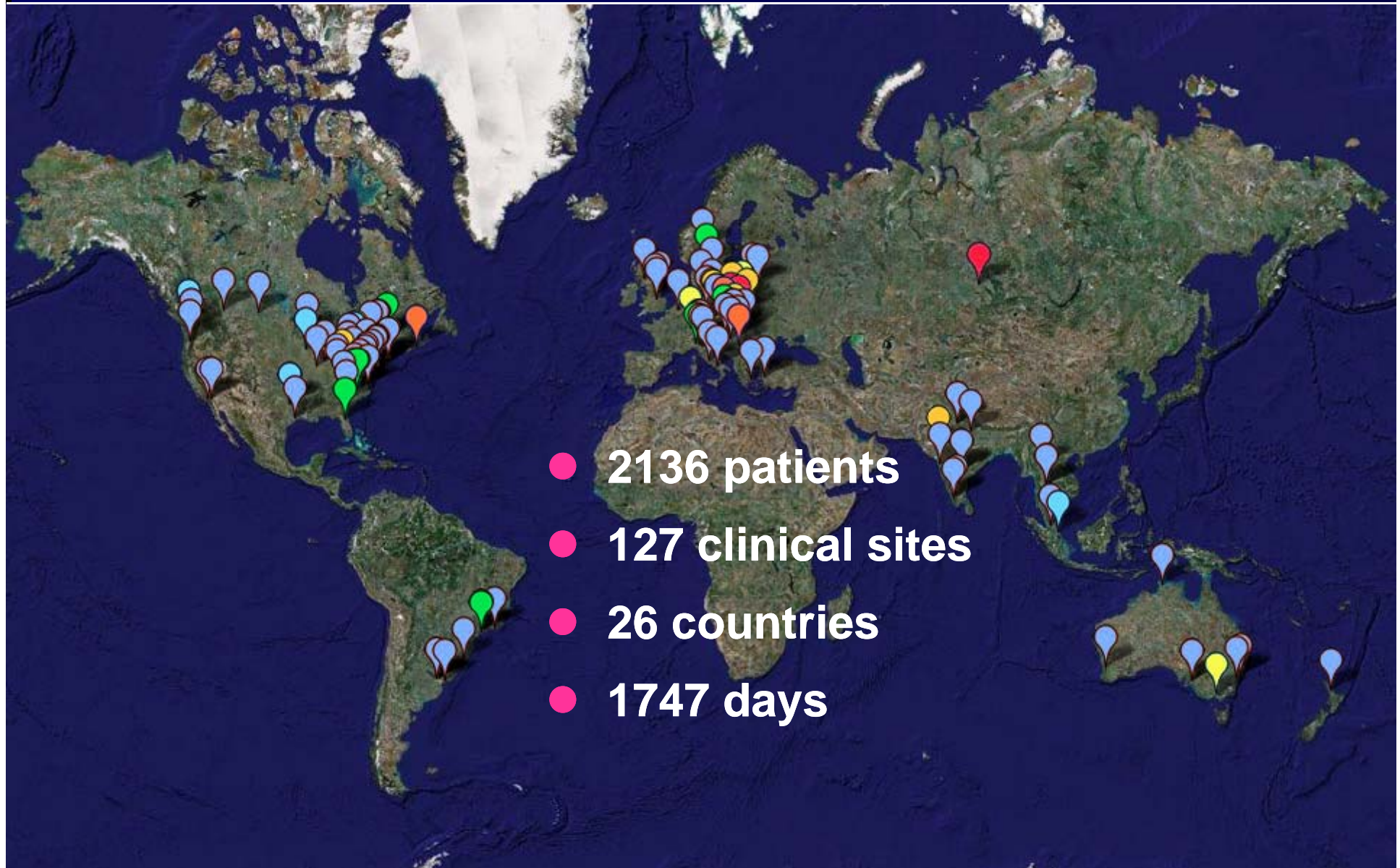
Jessup M, Brozena S. *N Engl J Med.* 2003;348:2007-18.

# Overall Objective

**Define the role of cardiac surgery in patients with ischemic cardiomyopathy by answering two questions:**

- 1. Does adding CABG to evidence-based medical therapy (MED) increase survival compared to MED alone?**
- 2. Does adding surgical ventricular reconstruction (SVR) to CABG and MED increase survival free of cardiac hospitalization?**

## All Enrolling Sites







EF  $\leq$  0.35, CAD amenable to CABG

Eligible for medical therapy (MED) without CABG?

Yes

No

Eligible for surgical ventricular reconstruction (SVR)?

Eligible for SVR?

No

Not in trial

No

Yes

Yes

Stratum A  
n = 1061

Stratum B  
n = 216

Stratum C  
n = 859

= 2136 Randomized pts

1  
MED

2  
MED  
+  
CABG

3  
MED

4  
MED  
+  
CABG

5  
MED  
+  
CABG  
+  
SVR

6  
MED  
+  
CABG

7  
MED  
+  
CABG  
+  
SVR

602 MED only

= 1033 CABG added

501 CABG + SVR added

(527)

(534)

(75)

(76)

(65)

(423)

(436)

MED

MED  
+  
CABG

(602)

(610)

MED  
+  
CABG

MED  
+  
CABG  
+  
SVR

(499)

(501)

Hypothesis 1  
n = 1212

+

Hypothesis 2  
n = 1000

= 2212 Primary endpoints

# Selected Baseline Characteristics

Variable	MED (N=602)	CABG (N=610)
Age, median (IQR), yrs	59 (53, 67)	60 (54, 68)
Female, %	12	12
Diabetes, %	40	39
Prior Myocardial infarction, %	78	76
Prior Heart Failure within 3 months, %	95	94
Prior PCI or CABG, %	15	16
LVEF (%) — median	28	27
Multi-vessel disease (>50%), %	91	91
Proximal LAD stenosis (>75%), %	69	67

# Medical Therapy

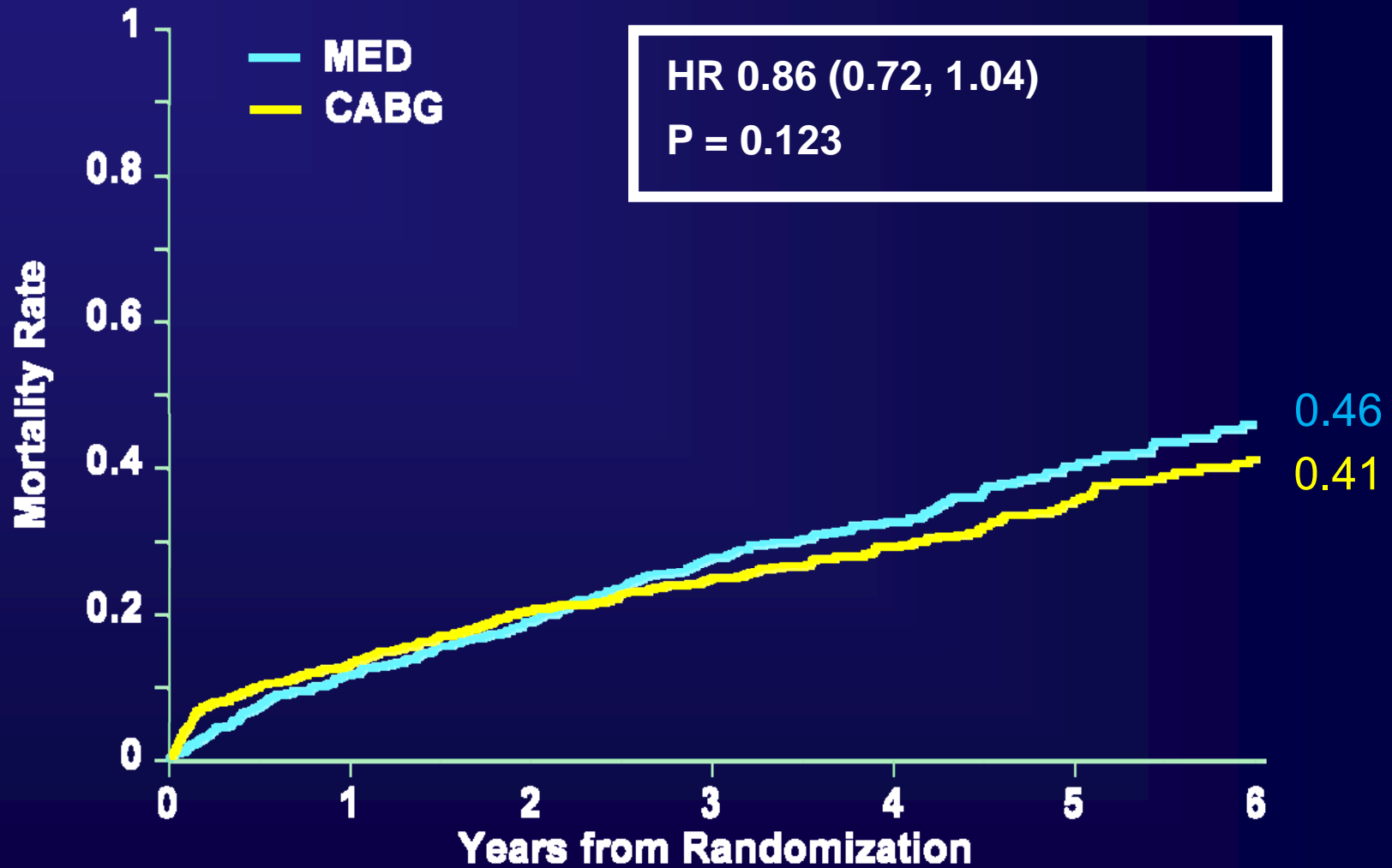
	MED (N=602)		CABG (N=610)	
Medication, %	Baseline	Latest Follow-up	Baseline	Latest Follow-up
Aspirin	85	84	80	84
Aspirin or warfarin	91	93	84	92
ACE inhibitor or ARB	88	89	91	89
Beta-blocker	88	90	83	90
Statin	83	87	79	90
K+ sparing diuretic	46	53	46	54
ICD	2	19	2	15

# CABG Conduct

Variable	CABG (N=610)
CABG received — no (%)	555 (91)
Time to CABG, days — Median (IQR)	10 (5, 16)
Performed electively, %	95
Arterial conduits $\geq 1$ , %	91
Venous conduits $\geq 1$ , %	86
Total grafts $\geq 2$ , %	88
Length of stay, days — Median (IQR)	9 (7, 13)

