



**Surgical Treatment for Ischemic
Heart Failure (STICH) Trial:
CABG versus CABG + SVR**

**Robert H. Jones, M.D.
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STICH Financial Disclosures

Original Recipient Institution	Principal Investigator	Activity
Duke University Medical Center	Robert H. Jones	Clinical Coordinating Ctr
Duke University Medical Center	Kerry L. Lee	Statistical and Data CC
Duke University Medical Center	Daniel B. Mark	EQOL Core Laboratory
Univ of Alabama-Birmingham	Gerald M. Pohost	CMR Core Laboratory
Mayo Clinic	Jae K. Oh	ECHO Core Laboratory
University of Pittsburgh	Arthur M. Feldman	NCG Core Laboratory
Northwestern University	Robert O. Bonow	RN Core Laboratory
Washington Hospital Center	Julio A. Panza	DECIPHER Substudy
Baylor University Medical Ctr	Paul Grayburn	MR TEE Substudy

Funding Sources:

National Heart, Lung and Blood Institute 97.3%

Abbott Laboratories 2.3%

Chase Medical 0.3%

CV Therapeutics 0.1%



Core STICH Study Organization

- Principal Investigator: Robert H Jones
- Co-Principal investigator: Eric Velazquez
- DCC Principal Investigator: Kerry L Lee
- Study Chair: Jean L Rouleau
- Executive Committee: Robert H Jones, Eric Velazquez, Kerry L Lee, Jean L Rouleau, Patrice Desvigne-Nickens, George Sopko, Chris O'Connor, Robert Michler, and Jae Oh.
- DSMB chair: Sid Goldstein
- Publications Committee chair: James Hill
- Clinical Endpoints Committee: Peter Carson



Hypothesis 2 Enrollment by Country

- 1000 patients
- 96 clinical sites
- 23 countries
- 1231 days



CAD, EF ≤ 0.35

Eligible for MED-only treatment?

Yes

No

Eligible for 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

(527)

2

MED
+
CABG

(534)

3

MED

(75)

4

MED
+
CABG

(76)

5

MED
+
CABG
+
SVR

(65)

6

MED
+
CABG

(423)

7

MED
+
CABG
+
SVR

(436)

602 MED only

1033 CABG added

501 CABG + SVR added

Randomized Patients

MED

(602)

MED
+
CABG

(610)

Hypothesis 1
n = 1212

MED
+
CABG

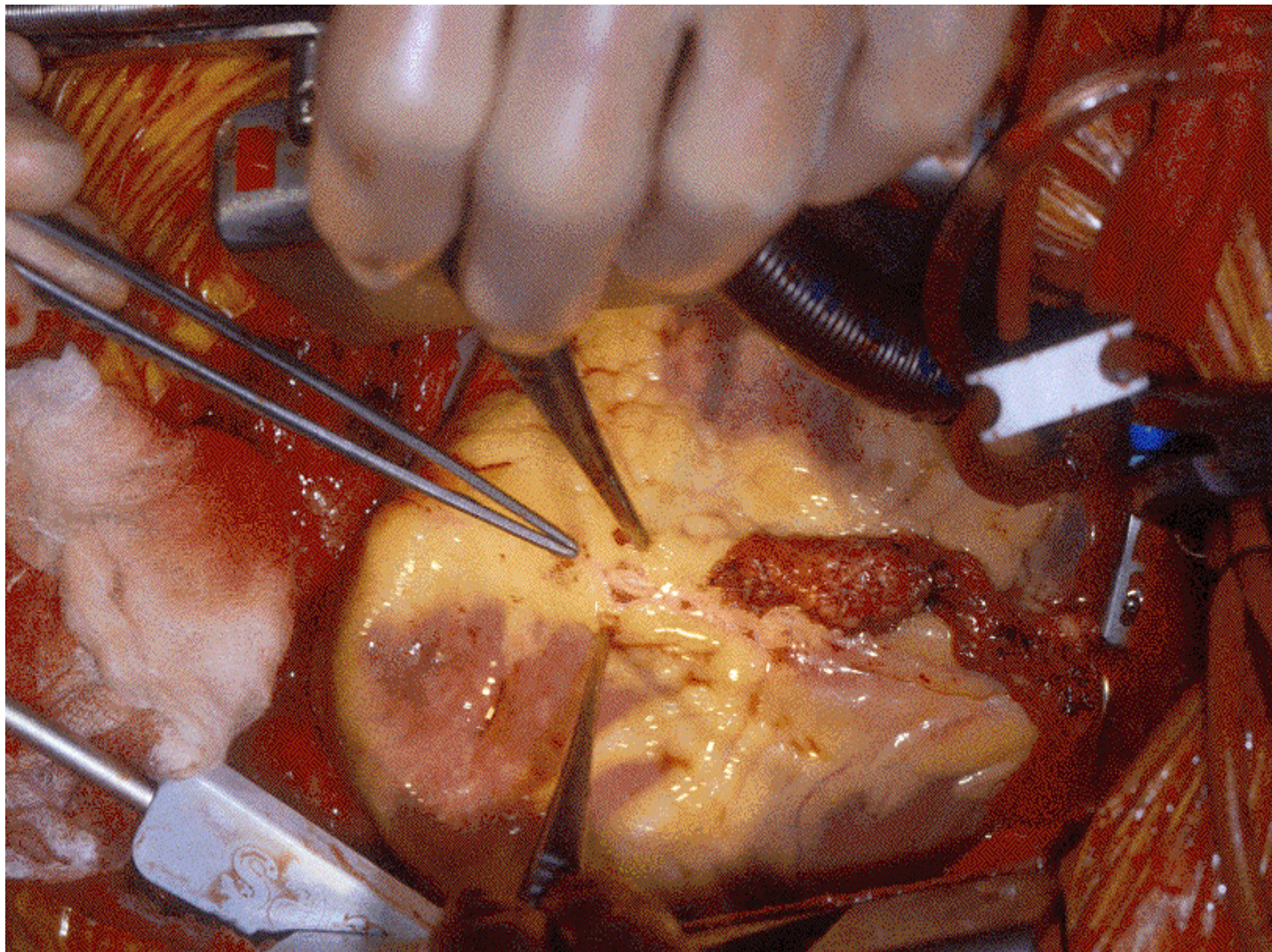
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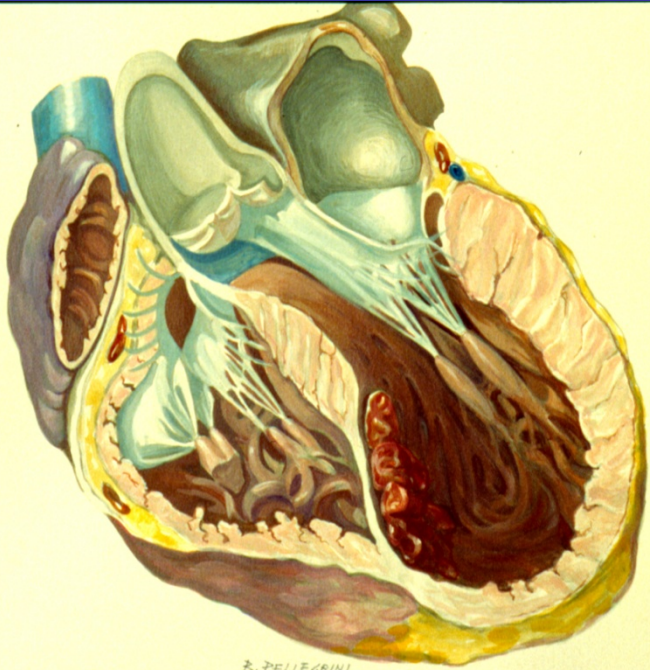
MED
+
CABG
+
SVR

