PCI is the Best Choice
Summit TCT Asia Pacific 2008
Seoul, Korea

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MAYO CLINIC

Presenter Disclosure Information

David R. Holmes, Jr., M.D.

"PCI is the Best Choice"

The following relationships exist related to this presentation:

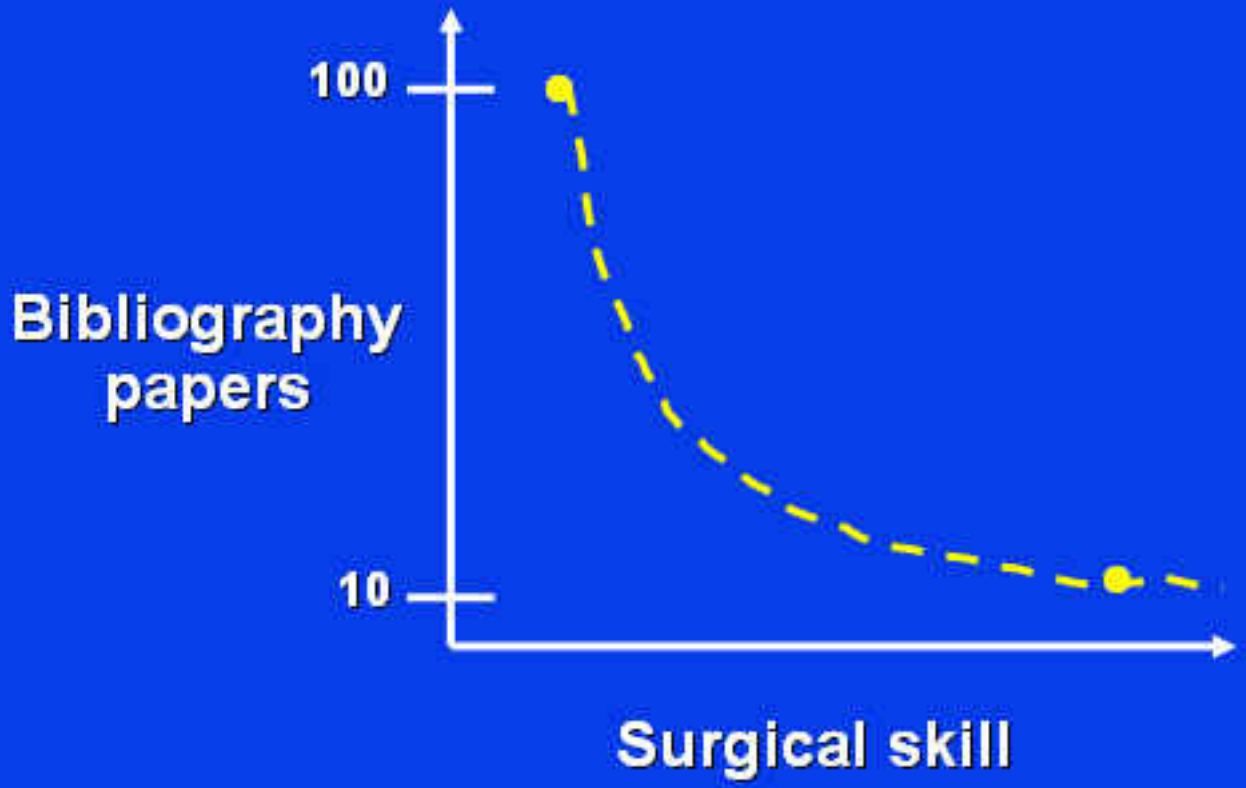
I am an enthusiastic Interventional Cardiologist


CHINA
NORTH KOREA
Hamhung K-25
Sea of Japan
Kimpo K-14
Seoul K-15
Yellow Sea
SOUTH KOREA
P'chang K-3
Taegu K-2
Pusan K-9
JAPAN
Iwakuni
Fukuoka
75 kms
50 mi

“Personally, I’m a Doer”

Surgical Aphorism

Academic productivity $\propto \frac{1}{\text{surgical skill}}$



D.P. Taggart

'New IRREVERSIBLE myocardial injury seen in 36% on-pump and 44% off-pump CABG patients'

'Neurocognitive dysfunction remains a limitation of cardiac surgery'

'Cerebral injury is a major cause of morbidity and mortality of CABG. Stroke occurs in 3% of patients'

'Cognitive dysfunction and post operation hypoxia are common sequelae of CABG'

'Aprotinin should be considered routinely in patients undergoing total arterial grafting'

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Systematic Review
PCI vs CABG

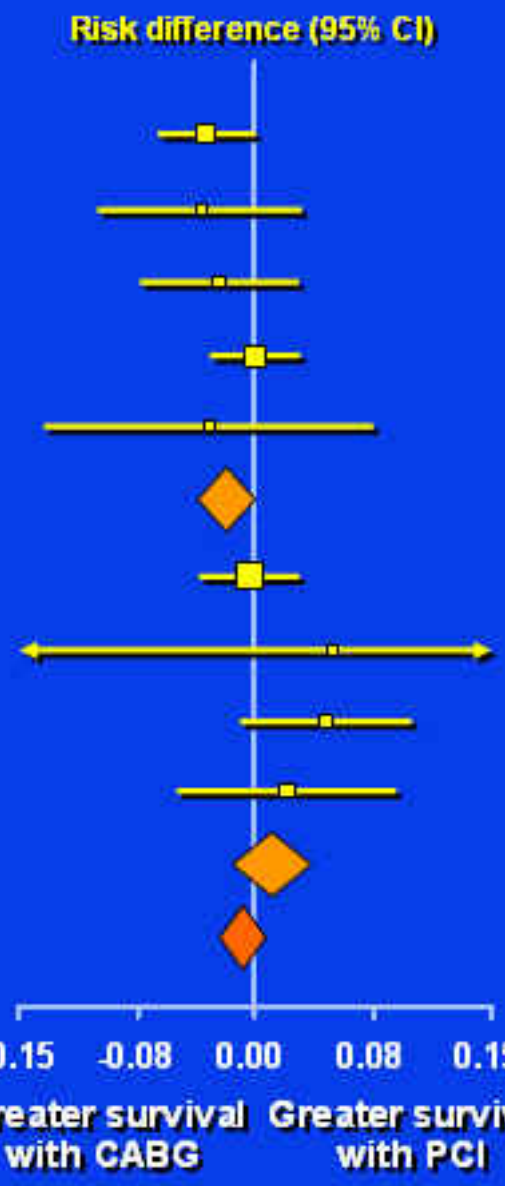
- 23 randomized clinical trials
- 5,019 patients assigned PCI
- 4,944 patients assigned CABG
- Outcomes of interest