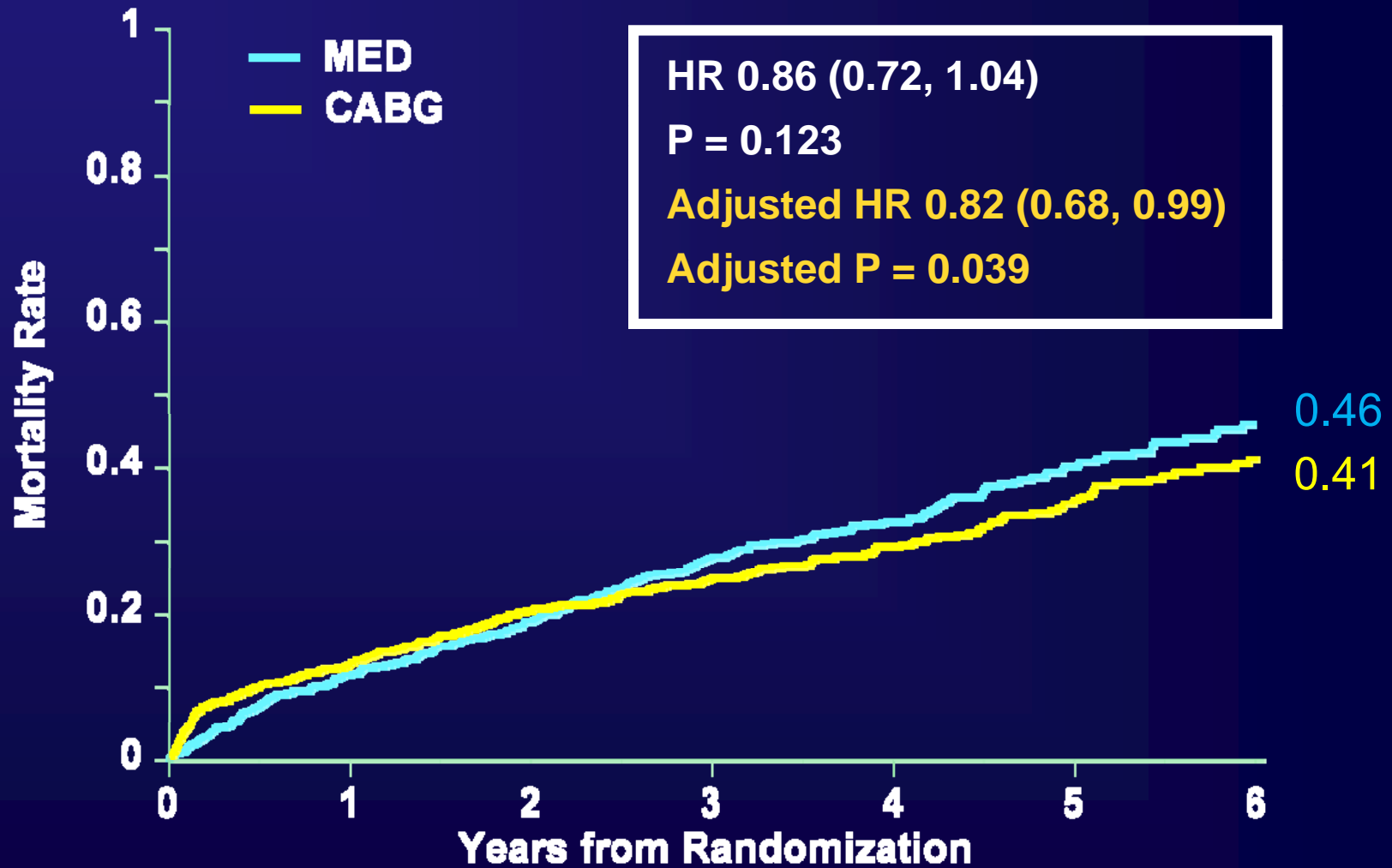


# All-Cause Mortality — As Randomized



<b>MED</b>	<b>602</b>	<b>532</b>	<b>487</b>	<b>435</b>	<b>312</b>	<b>154</b>	<b>80</b>
<b>CABG</b>	<b>610</b>	<b>532</b>	<b>486</b>	<b>459</b>	<b>340</b>	<b>174</b>	<b>91</b>

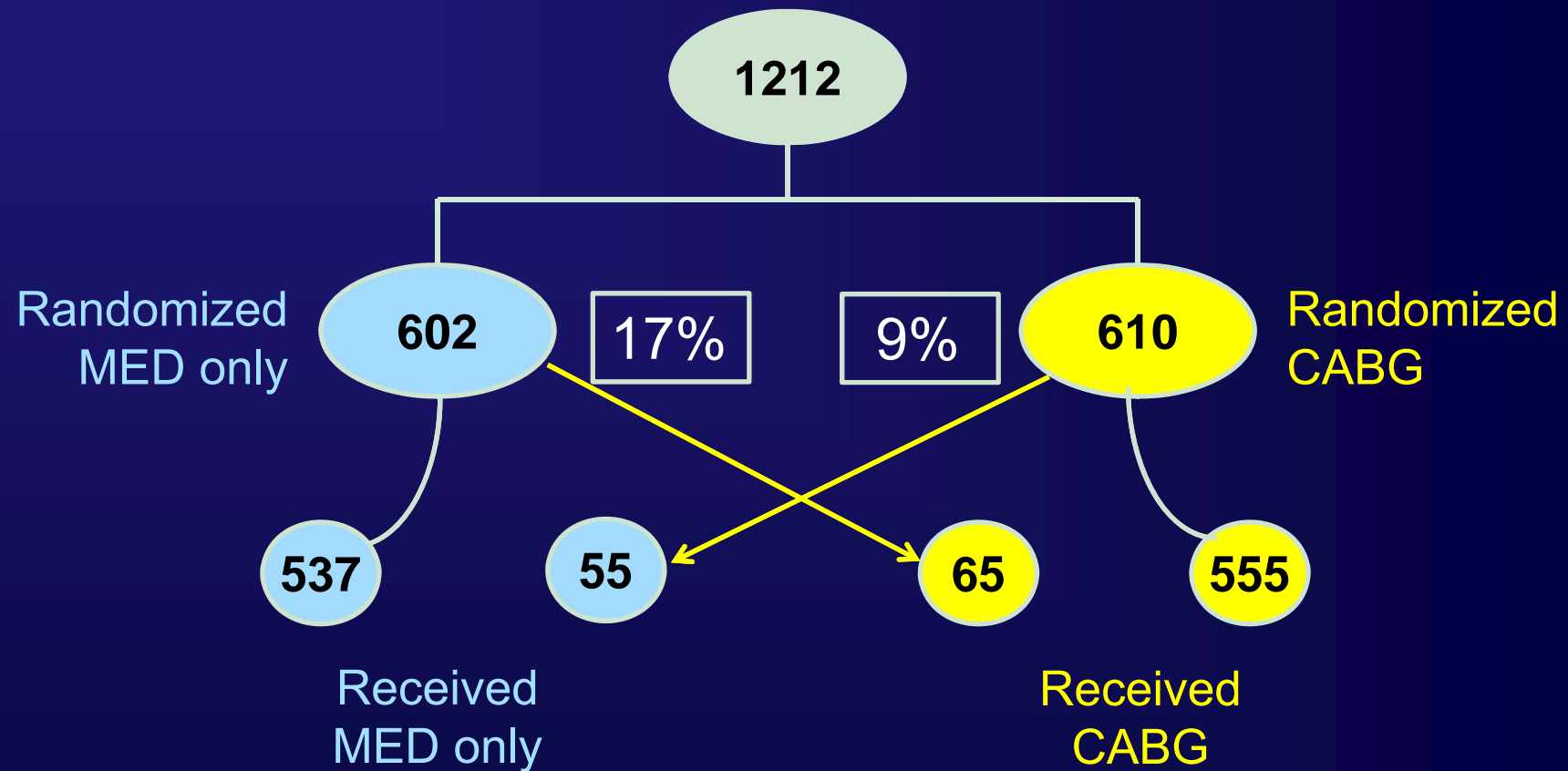
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<b>CABG</b>	<b>610</b>	<b>532</b>	<b>486</b>	<b>459</b>	<b>340</b>	<b>174</b>	<b>91</b>

# STICH Revascularization Hypothesis

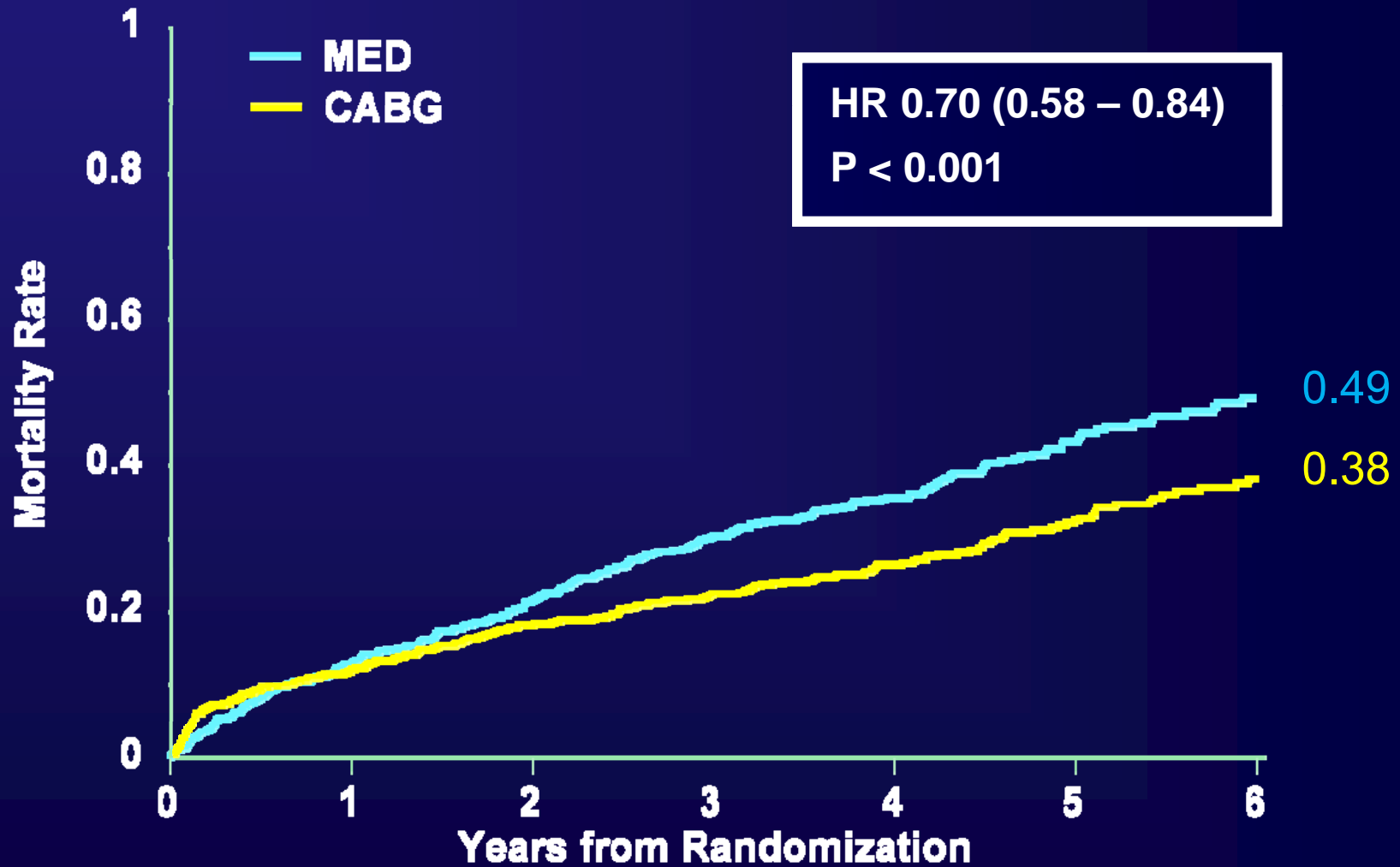
## Treatment As Received



As treated MED (592) vs. CABG (620)