(501)

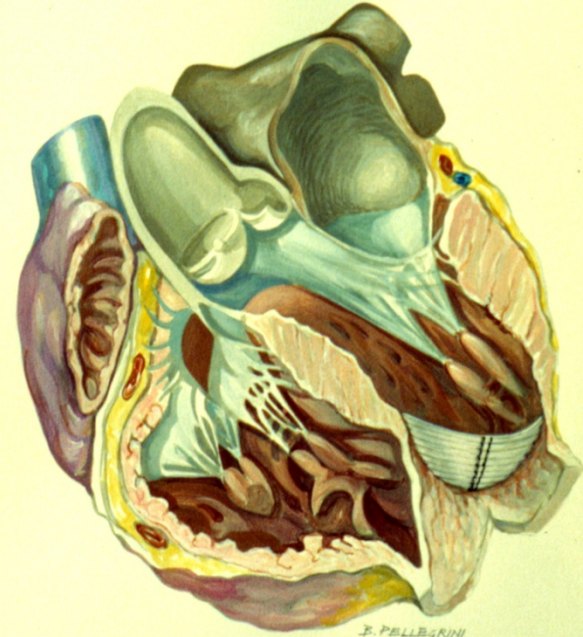
Hypothesis 2
n = 1000

**Numbers for Analysis
by Hypothesis**





E. PELLEGRINI



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Hypothesis 2

- Surgical ventricular reconstruction (SVR) combined with CABG and evidence-based medical therapy (MED) decreases death or cardiac hospitalization compared to CABG and MED without SVR.
- 90% power for 20% reduction assuming $\geq 45\%$ 3-year event rate allowing for 20% treatment crossovers.
- 7% of CABG and 9% of CABG + SVR patients did not receive assigned operation.
- Follow-up 99% complete over median of 48 months.
- All outcomes reported by operation assigned by randomization.
- Conduct of operation reported by procedure received.

Baseline Clinical Characteristics

Characteristic	CABG N = 499	CABG + SVR N = 501
Age, median 25 th , 75 th , years	62 (54, 66)	62 (56, 69)
Female	78 (16%)	69 (14%)
White	90%	92%
Diabetes	35%	34%
Creatinine, >0.5 mg/dL	8%	9%
Prior stroke	6%	6%

Mitral Regurgitation by Treatment in 1,000 Hypothesis 2 Patients

Mitral Regurgitation Severity	CABG N = 499	CABG + SVR N = 501
None or trace	173 (35%)	190 (38%)
Mild ($\leq 2+$)	233 (47%)	216 (44%)
Moderate (3+)	72 (15%)	70 (14%)
Severe (4+)	16 (3%)	20 (4%)
Not assessed	5 (4%)	5 (3%)

18%

Site Reported Left Ventricular Function for 1,000 Hypothesis 2 Patients by Treatment

LV Function	CABG N = 499	CABG + SVR N = 501
Site Qualifying Study		
Echocardiogram (%)	66%	63%
Contrast ventriculogram	13%	18%
CMR	11%	9%
Gated SPECT	10%	10%
LVEF, median (25th, 75th)	.28 (.23, .31)	.28 (.24, .31)
ESVI, median (25th, 75th), mL/m²	82 (65, 102)	82 (66, 105)
% anterior wall with akinesia/ dyskinesia, median (25th, 75th)	56 (40, 60)	50 (40, 60)

Coronary Anatomy by Treatment for 1,000 Hypothesis 2 Patients

Major Coronary Arteries with Stenosis	% Stenosis	CABG N = 499	CABG + SVR N = 501
One	≥50%	7%	10%
LM stenosis	50-74%	14%	12%
One	≥ 75%	17%	20%
Two	≥ 75%	41%	42%
Three	≥ 75%	41%	36%
Proximal LAD	≥ 75%	78%	74%
LM stenosis	≥ 75%	6%	7%
Duke coronary disease index*	Median (25 th , 75 th)	65 (43, 91)	65 (39, 91)

* 0 = coronary angiogram shows no coronary disease, 100 = ≥95% LM stenosis

Medication at Baseline

Medication	CABG N = 499	CABG + SVR N = 501
Beta blocker	85%	87%
ACE inhibitor or angiotensin receptor blocker	87%	89%
ACE inhibitor	80%	82%
Digoxin	17%	14%
Diuretic	69%	66%
Aspirin	77%	77%
Aspirin or warfarin	81%	83%
Statin	79%	75%