  Survival, myocardial infarction, stroke, angina, additional revascularization

Bravata: Ann Intern Med 147:703, 2007

5-Year Survival PCI vs CABG

Study, year	Surviving patients/all patients: PCI	CABG
BARI, 1996	790/915	816/914
EAST, 2000	153/174	161/177
GABI, 2005	164/177	157/165
RITA, 1998	483/510	474/501
French Monocentric Study, 1997	66/76	68/76
Balloon overall	1,656/1,852	1,676/1,833
ARTS, 2005	542/590	538/584
AWESOME, 2001	30/38	19/26
ERACI II, 2005	209/225	199/225
MASS II, 2006	177/205	171/203
BMS overall	958/1,058	927/1,038
MVD overall	2,614/2,910	2,603/2,871



Ann Int Med 147:708, 2007

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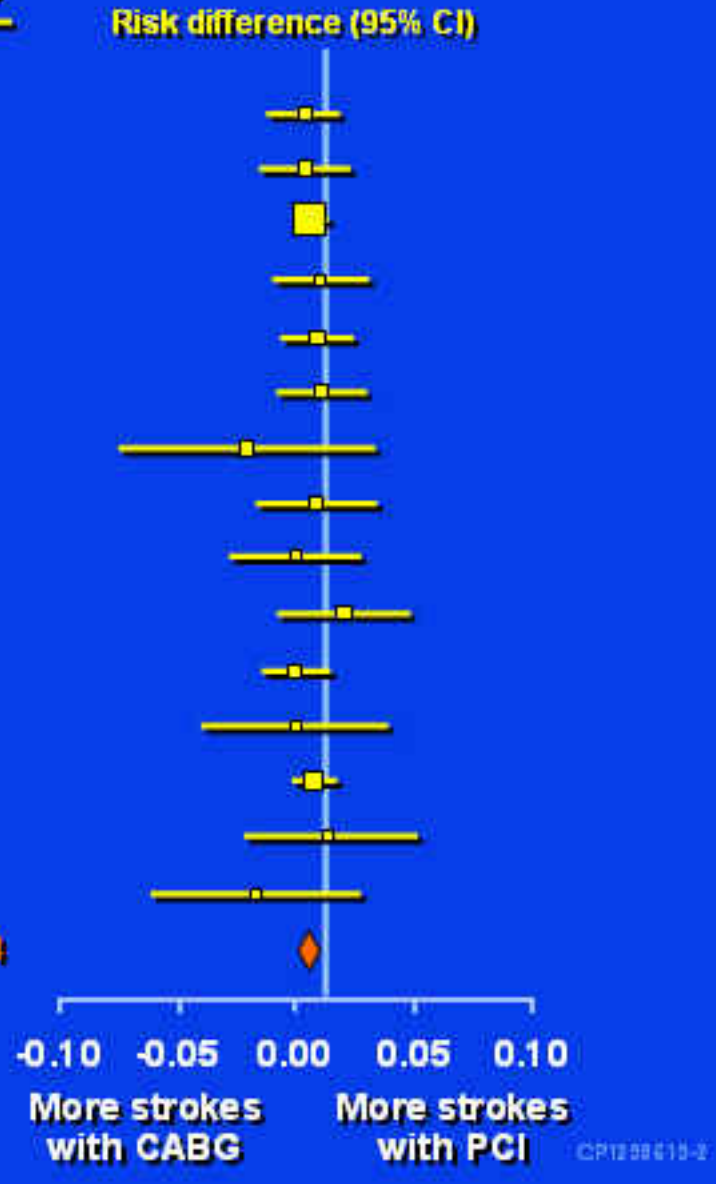
Procedural Stroke Risk

Study, year Procedural stroke	Surviving patients/all patients PCI	 CABG
ARTS, 2001	590/600	592/605
AWESOME, 2001	220/222	229/232
BARI, 1996	913/915	907/914
EAST, 1994	197/198	191/194
ERACI II,2001	225/225	223/225
GABI, 1994	182/182	175/177
Drenth et al, 2002	50/51	51/51
Diegeler et al, 2002	110/110	109/110
MASS, 1995	72/72	70/70
MASS II, 2004	203/205	197/203
Octostent, 2003	138/138	142/142
Cisowski et al, 2002	50/50	50/50
RITA, 1992	509/510	496/501
Hong et al, 2005	119/119	69/70
SIMA, 2000	62/63	60/60
Overall	3,640/3,660	3,561/3,604



Ann Int Med 147:708, 2007

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Systematic Review
PCI vs CABG

Conclusions

1) In 23 RCTs, over 10 years of follow-up
   Difference in survival after PCI or CABG was <1%