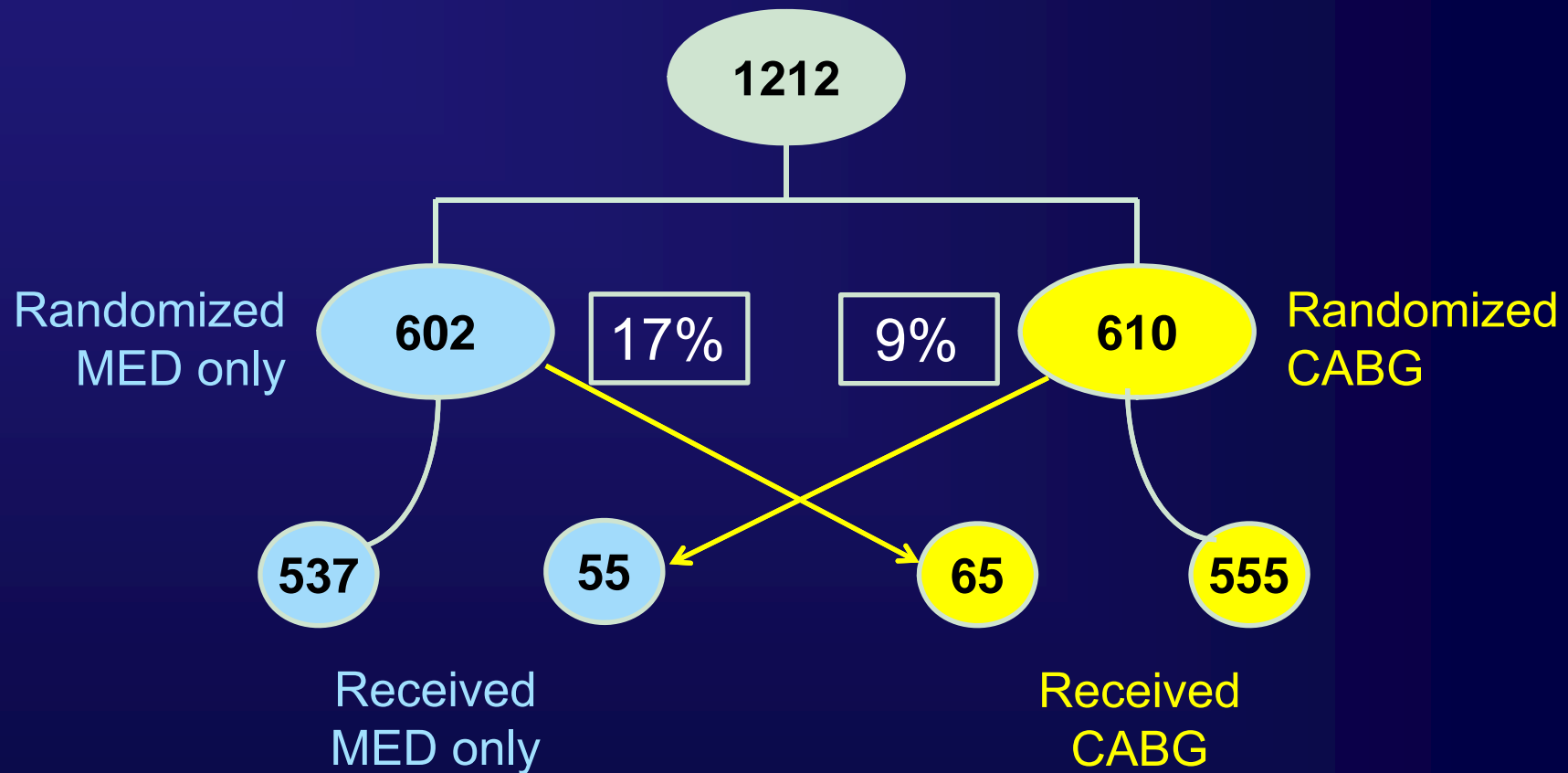
# All-Cause Mortality — As Treated



<b>MED</b>	<b>592</b>	<b>516</b>	<b>464</b>	<b>412</b>	<b>297</b>	<b>146</b>	<b>74</b>
<b>CABG</b>	<b>620</b>	<b>548</b>	<b>509</b>	<b>482</b>	<b>355</b>	<b>182</b>	<b>97</b>

# STICH Revascularization Hypothesis

## Treatment Per Protocol

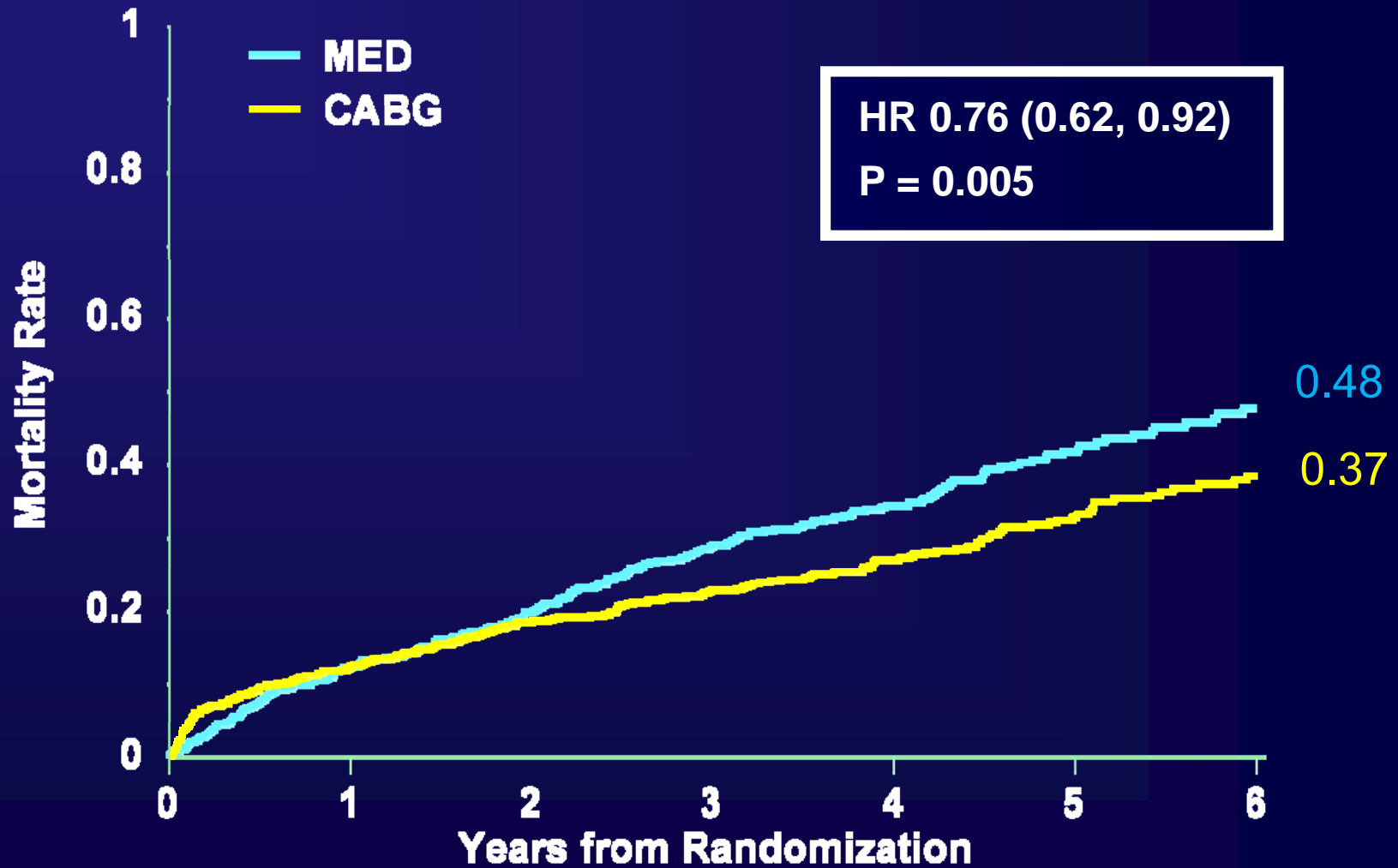


Per protocol: MED (537)

vs.

CABG (555)