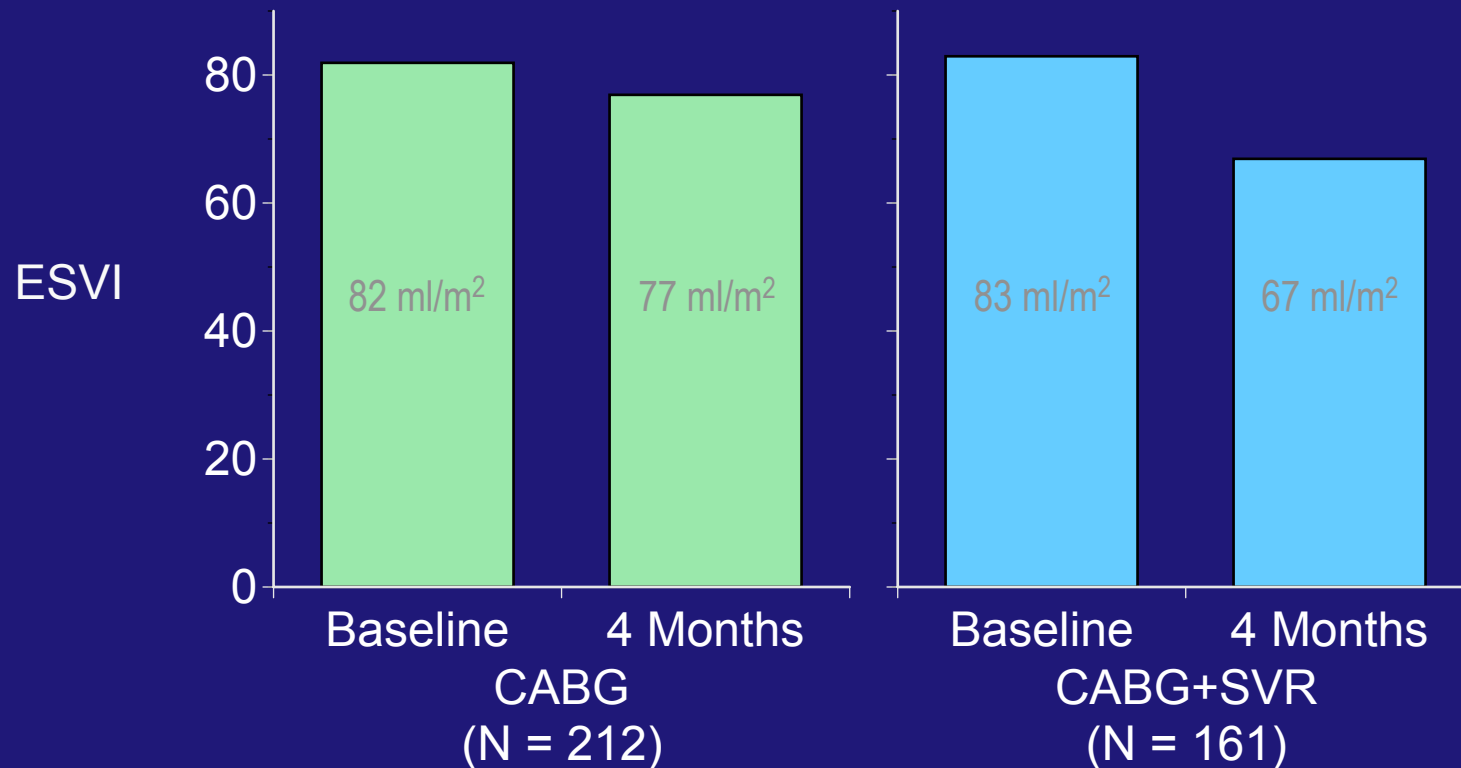
Operative Conduct by Operation Received in 979 Hypothesis 2 Patients

Variable	CABG N = 490	CABG + SVR N = 489	P
Status at Operation			
Elective operation	84%	83%	0.54
Urgent	13%	13%	
Emergency	3%	4%	
Bypass Grafts			
1 or more arterial grafts	93%	89%	0.34
2 or less total grafts	27%	30%	
3 or more total grafts	73%	70%	
Mitral surgery	17%	19%	0.50
SVR patch		59%	

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 th , 75 th), hours	4.9 (4.1, 6.0)	5.5 (4.7, 6.6)	<0.001
Cardiopulmonary bypass time (median, 25th, 75th), minutes	99 (73, 125)	124 (99, 158)	<0.001
Aortic occlusion (median, 25 th , 75 th), minutes	62 (45, 84)	80 (62, 106)	<0.001
Requirements for Postoperative Care			
Endotracheal intubation (median, 25 th , 75 th), hours	15.1 (10.9, 22.1)	16.6 (12.0, 25.2)	0.002
Acute care (median, 25 th , 75 th), hours	49.8 (28.8, 95.5)	69.5 (42, 137)	<0.001
Hospitalization >30 days	22 (5%)	31 (6%)	0.20

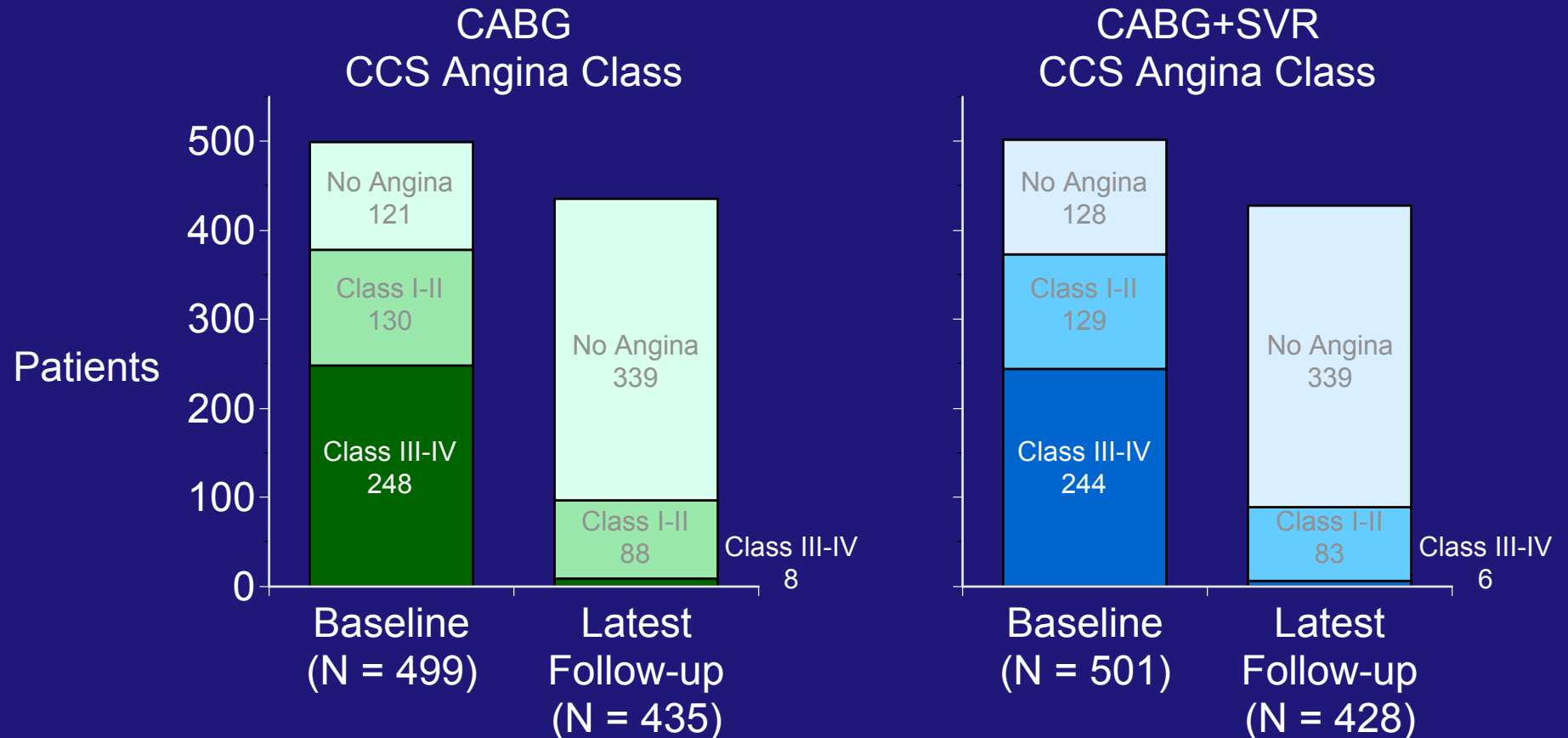
Baseline and Four Month End-Systolic Volume Index (ESVI) in 373 Hypothesis 2 Patients With Quantitative Echocardiogram at Both Intervals