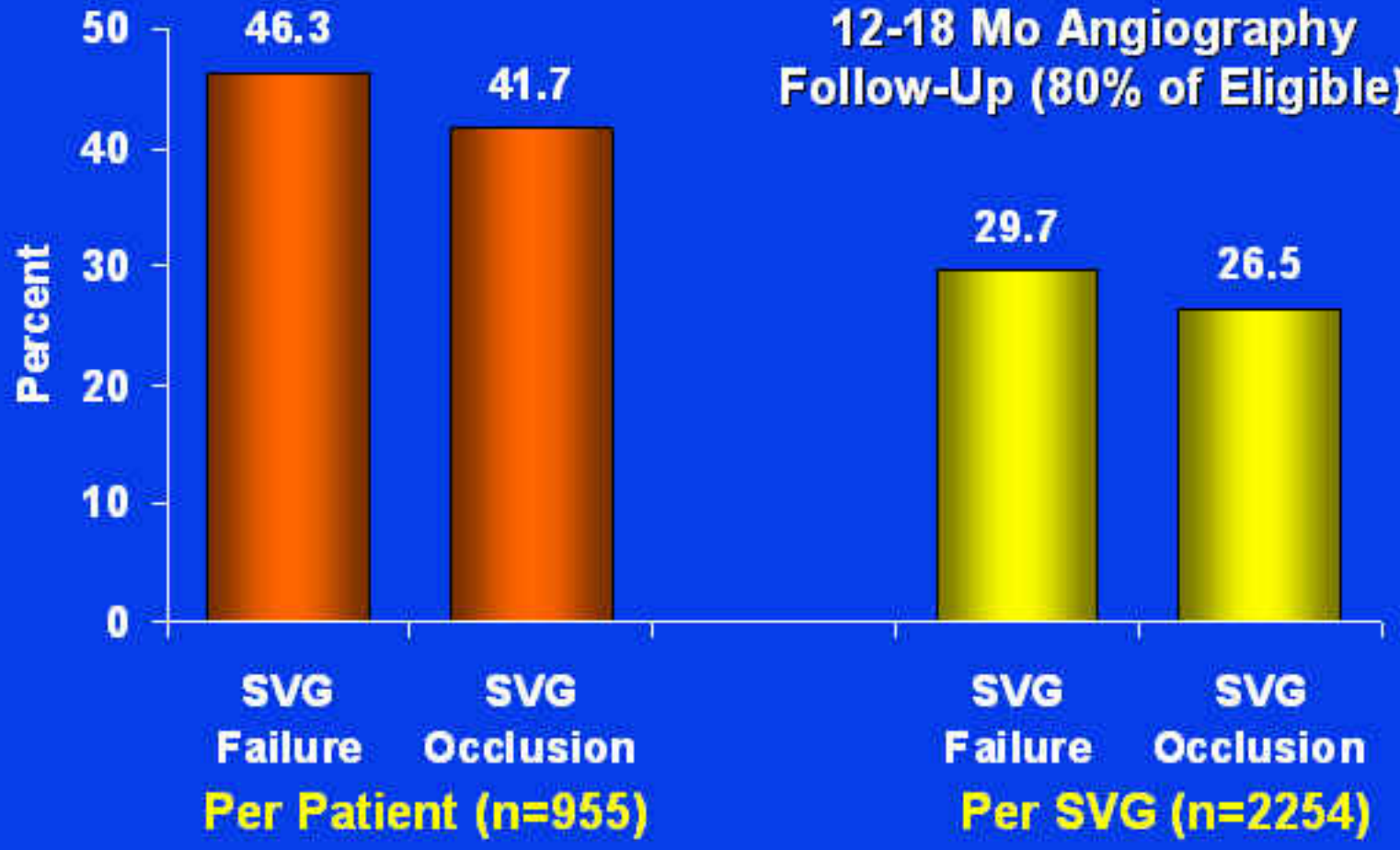
2) Survival did not differ between PCI and CABG for patients with diabetes

3) Angina relief greater after CABG than PCI
   Risk differences 5-8% at 1-5 yr (P<0.001)

4) Procedural-related strokes are more common
   After CABG than after PCI (1.2% vs 0.6%)
   (P=0.002)

Bravata: Ann Intern Med 147:703, 2007

12 Month Vein Graft Failure
PREVENT IV Placebo Cohort



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PREVENT IV Invest. *JAMA* 294:2446

Guidelines

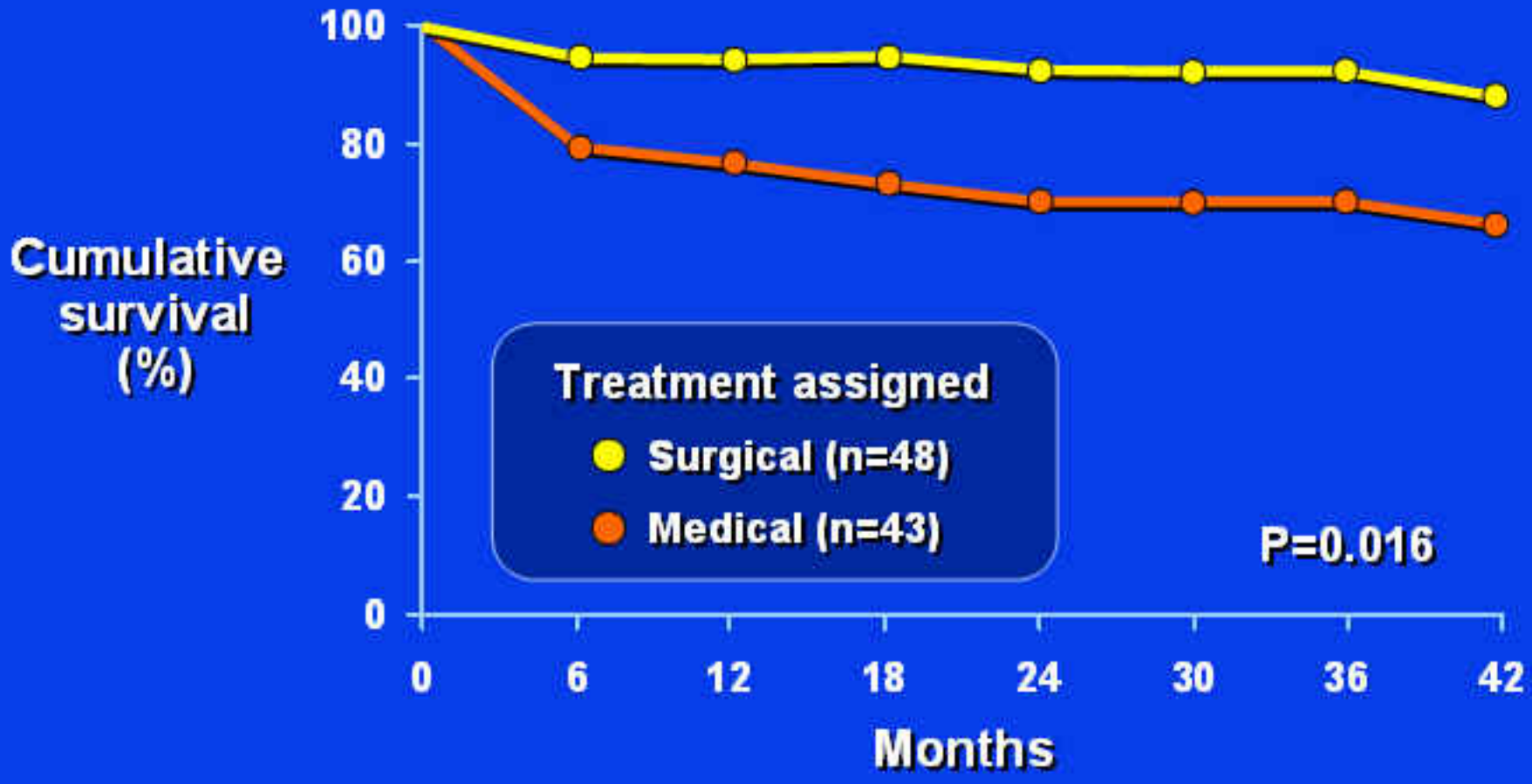
- "CABG should remain the preferred revascularization treatment in good surgical candidates with left main coronary artery disease."