# All-Cause Mortality — Per Protocol

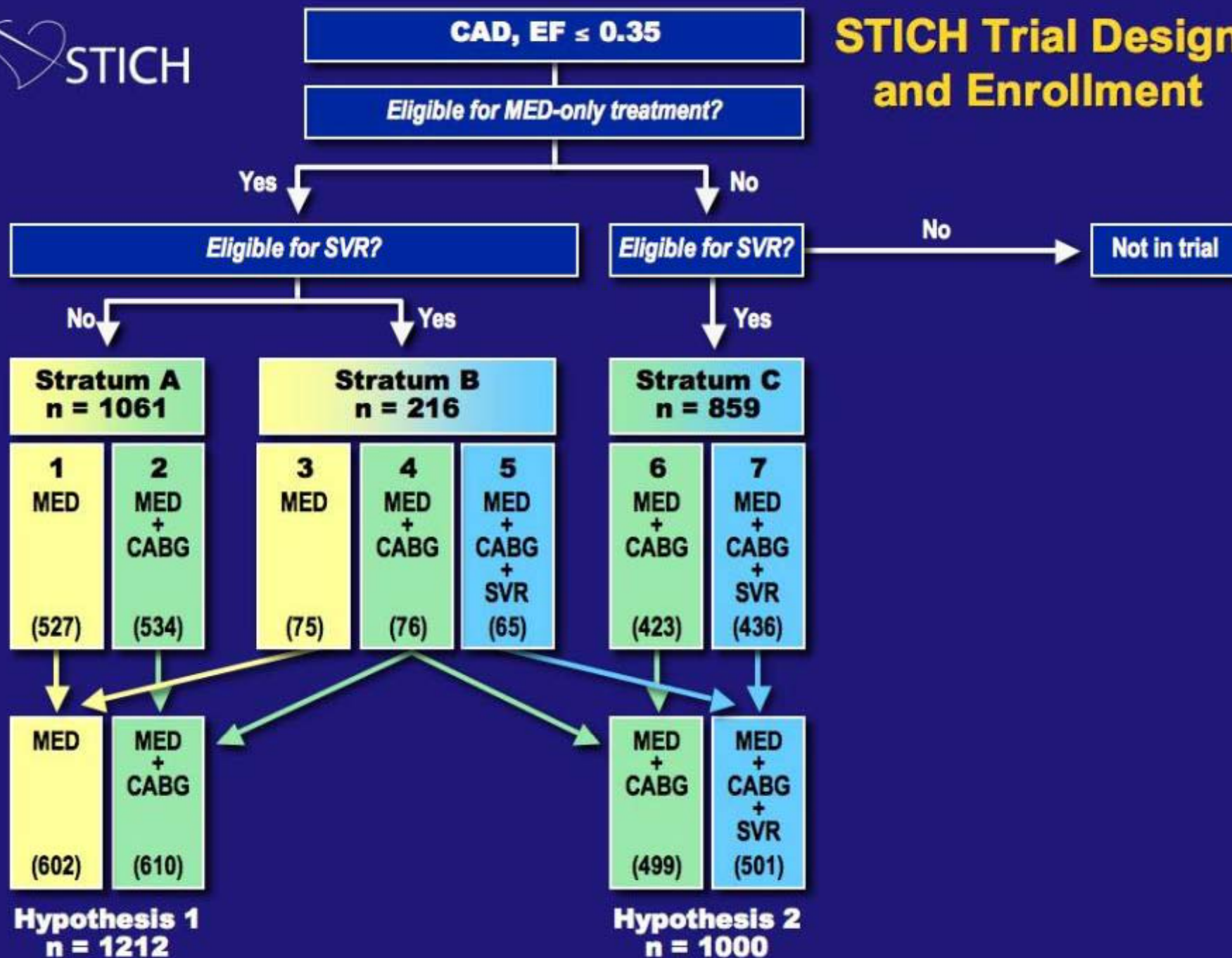


<b>MED</b>	<b>537</b>	<b>471</b>	<b>430</b>	<b>381</b>	<b>276</b>	<b>139</b>	<b>72</b>
<b>CABG</b>	<b>555</b>	<b>487</b>	<b>452</b>	<b>428</b>	<b>319</b>	<b>167</b>	<b>89</b>

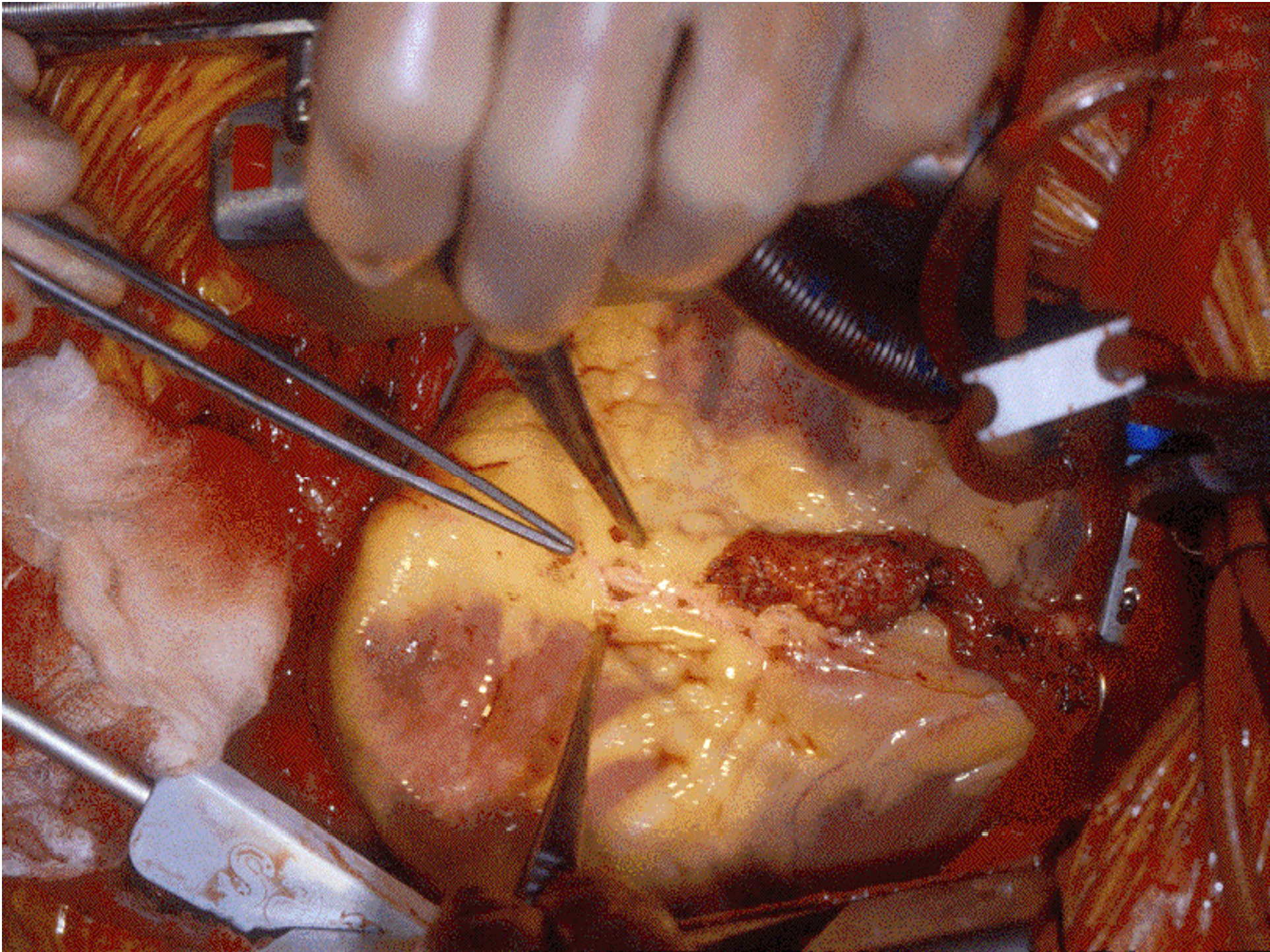




# STICH Trial Design and Enrollment











J. PELLERIN

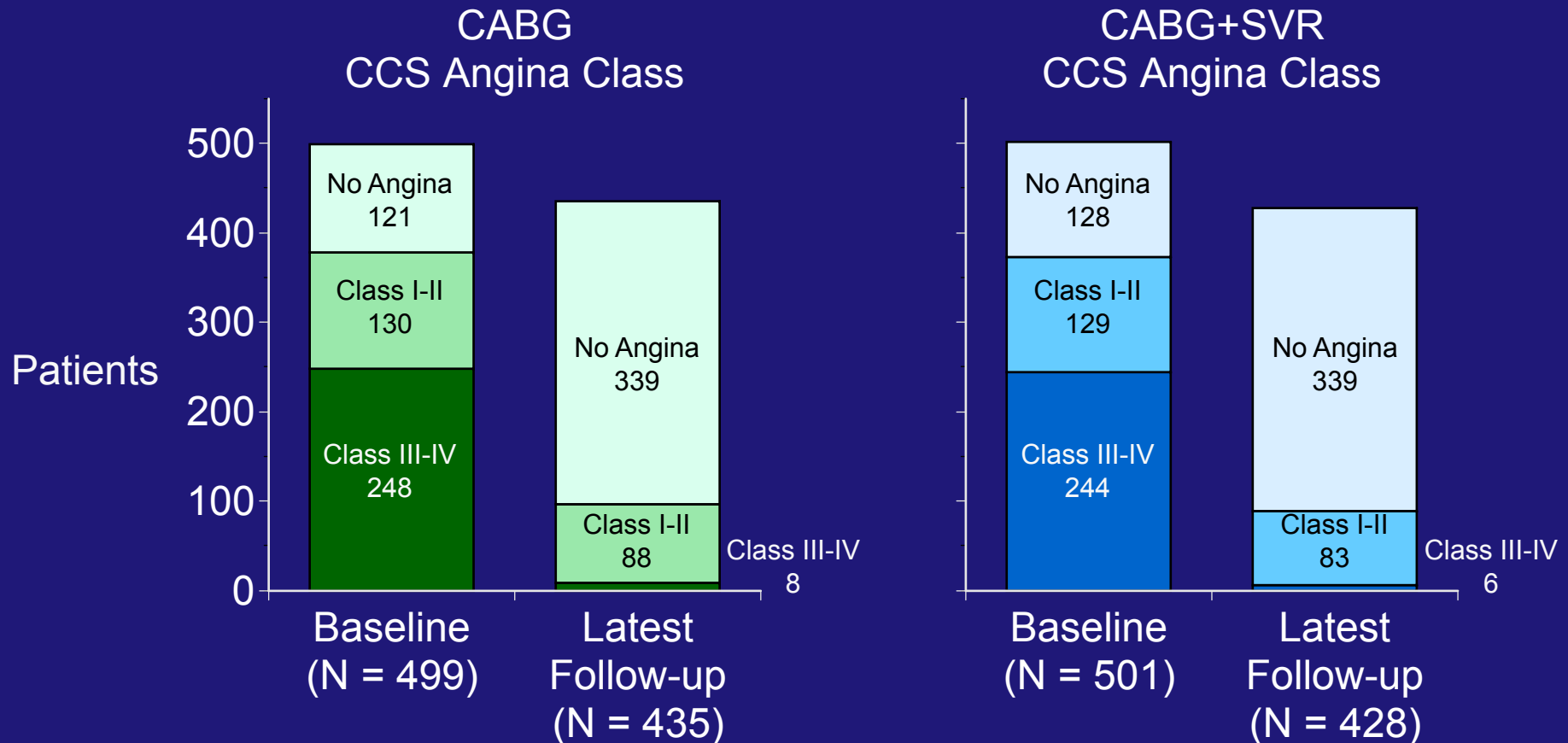


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## Efficiency of Operative Care in 979 Hypothesis 2 Patients

Duration of Operation	CABG N = 490	CABG + SVR N = 489	P
Total time in operating room (median, 25 <sup>th</sup> , 75 <sup>th</sup> ), hours	4.9 (4.1, 6.0)	5.5 (4.7, 6.6)	<0.001
<b>Cardiopulmonary bypass time (median, 25<sup>th</sup>, 75<sup>th</sup>), minutes</b>	<b>99 (73, 125)</b>	<b>124 (99, 158)</b>	<b>&lt;0.001</b>
Aortic occlusion (median, 25 <sup>th</sup> , 75 <sup>th</sup> ), minutes	62 (45, 84)	80 (62, 106)	<0.001
<b>Requirements for Postoperative Care</b>			
Endotracheal intubation (median, 25 <sup>th</sup> , 75 <sup>th</sup> ), hours	15.1 (10.9, 22.1)	16.6 (12.0, 25.2)	0.002
Acute care (median, 25 <sup>th</sup> , 75 <sup>th</sup> ), hours	49.8 (28.8, 95.5)	69.5 (42, 137)	<0.001
Hospitalization >30 days	22 (5%)	31 (6%)	0.20