P<0.001



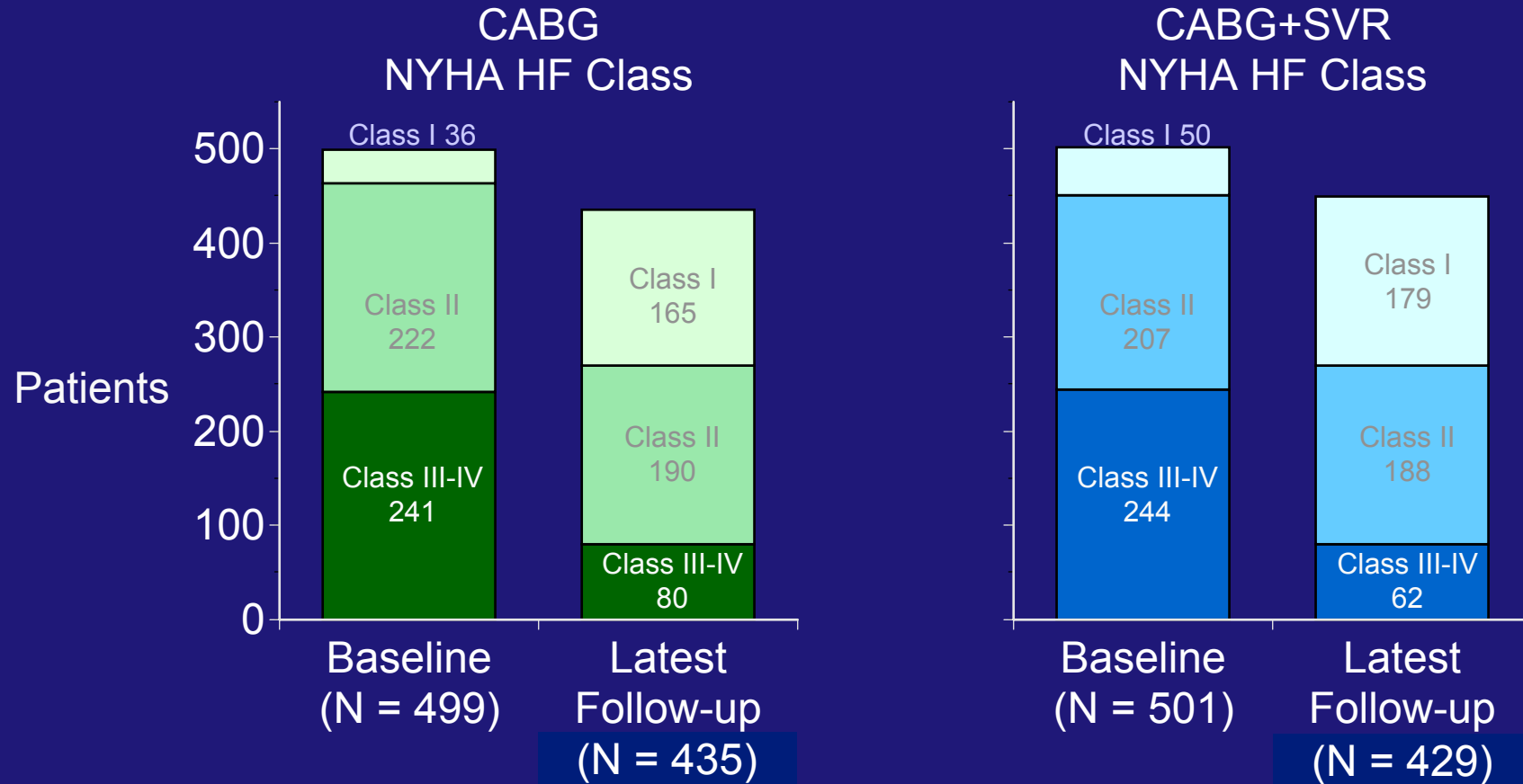
Canadian Cardiovascular Society Angina Class in Hypothesis 2 Patients at Baseline and Latest Follow-up



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



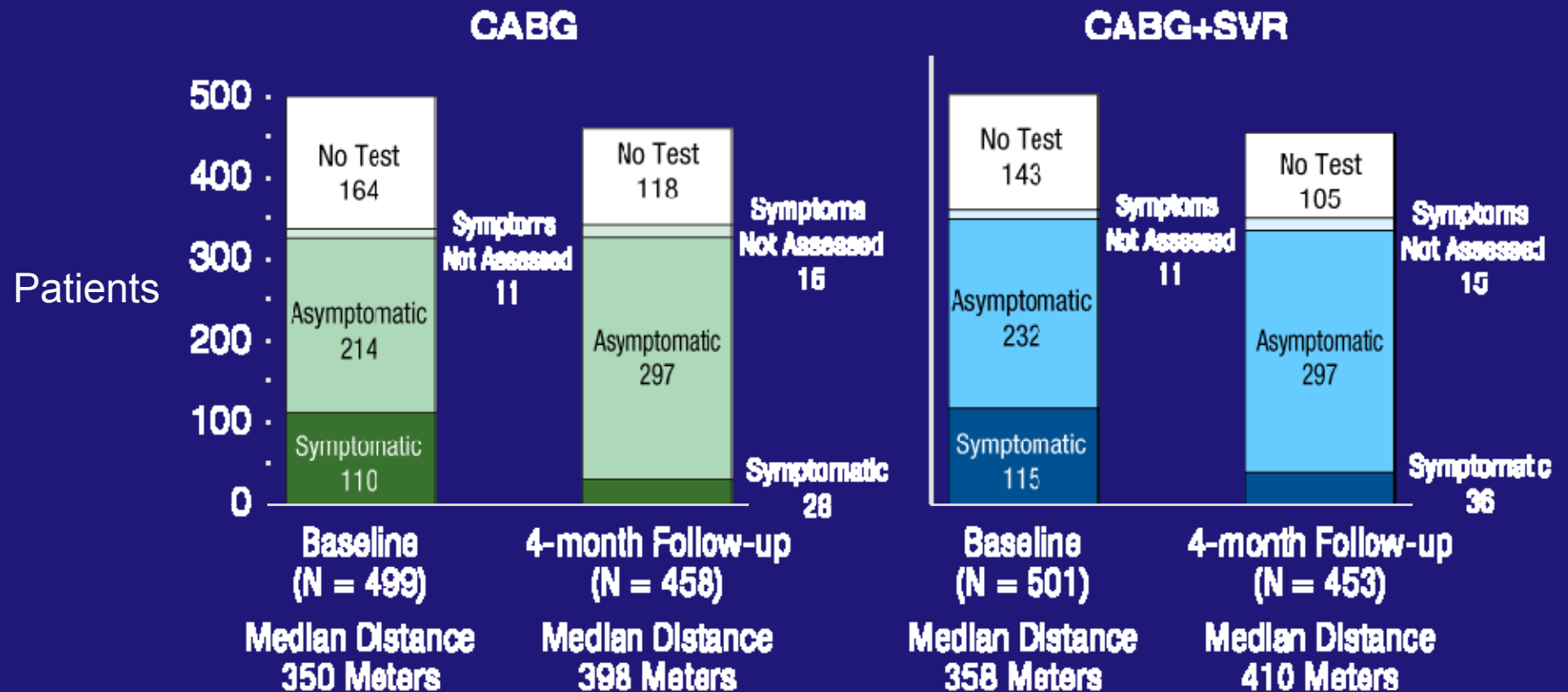
New York Heart Association Heart Failure Class in Hypothesis 2 Patients at Baseline and Latest Follow-up