I - V
VI - X
XI - XV

LMCA Management

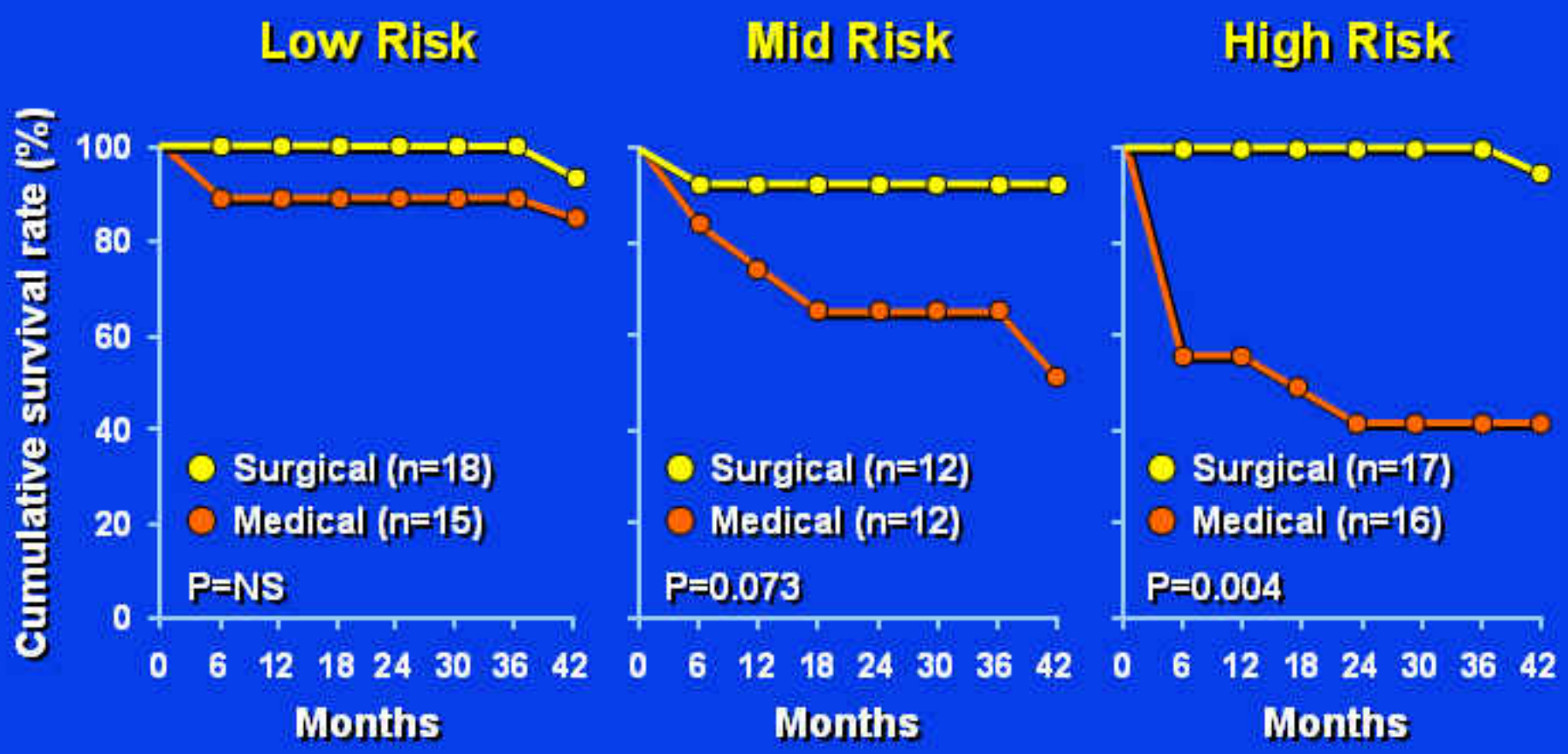
- VA Coop study of 91 patients with LMCA randomized from 1972 to 1974 to either surgery or medical management

Left Main Disease



Takaro T et al: Prog Cardiovasc Dis 3:229, 1985

Left Main Disease



Takaro T et al: Prog Cardiovasc Dis 3:229, 1985

Conclusions

A more recent report identified two additional sub-groups of patients with substantially improved survival with surgery: patients with >75% left main stenosis and those with multiple clinical risk factors.