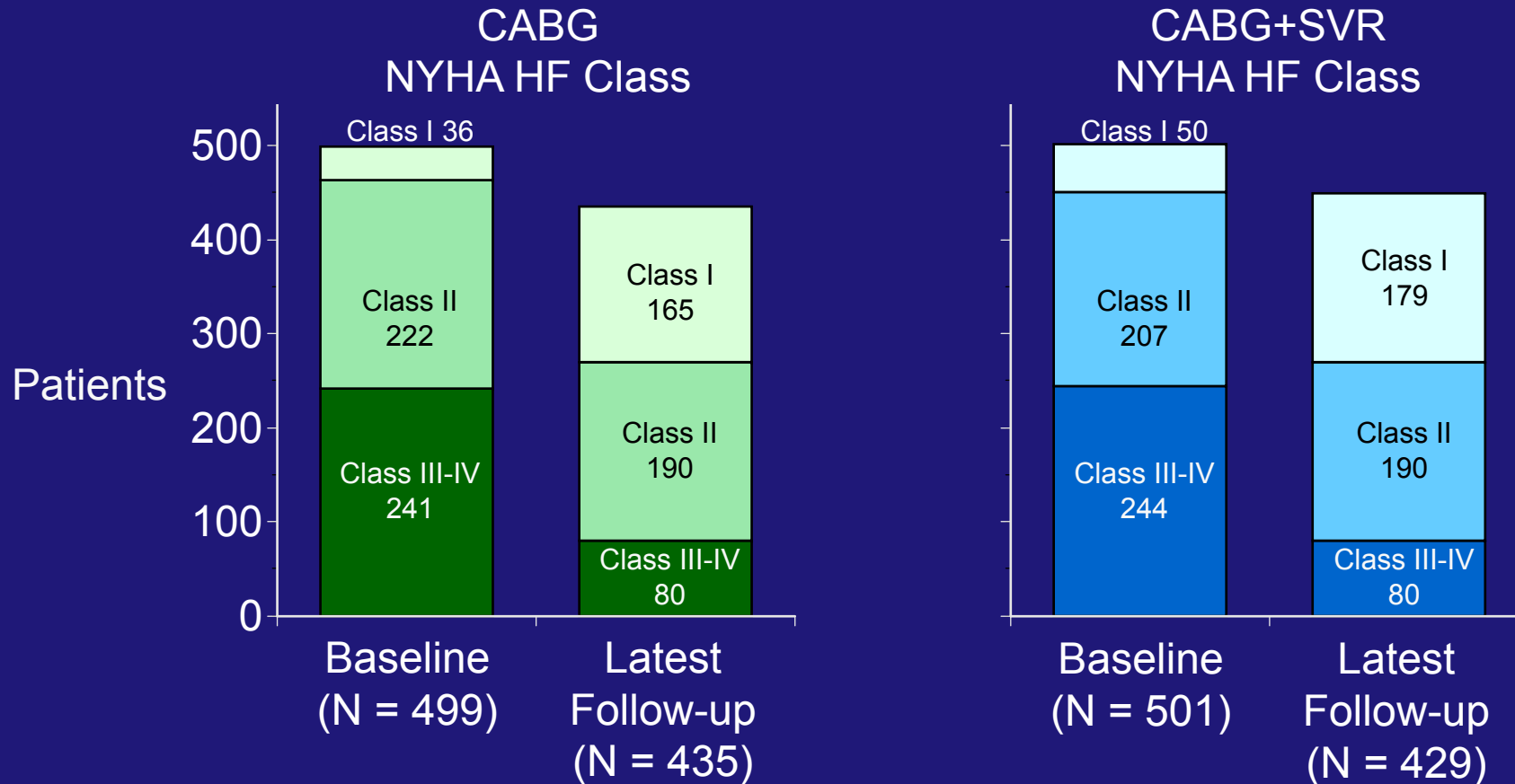
# Canadian Cardiovascular Society Angina Class in Hypothesis 2 Patients at Baseline and Latest Follow-up



**Angina symptoms improved by an average of 1.7 classes in both cohorts (P=0.84).**



# New York Heart Association Heart Failure Class in Hypothesis 2 Patients at Baseline and Latest Follow-up

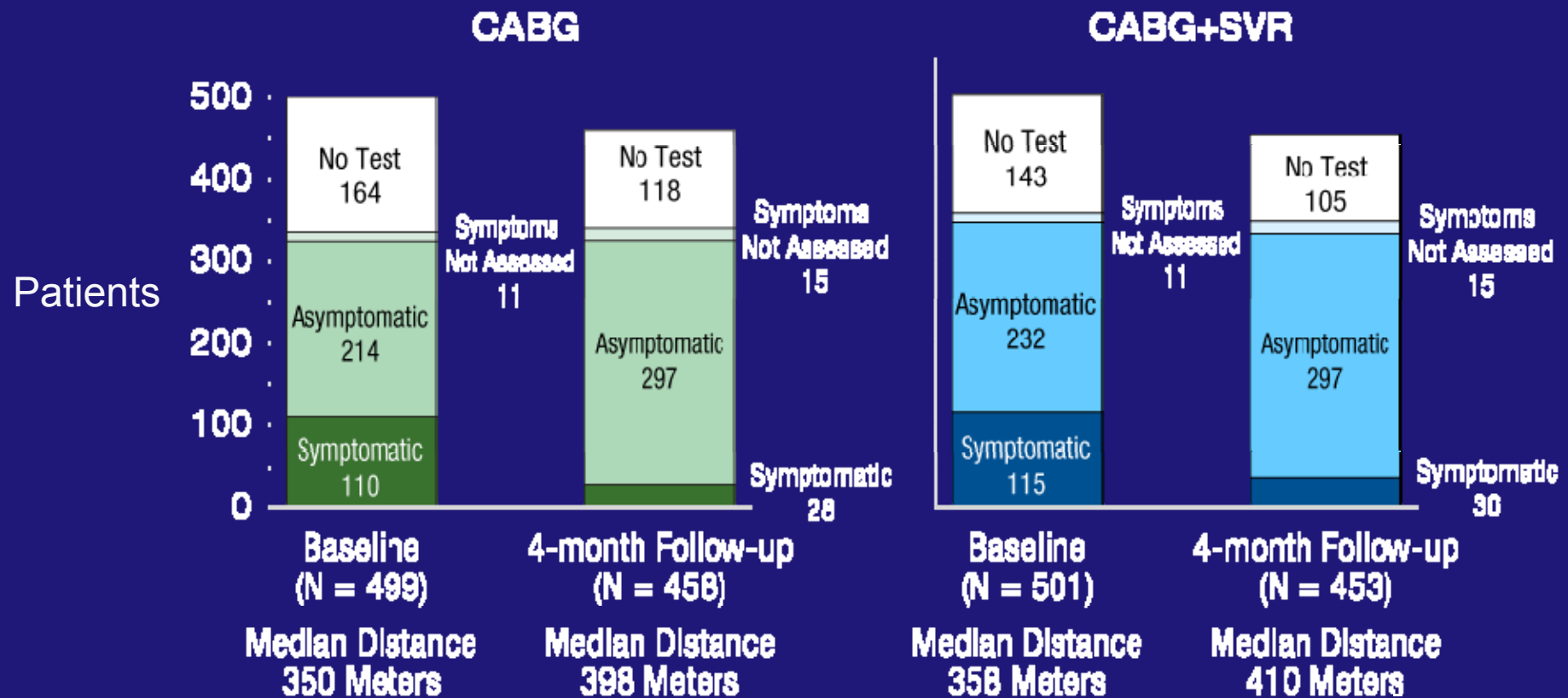


**Heart failure symptoms improved by an average of one class in both cohorts (P=0.70).**





# Baseline and Four Month 6-Minute Walk in 693 Hypothesis 2 Patients with Baseline Assessment



# 30-Day Mortality

Outcome	CABG N = 499	CABG + SVR N = 501	P
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## *Death Within 30 Days After Randomization*

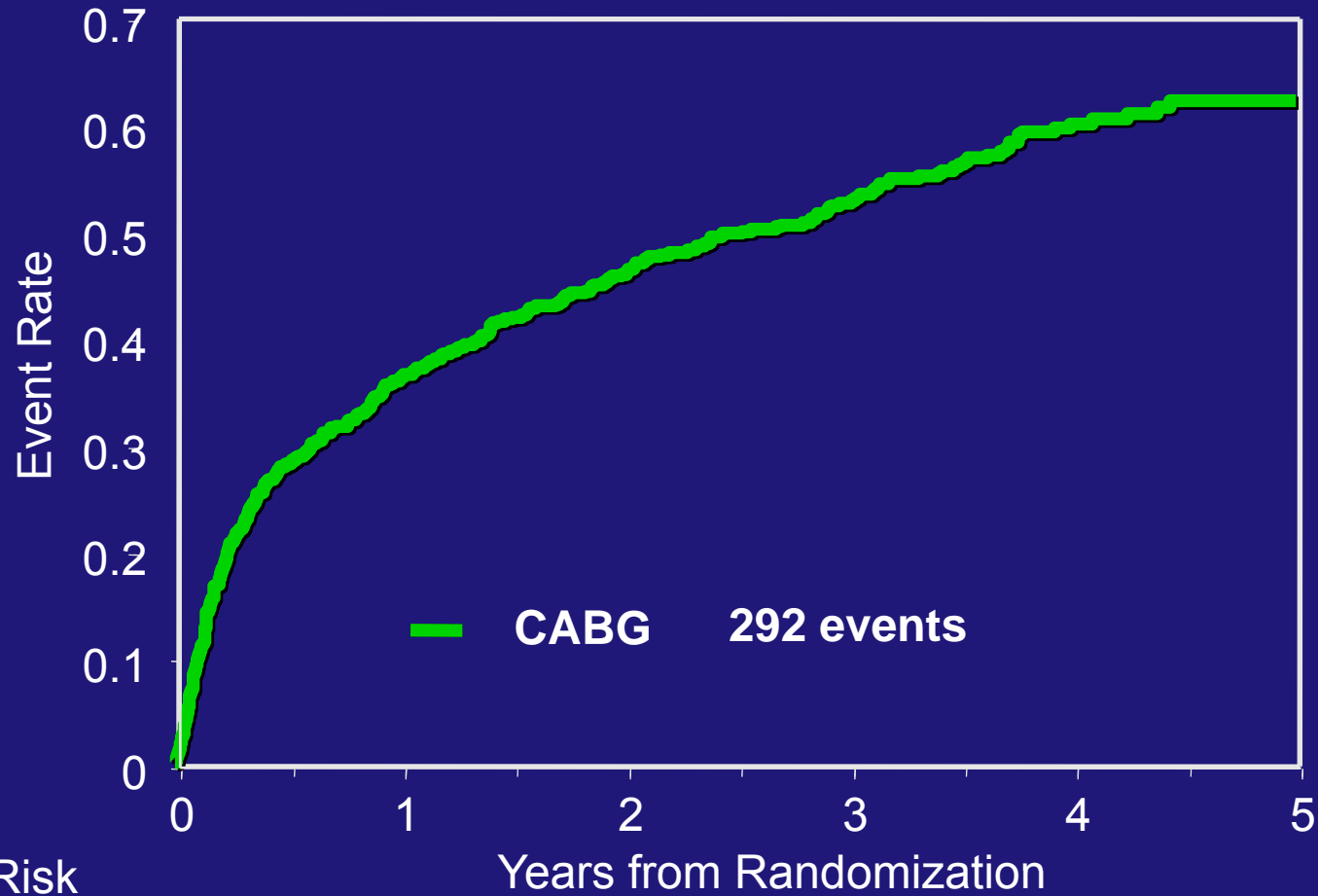
All patients by intention to treat	22/499 (4.4%)	30/501 (6.0%)	0.26
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## *Death During or Within 30 Days of Operation*