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



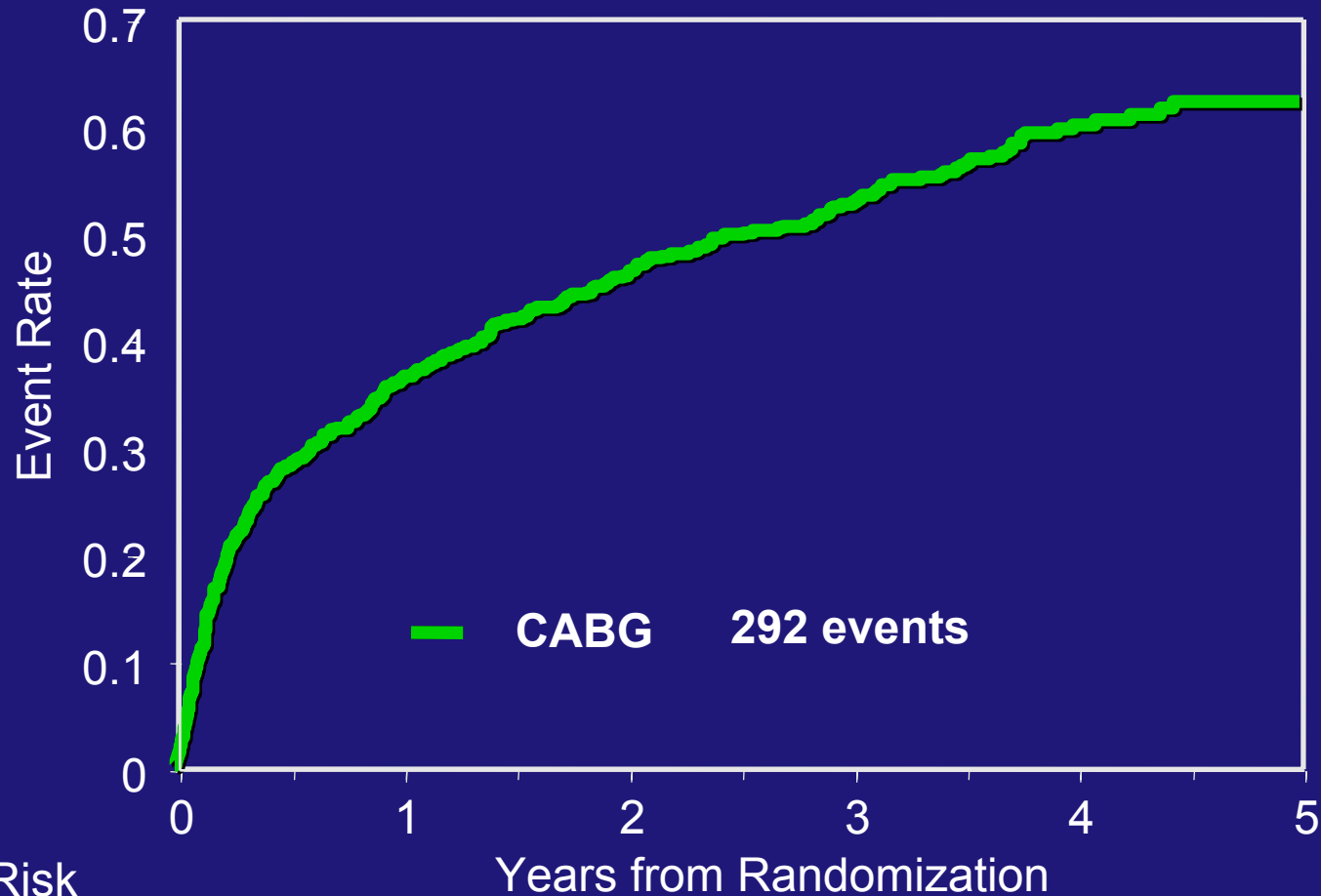
Baseline and Four Month 6-Minute Walk in 693 Hypothesis 2 Patients with Baseline Assessment



30-Day Mortality

Outcome	CABG N = 499	CABG + SVR N = 501	P
<i>Death Within 30 Days After Randomization</i>			
All patients by intention to treat	22/499 (4.4%)	30/501 (6.0%)	0.26
<i>Death During or Within 30 Days of Operation</i>			
Operated patients by intention to treat	25/490 (5.1%)	26/489 (5.3%)	0.88
Operated patients by operation received	23/498 (4.6%)	28/481 (5.8%)	0.40