Although patients with left main disease are not a homogeneous group, we found that surgery was superior to medical treatment in nearly every subgroup examined.

Takaro T et al: Prog Cardiovasc Dis 3:229, 1985

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STATE-OF-THE-ART PAPER AND COMMENTARY

Revascularization for Unprotected Left Main Stem Coronary Artery Stenosis

Stenting or Surgery

David P. Taggart, MD (Hons), PhD, FRCS,* Sanjay Kaul, MD, FACC,†
William E. Boden, MD, FACC,‡ T. Bruce Ferguson, Jr, MD, FACC,§
Robert A. Guyton, MD, FACC,¶ Michael J. Mack, MD,# Paul T. Sergeant, MD, PhD,††
Richard J. Shemin, MD, FACC,** Peter K. Smith, MD, FACC,‖
Salim Yusuf, DPhil, FRCPC, FRSC, FACC‡‡

Oxford, United Kingdom; Los Angeles, California; Buffalo, New York; Greenville and Durham, North Carolina; Atlanta, Georgia; Dallas, Texas; Leuven, Belgium; and Hamilton, Ontario, Canada

We conclude that CABG should indeed remain the preferred revascularization treatment in good surgical candidates with unprotected LMS stenosis

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J AM Coll Cardiol 2008; 51:885-92

"In the largest individual study, the Society of Cardiothoracic Surgery in the UK reported a mortality of 3% for all 5,003 patients undergoing CABG for LMS in 2003" (ref 31)

Taggart DP, JACC 2008; 51:885-92

Yet

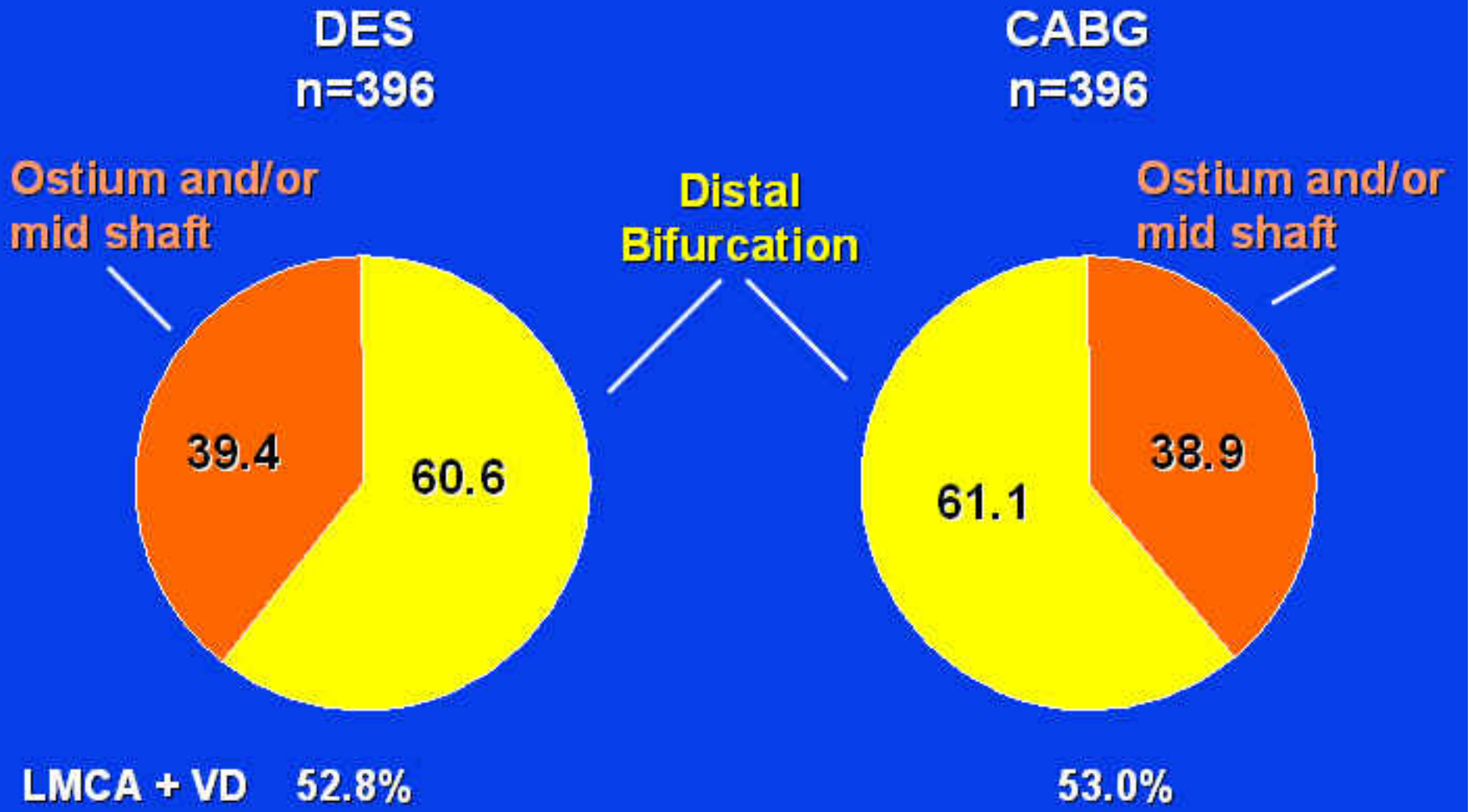
Reference 31 deals with

"1,888 patients operated at Karolinska Hospital in Stockholm, Sweden"