Operated patients by intention to treat	25/490 (5.1%)	26/489 (5.3%)	0.88
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Operated patients by operation received	23/498 (4.6%)	28/481 (5.8%)	0.40
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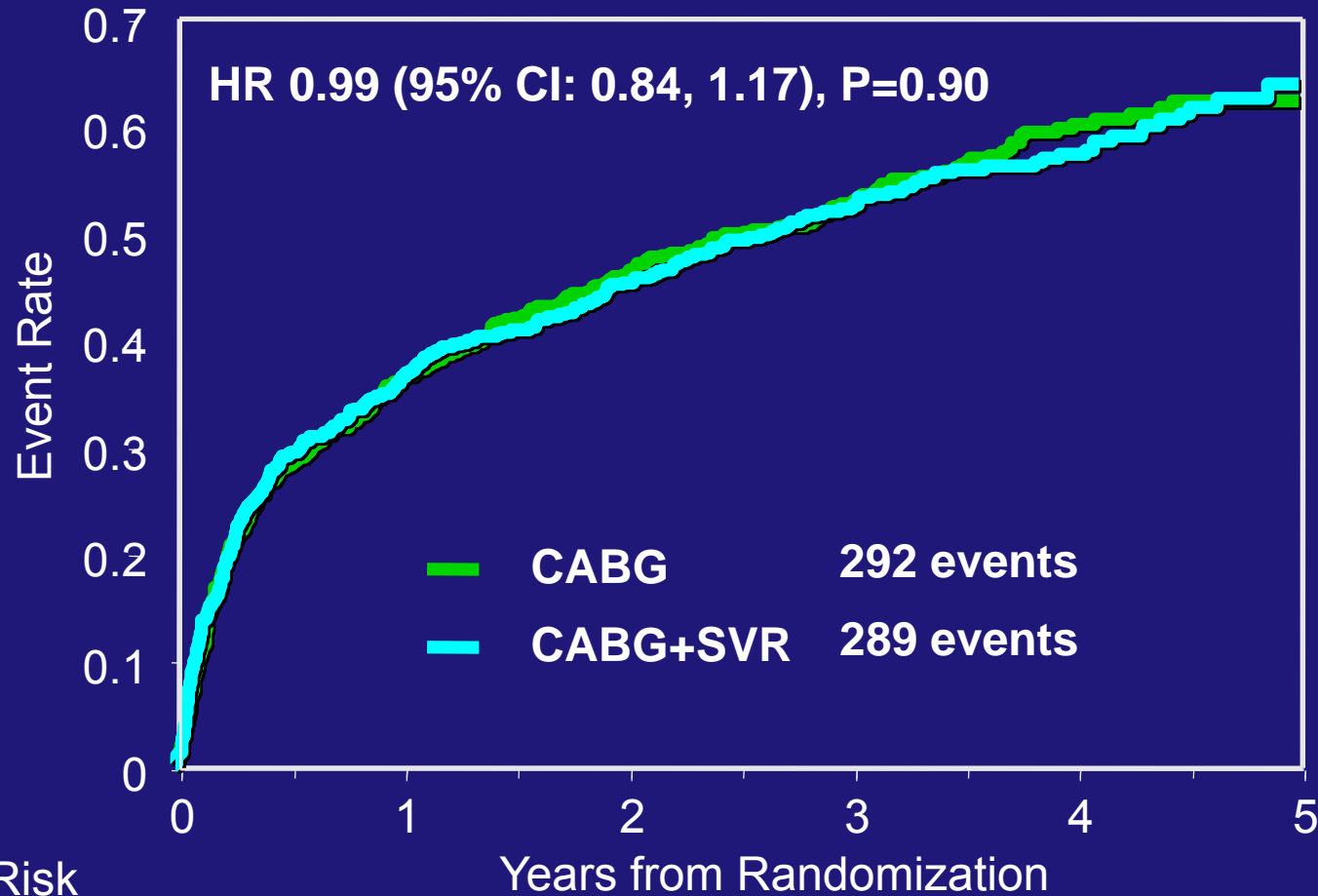
# Death or Cardiac Hospitalization Kaplan-Meier Estimates of Primary Endpoint



No. at Risk

	0	1	2	3	4	5
CABG	499	319	270	220	99	23
CABG+SVR	501	319	275	216	11	23

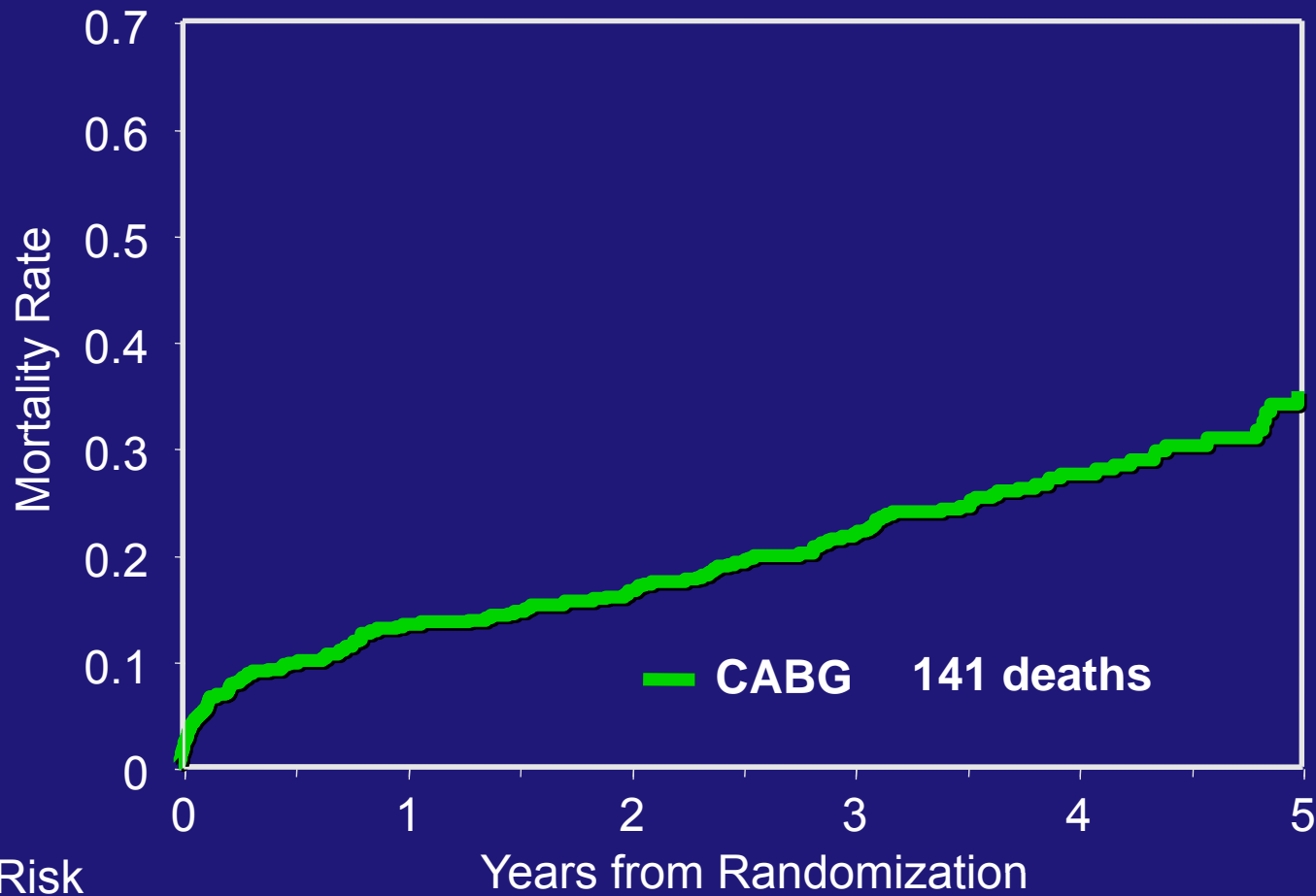
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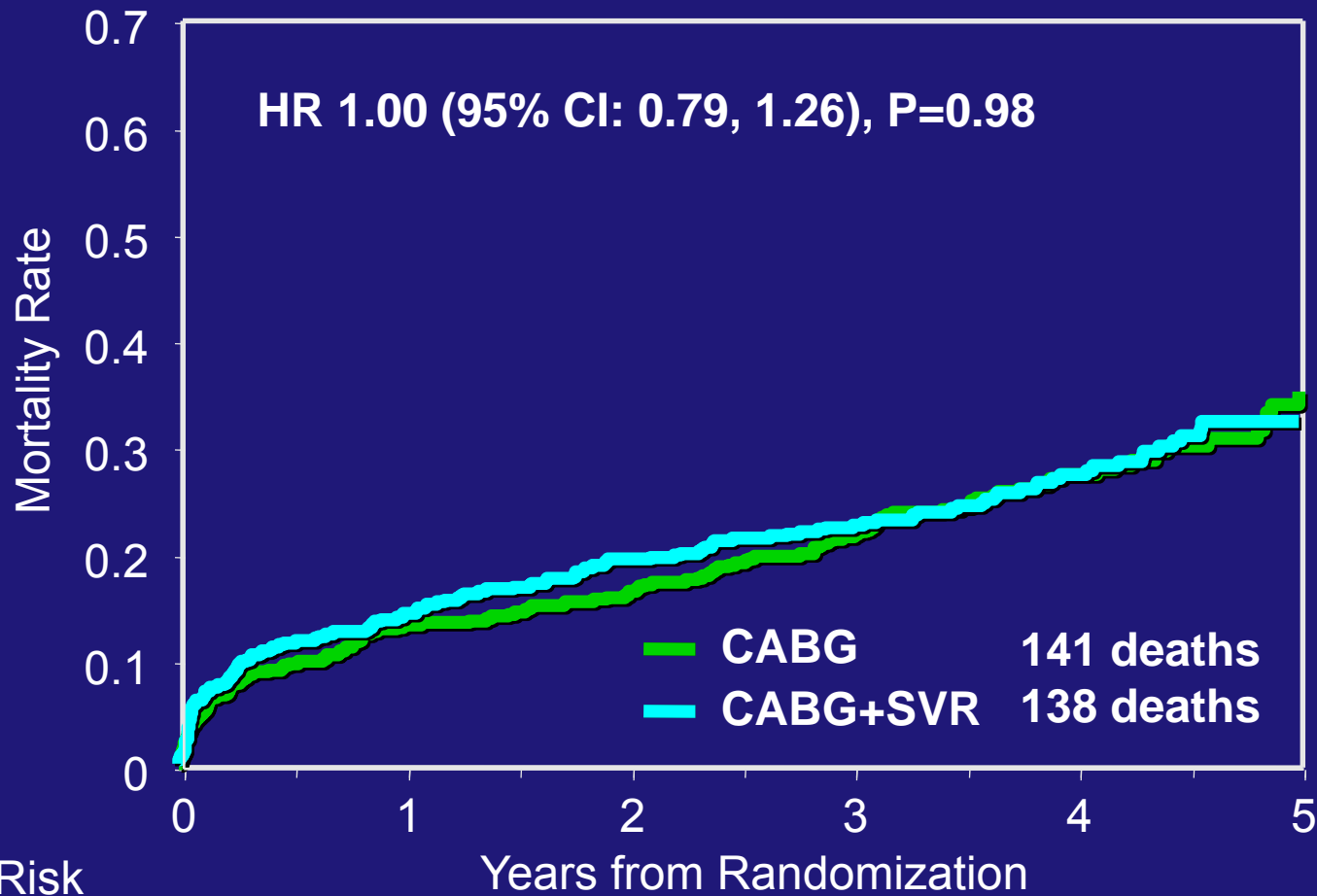
# Mortality (All-Cause) Kaplan-Meier Estimates