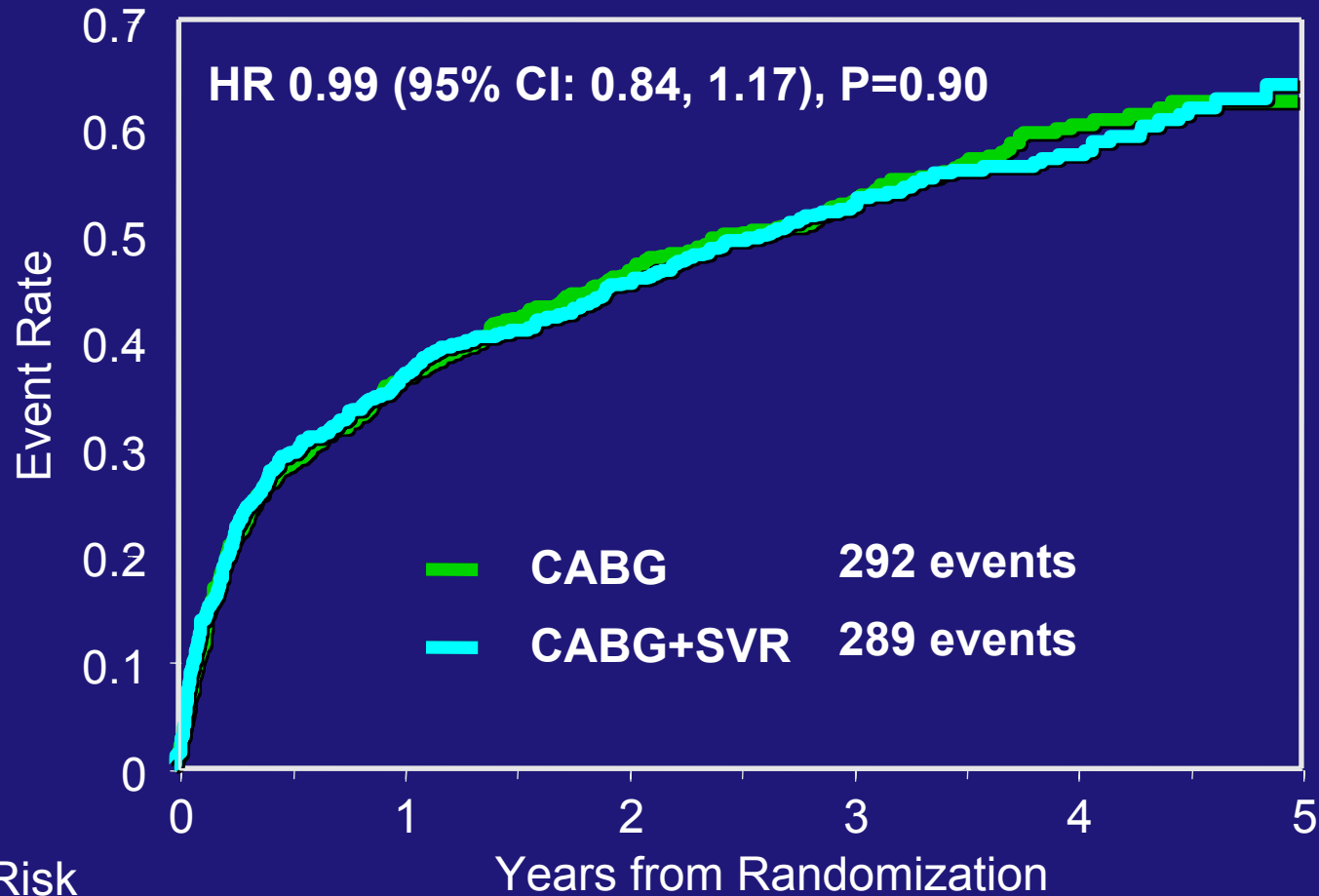
Death or Cardiac Hospitalization Kaplan-Meier Estimates of Primary Endpoint



No. at Risk

CABG	499	319	270	220	99	23
CABG+SVR	501	319	275	216	11	23

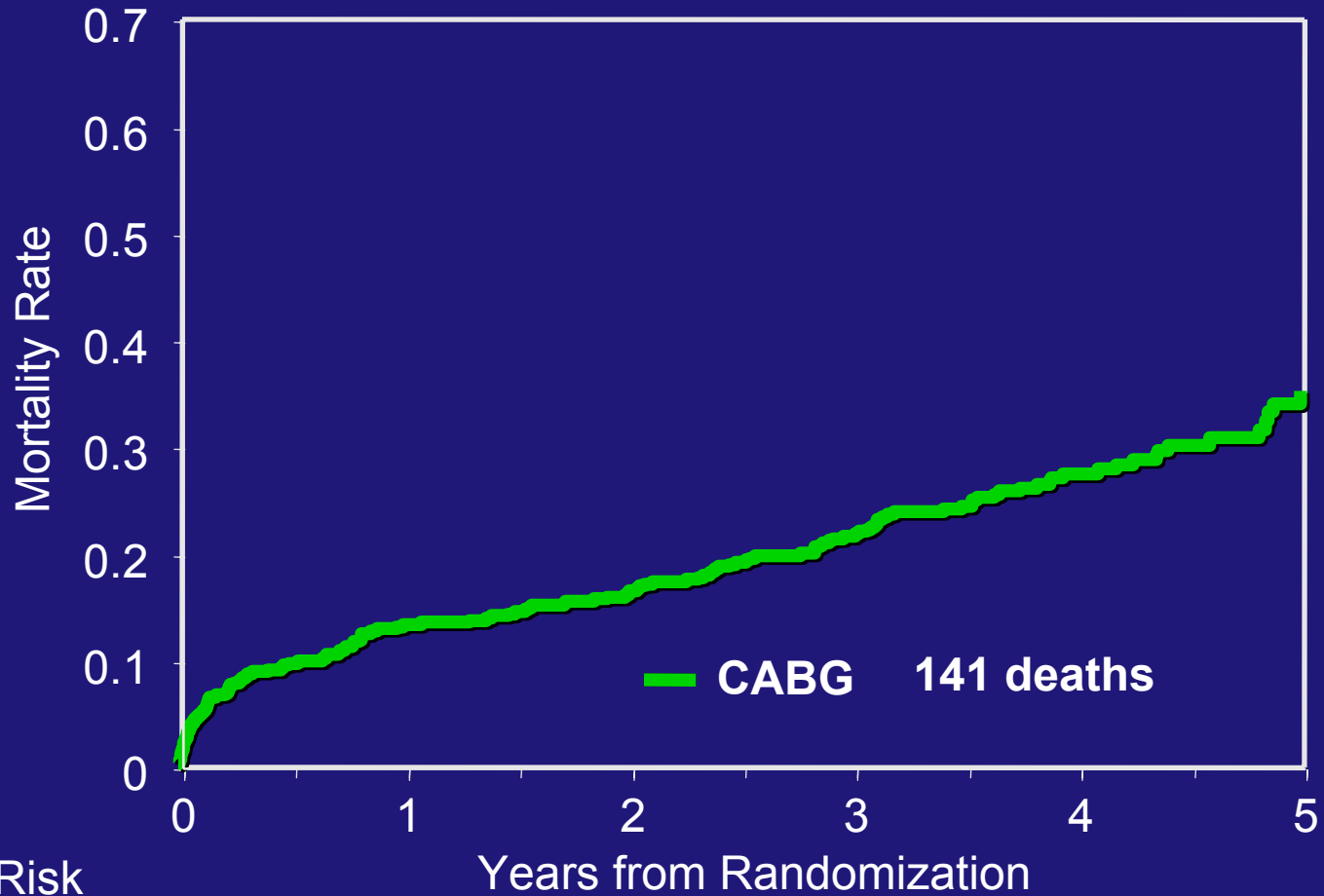
Death or Cardiac Hospitalization Kaplan-Meier Estimates of Primary Endpoint