The MAIN-COMPARE Study
Crucial Points

- 97% of 1102 patients suitable for either PCI or CABG
- DES used in 71%
- Skilled experienced operators
- Standardized technical approaches
- Propensity matched patients
- Central adjudication of events

The Main-COMPARE Study
Crucial Points



Hazard Ratios for Clinical Outcomes
DES and Contemporary CABG Matched Cohort: 396 Pairs

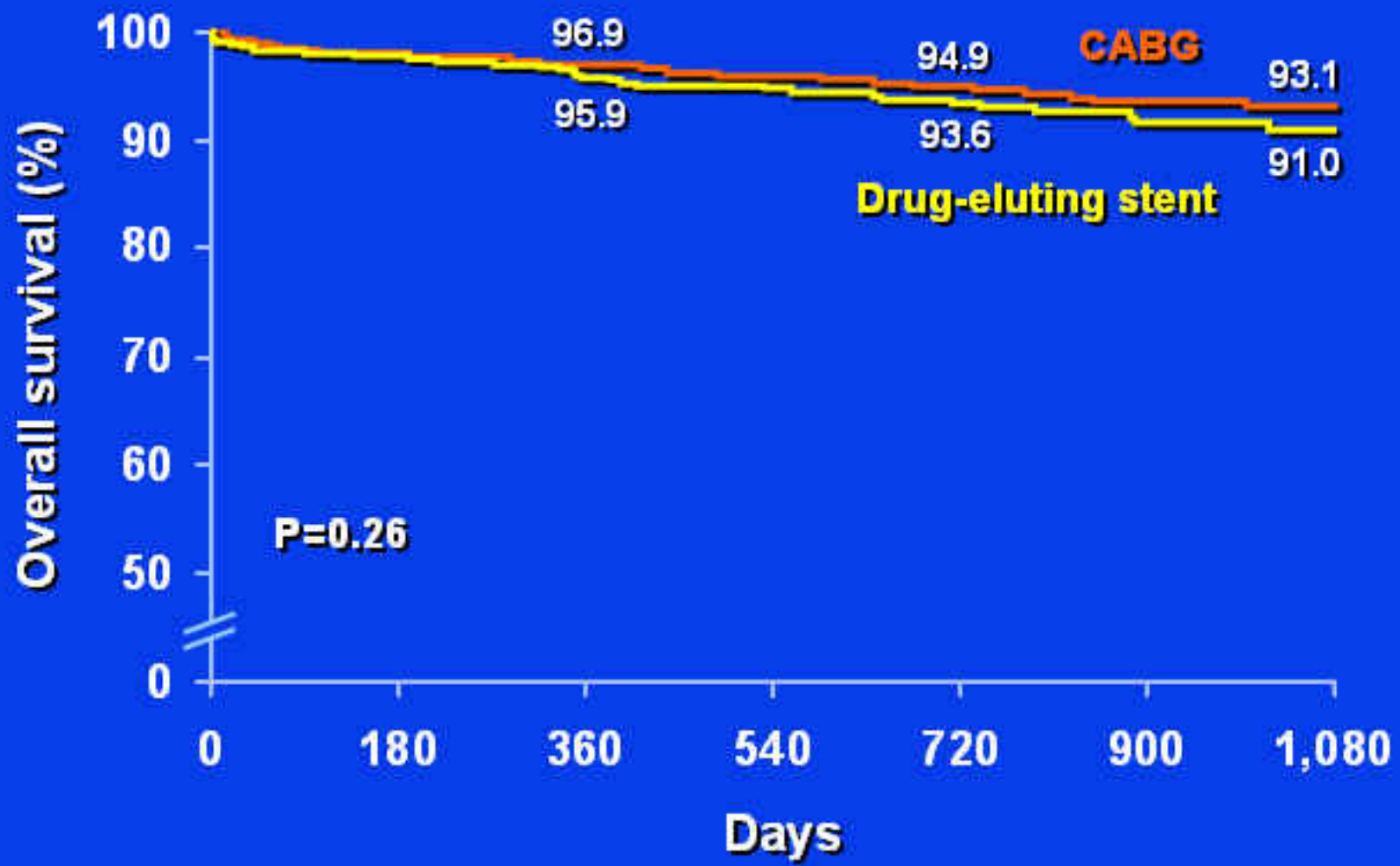
Outcome	Wave 2 (396 pairs) Hazard ratio* (95% CI)	P
Death	1.36 (0.80-2.30)	0.26
Composite outcome (death, Q-wave myocardial infarction, or stroke)	1.40 (0.88-2.22)	0.15
Target-vessel revascularization	5.96 (2.51-14.10)	<0.001