No. at Risk

	0	1	2	3	4	5
CABG	499	434	417	363	201	59
CABG+SVR	501	429	404	352	193	53

# Mortality (All-Cause) Kaplan-Meier Estimates



	0	1	2	3	4	5
CABG	499	434	417	363	201	59
CABG+SVR	501	429	404	352	193	53

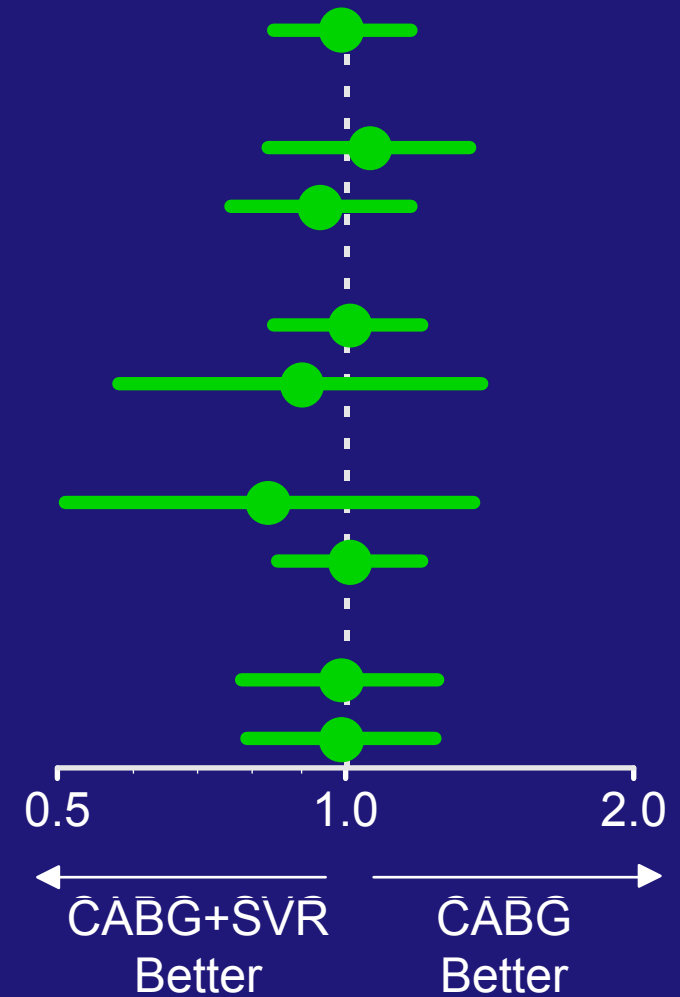


## Summary of Outcomes in STICH H2

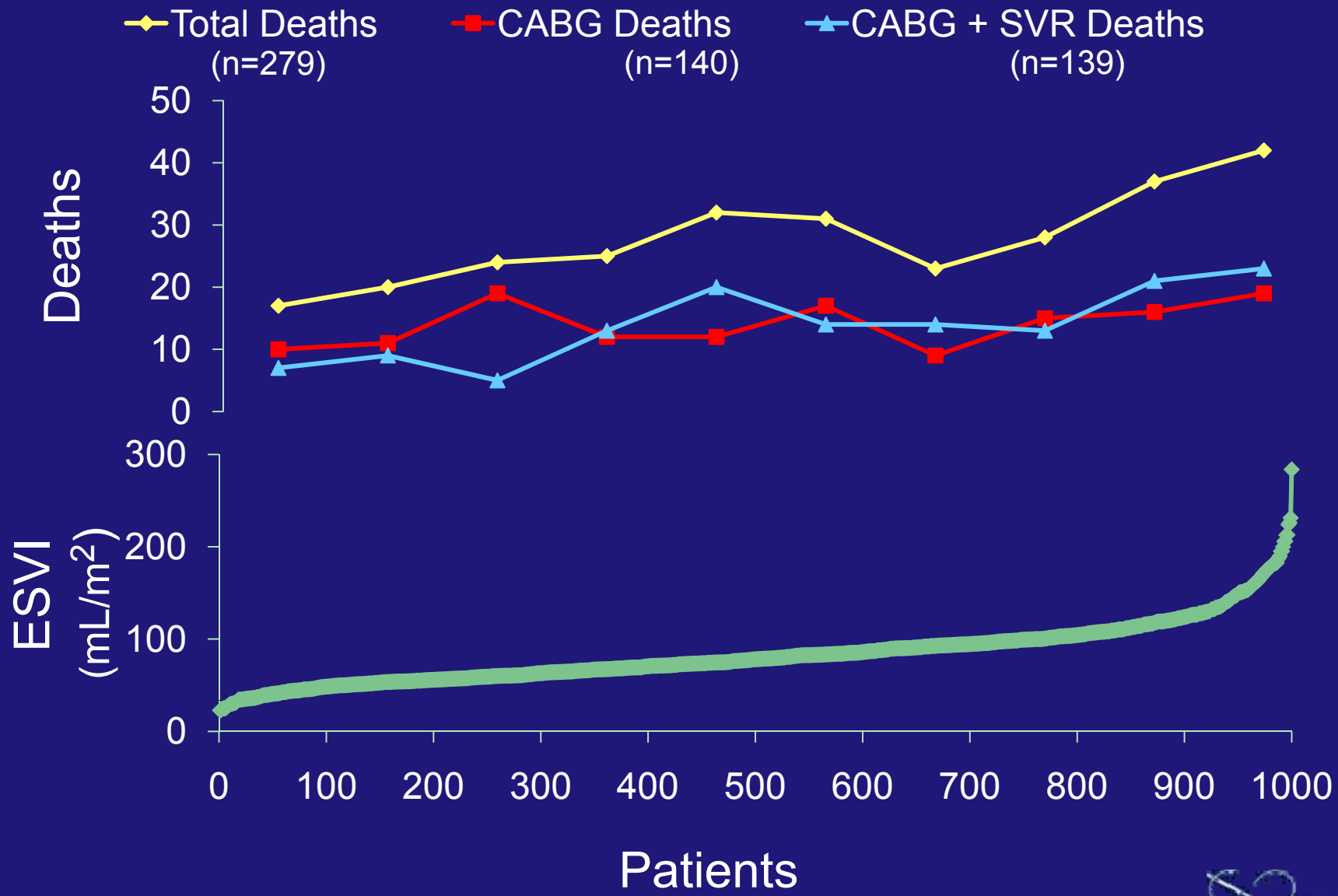
Outcomes	CABG N = 499	CABG + SVR N = 501	Hazard Ratio 95% CI	P
Death or cardiac hospitalization	292 (59%)	289 (58%)	0.99 (0.84, 1.17)	0.90
Death	141 (28%)	138 (28%)	1.00 (0.79, 1.26)	0.98
Hospitalization (cardiac)	211 (42%)	204 (41%)	0.97 (0.80, 1.18)	0.73
Hospitalization (all cause)	272 (55%)	268 (53%)	0.98 (0.83, 1.16)	0.82
Acute MI	22 (4%)	20 (4%)	1.01 (0.54, 1.87)	0.96
Stroke	31 (6%)	23 (5%)	0.77 (0.45, 1.32)	0.35