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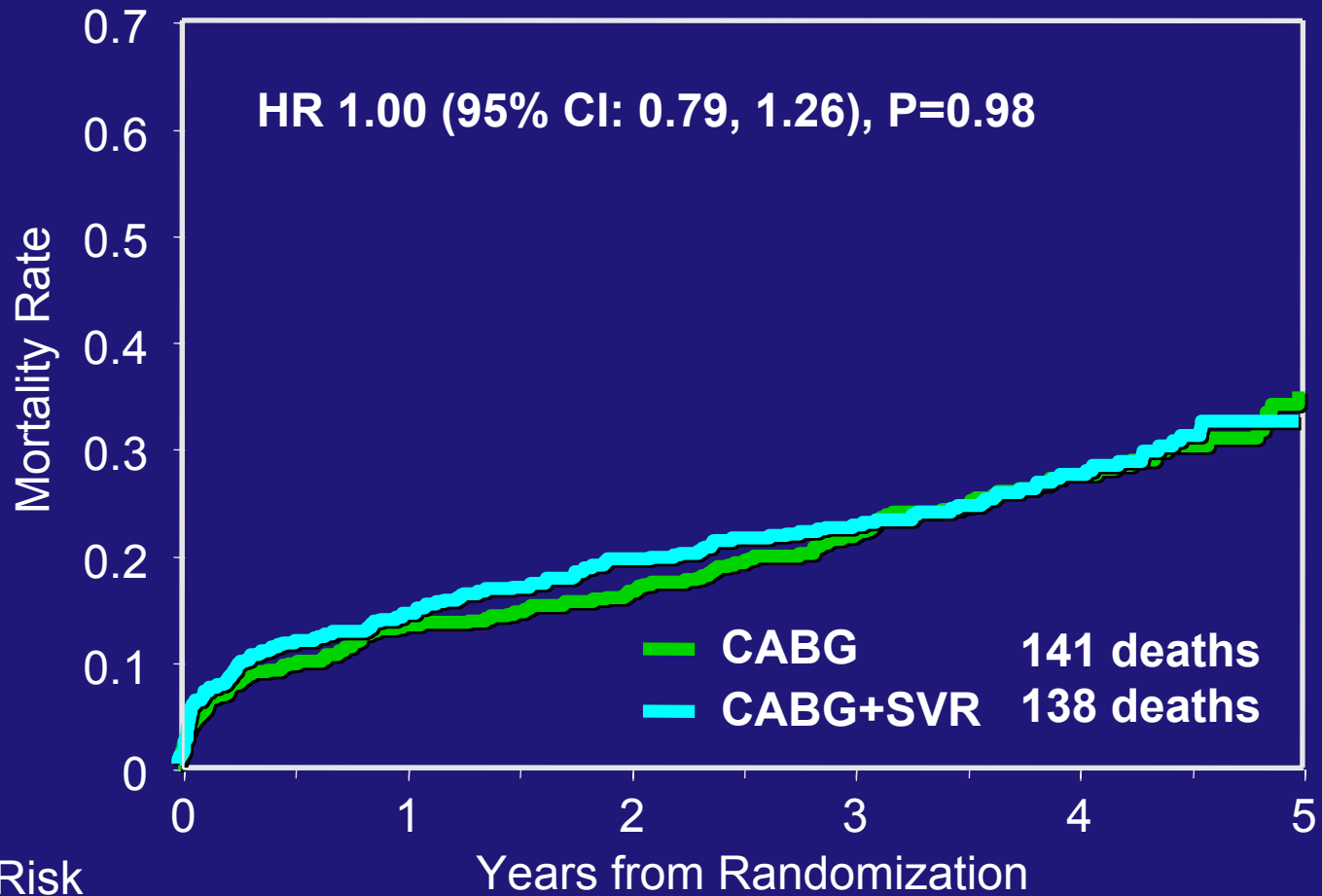
Mortality (All-Cause) Kaplan-Meier Estimates



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



No. at Risk

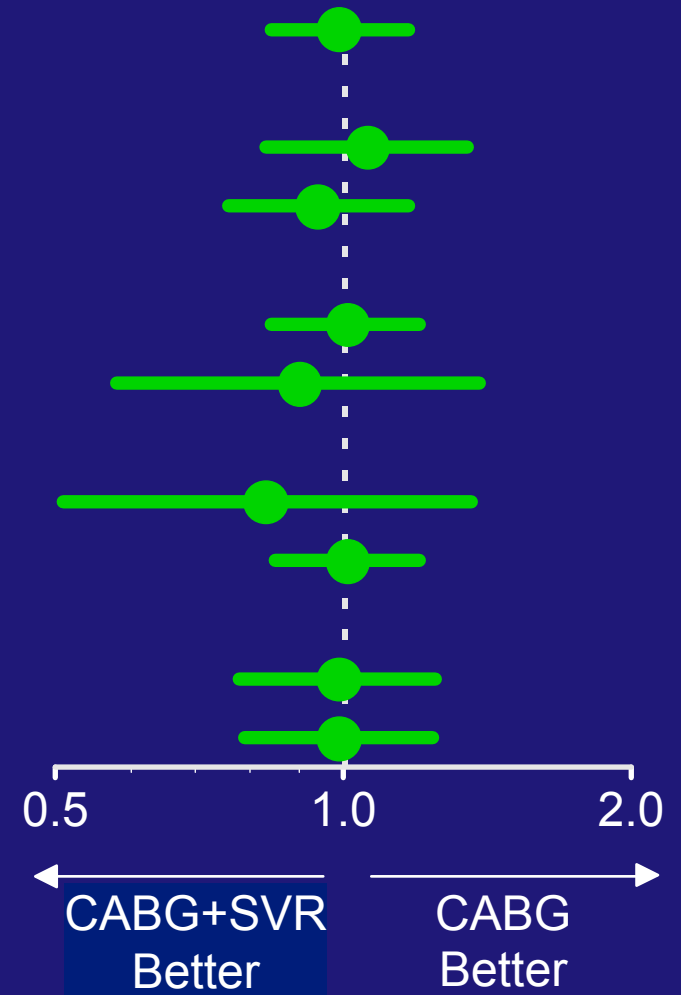
CABG	499	434	417	363	201	59
CABG+SVR	501	429	404	352	193	53