*HR are for the stenting group, as compared with CABG group

Seung KB et al: N Engl J Med 2008; 358

Death

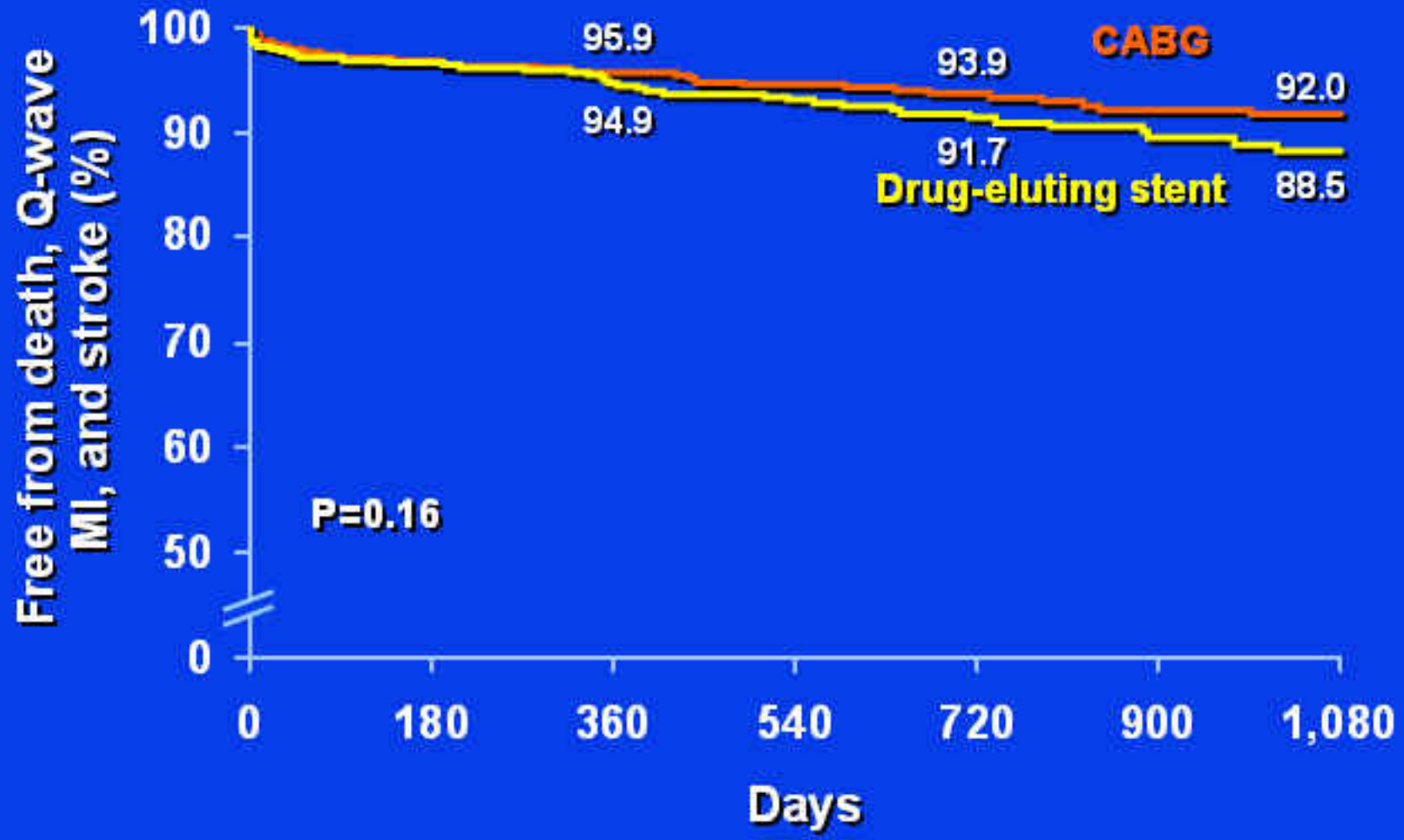
DES and Contemporary CABG Matched Cohort: 396 Pairs



Seung KB et al: N Engl J Med 2008; 358

Death, Q-MI, or Stroke

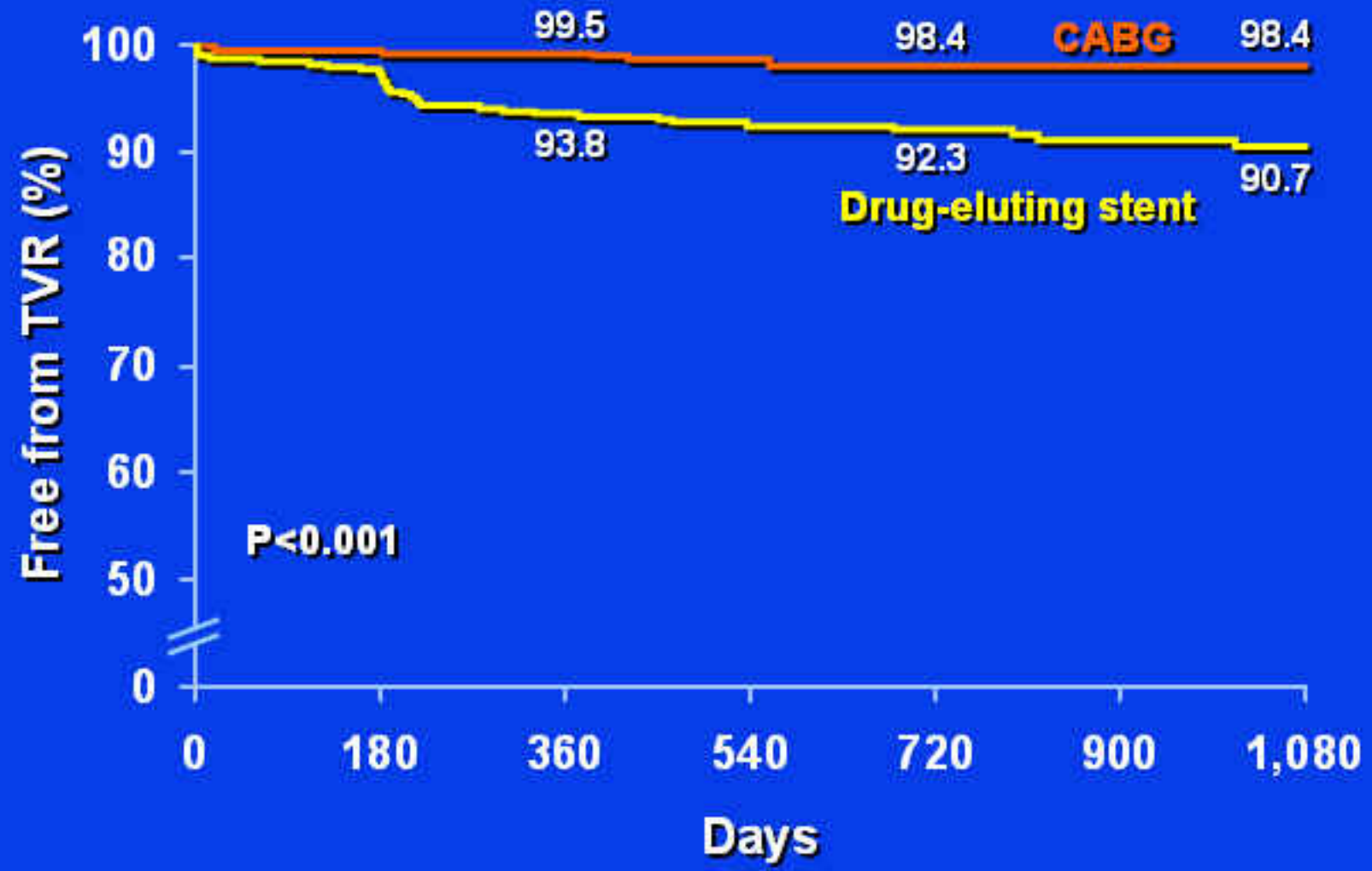
DES and Contemporary CABG Matched Cohort: 396 Pairs