## Hazard Plots of Selected Baseline Characteristics

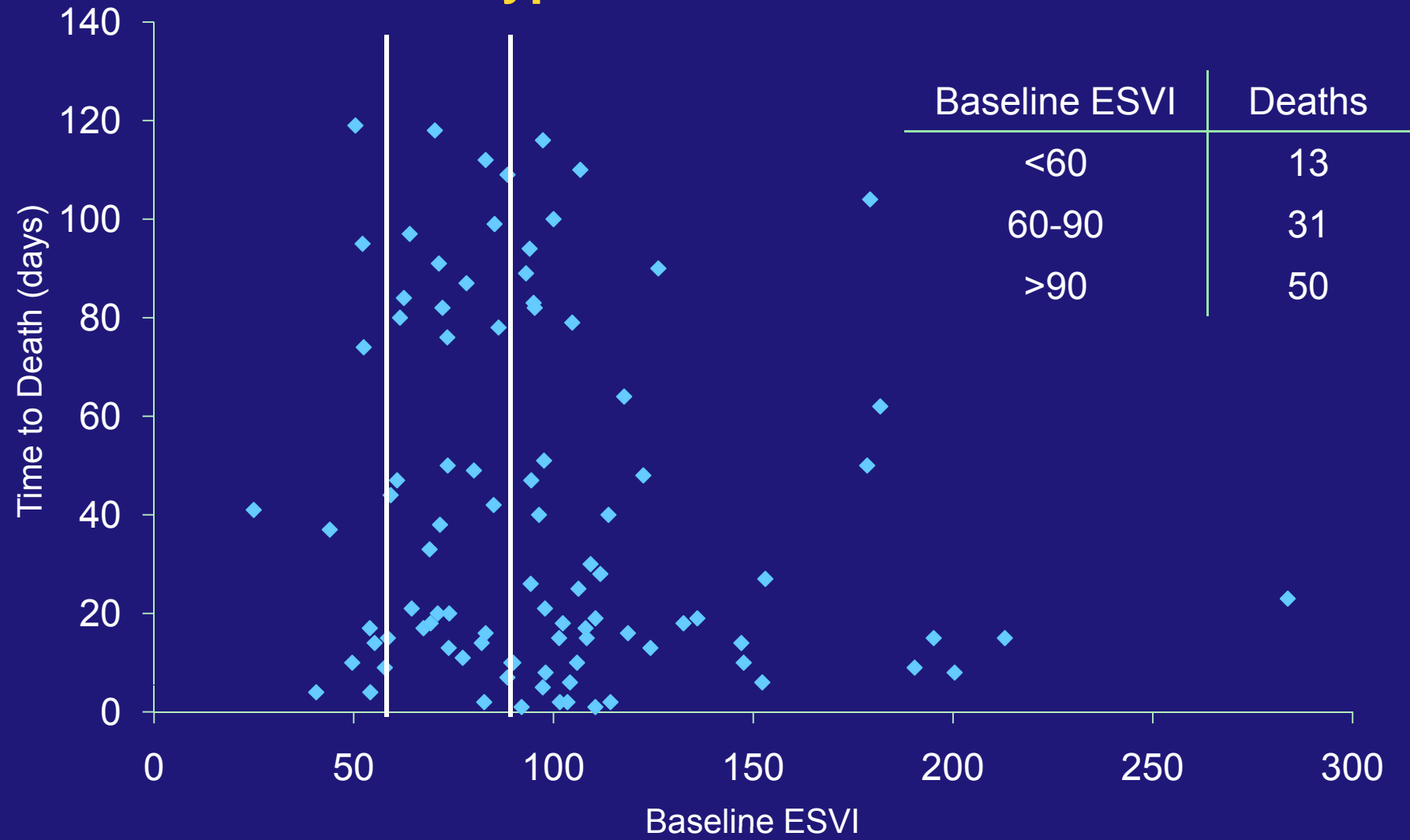
Subgroup	N	HR (95% CI)	P Value
All Subjects	1000	0.99 (0.84, 1.17)	
Age			0.48
≥ 65	391	1.06 (0.83, 1.35)	
< 65	609	0.94 (0.76, 1.17)	
Gender			0.60
Male	853	1.01 (0.84, 1.20)	
Female	147	0.90 (0.58, 1.39)	
Race			0.44
Minority	124	0.83 (0.51, 1.36)	
Non-minority	876	1.01 (0.85, 1.20)	
Current NYHA HF class			0.97
I or II	515	0.99 (0.78, 1.25)	
III or IV	485	0.99 (0.79, 1.24)	



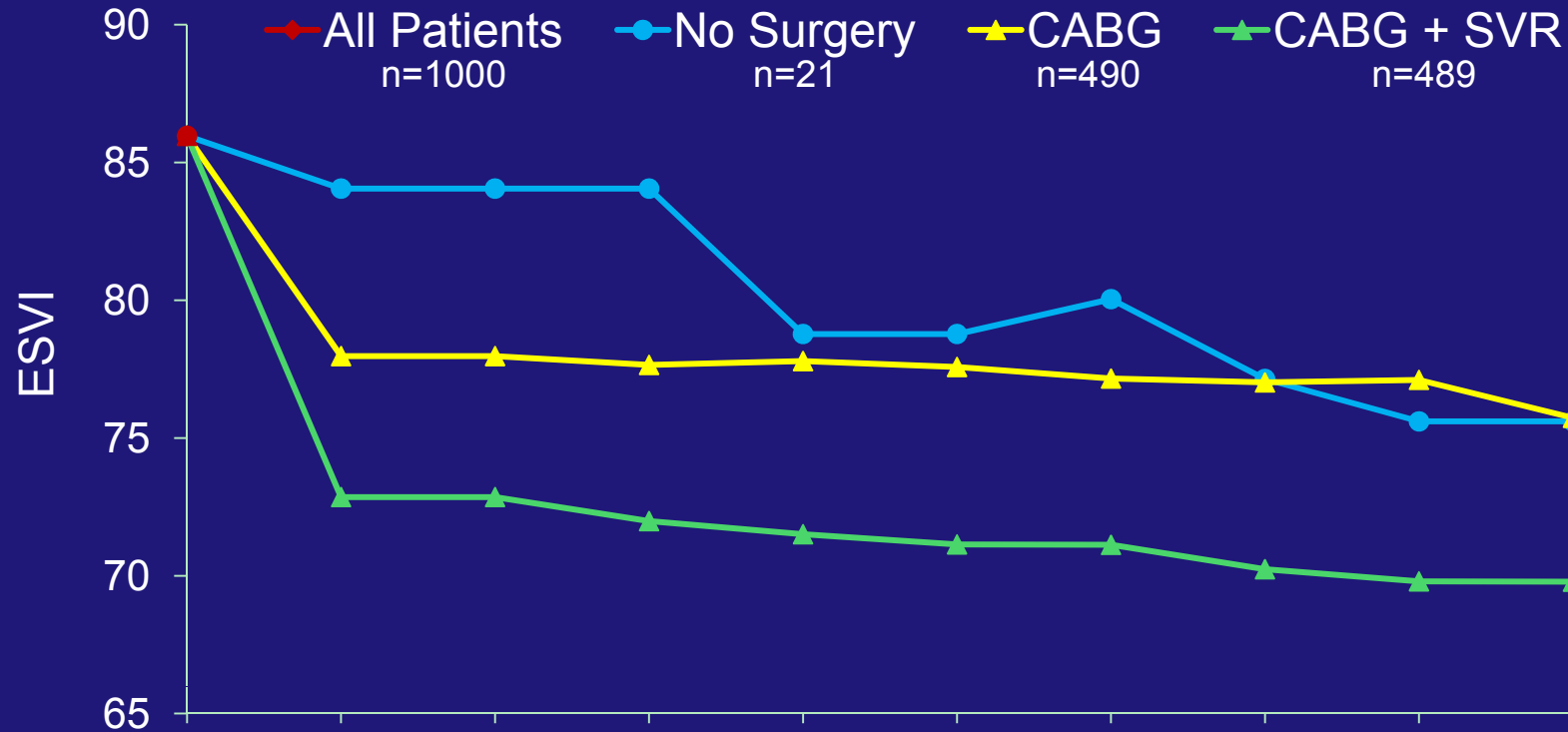
# Relationship of Death at 4-Years in 1,000 SVR Hypothesis Patients and All Cause Death in 10 Groupings of 100 Patients



# 94 Deaths within 4 Months After Randomization in 1000 Hypothesis 2 Patients

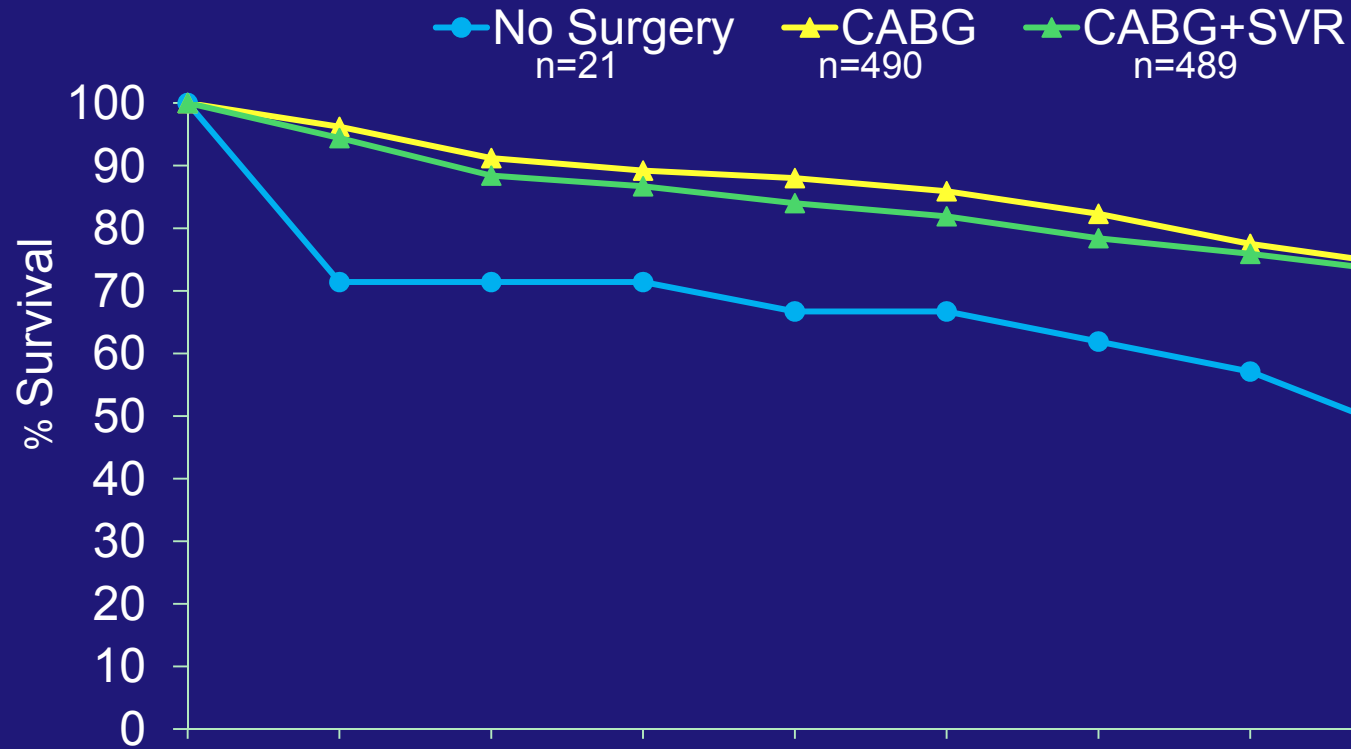


# Influence of Death on SVR Hypothesis Population ESVI



Time Interval	Baseline	0-30 Days	4-6 Months	8 Months	12 Months	18 Months	24 Months	30 Months	48 Months	60 Months	72 Months
Interval ESVI											
No Surgery	86	84	84	84	79	79	80	77	76	76	76
CABG	86	78	78	78	78	77	77	77	76	76	76
CABG+SVR	86	73	72	72	71	71	70	70	70	70	70

# Survival of 1000 SVR Hypothesis Patients as a Function of Baseline (n=445) or Postoperative ESVI (n=555)



Time Interval	Baseline	0-30 Days	4-6 Months	8 Months	12 Months	18 Months	24 Months	30 Months	48 Months	60 Months	72 Months
Interval Survival %											
No Surgery	100	71	71	71	67	67	62	57	48	48	48
CABG	100	96	91	89	88	86	82	78	74	73	73
CABG+SVR	100	94	88	87	84	82	78	76	73	73	73

**Jones, et al. for the STICH Investigators.  
Coronary bypass surgery with or without  
surgical ventricular reconstruction.**

***N Engl J Med 2009;360:1705-1717***

**Velazquez, et al. for the STICH Investigators.  
Coronary artery bypass surgery in patients  
with left ventricular dysfunction.**

***N Engl J Med 2011;364:1607-1616***

**Bonow, et al. for the STICH Investigators.  
Myocardial viability and survival in ischemic  
left ventricular dysfunction.**

***N Engl J Med 2011;364:1617-1625***