Summary of Outcomes in STICH H2

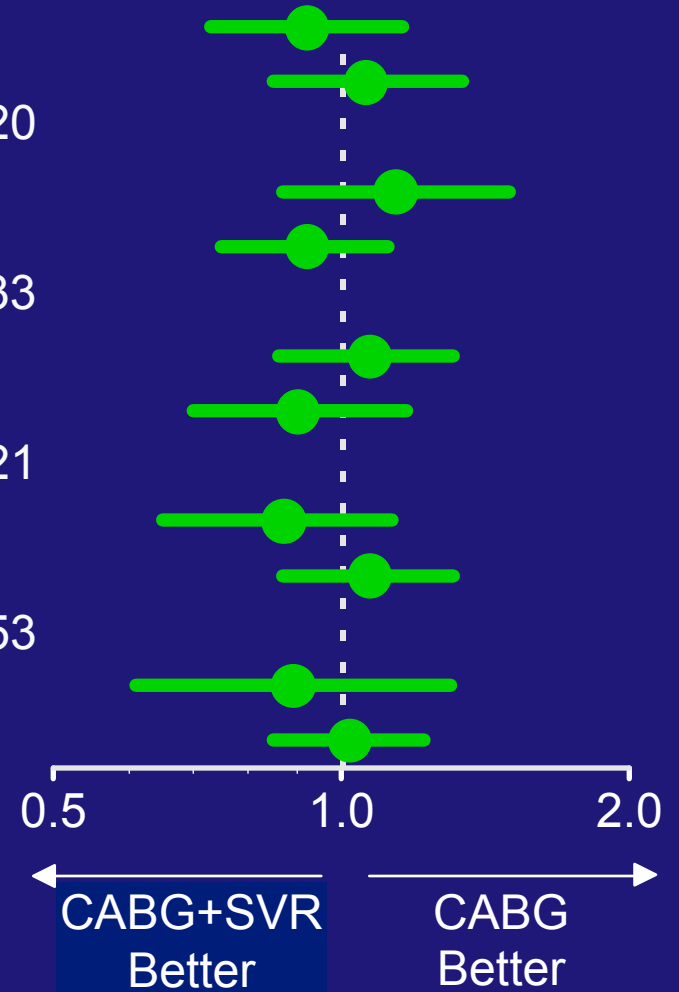
Outcomes	CABG N = 499	CABG + SVR N = 501	Hazard Ratio 95% CI	P
Death or cardiac hospitalization	292 (59%)	289 (58%)	0.99 (0.84, 1.17)	0.90
Death	141 (28%)	138 (28%)	1.00 (0.79, 1.26)	0.98
Hospitalization (cardiac)	211 (42%)	204 (41%)	0.97 (0.80, 1.18)	0.73
Hospitalization (all cause)	272 (55%)	268 (53%)	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 Ratios, Confidence Intervals, and Tests for Interaction

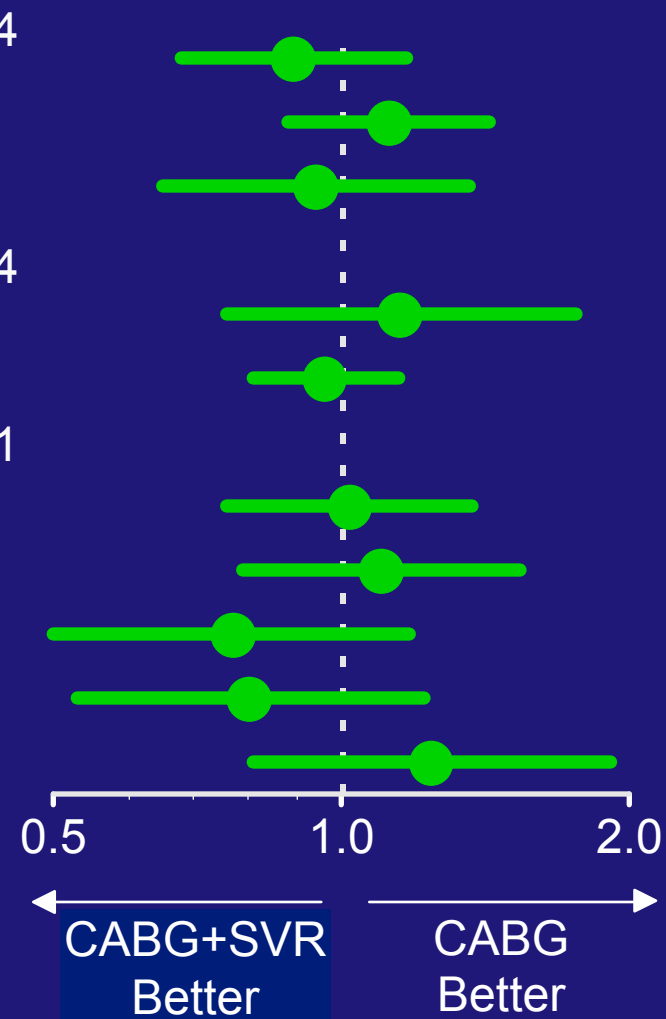
Subgroup	N	HR (95% CI)	P Value
All Subjects	1000	0.99 (0.84, 1.17)	
Age			0.48
≥ 65	391	1.06 (0.83, 1.35)	
< 65	609	0.94 (0.76, 1.17)	
Gender			0.60
Male	853	1.01 (0.84, 1.20)	
Female	147	0.90 (0.58, 1.39)	
Race			0.44
Minority	124	0.83 (0.51, 1.36)	
Non-minority	876	1.01 (0.85, 1.20)	
Current NYHA HF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



Subgroup	N	HR (95% CI)	P Value
CCS angina class			0.39
≤ Class II	508	0.92 (0.73, 1.16)	
Class III or IV	492	1.06 (0.85, 1.34)	
Baseline diabetes			0.20
Yes	344	1.14 (0.87, 1.50)	
No	656	0.92 (0.75, 1.12)	
LVEF (site reported)			0.33
≤ 28	534	1.07 (0.86, 1.31)	
> 28	466	0.90 (0.70, 1.17)	
# of diseased vessels ≥ 50%			0.21
1 or 2	362	0.87 (0.65, 1.13)	
3	638	1.07 (0.87, 1.31)	
Left main ≥ 50% or proximal LAD ≥ 75%			0.53
No	179	0.89 (0.61, 1.30)	
Yes	821	1.02 (0.85, 1.22)	



Subgroup	N	HR (95% CI)	P Value
Mitral regurgitation			
None or trace	363	0.89 (0.68, 1.17)	0.44
Mild ($\leq 2+$)	449	1.12 (0.88, 1.43)	
Mod. or severe	178	0.94 (0.65, 1.36)	
Stratum			
B	141	1.15 (0.76, 1.76)	0.44
C	859	0.96 (0.81, 1.15)	
Region			
Poland	288	1.02 (0.76, 1.37)	0.41
USA	200	1.10 (0.79, 1.54)	
Canada	154	0.77 (0.50, 1.18)	
West Europe	164	0.80 (0.53, 1.22)	
Other	194	1.24 (0.81, 1.91)	



Conclusions

- **The STICH trial definitively shows adding SVR to CABG provides no clinical benefit beyond that of CABG alone in the study population.**
- **Both operative strategies provided similar short- and long-term relief of angina and HF and improvement in 6-minute walk test performance.**
- **SVR added to CABG decreased LV size significantly more than CABG alone and confirms the anatomic change reported in prior SVR studies.**
- **Further analyses of STICH Hypothesis 2 data may identify patient characteristics associated with benefit or harm from adding SVR to CABG.**

- To learn more about STICH and ongoing Hypothesis 1, after the session look for investigators wearing STICH name tags.
- Visit [NEJM.org](https://www.nejm.org) to read the Hypothesis 2 primary outcome article.