Seung KB et al: N Engl J Med 2008; 358

Target-Vessel Revascularization

DES and Contemporary CABG Matched Cohort: 396 Pairs



Seung KB et al: N Engl J Med 2008; 358

The MAIN-COMPARE Study
Main Points

- Hard endpoints of D, QMI and stroke at 1080 days not statistically different
  - 8% of surgical cases
  - 11.5% of DES cases

  } P = 0.16
- TVR rates remain higher with DES at 1080 days
  - 9.3% with DES
  - 1.6% with CABG
- Stent thrombosis infrequent

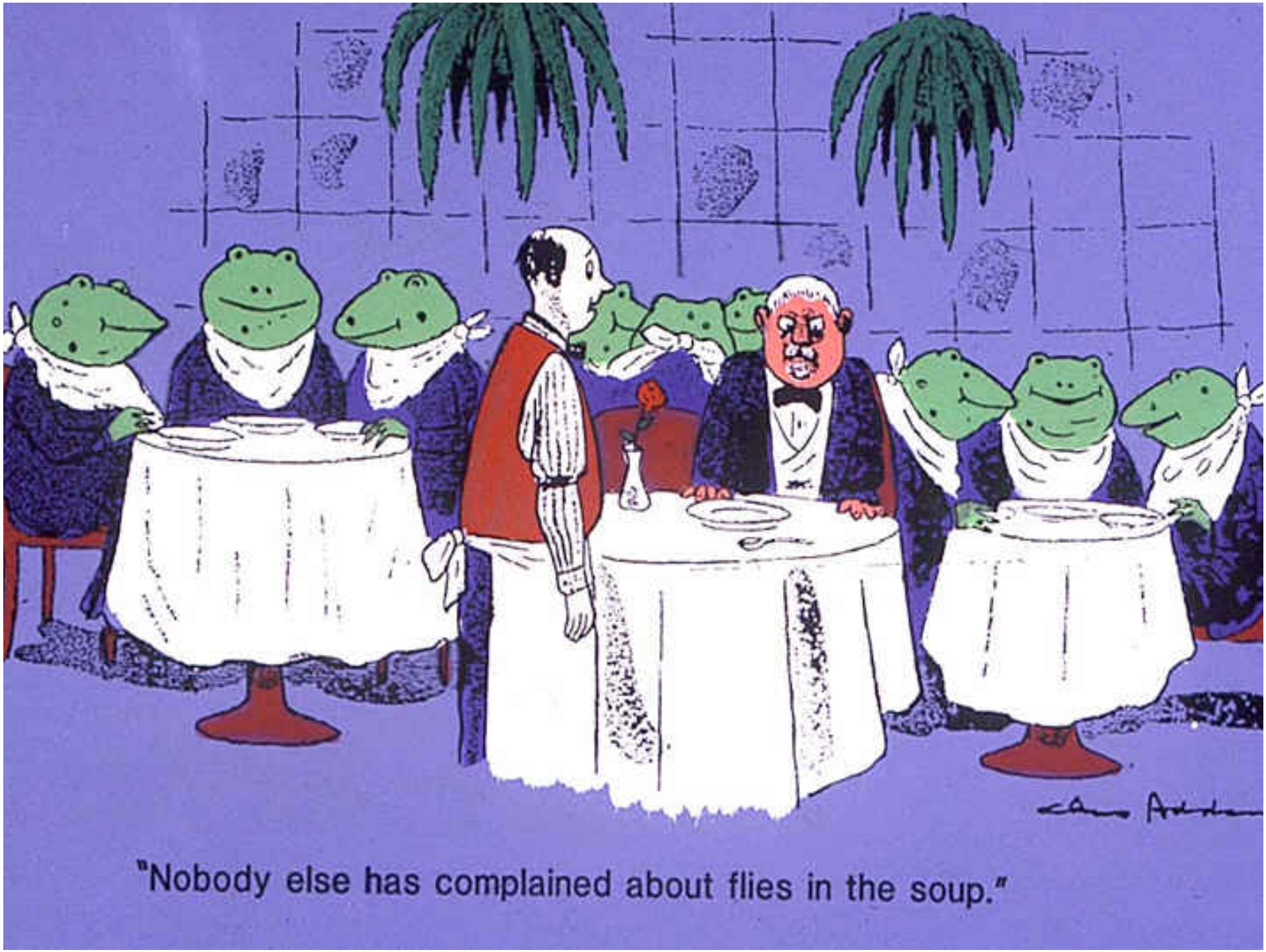
The MAIN-COMPARE Study
Main Points

- Hard endpoints of D, QMI and stroke at 1080 days not statistically different
  - 8% of surgical cases
  - 11.5% of DES cases

  } P = 0.16
- TVR rates remain higher with DES at 1080 days
  - 9.3% with DES
  - 1.6% with CABG
- No difference in Death at 1080 days; 6.9% of surgical cases, 9% of DES. (p=0.26)

The MAIN-COMPARE Study
Take Home Messages

- All surgical patients had surgery
- PCI gives similar results in hard end points of D/QMI/Stroke
- We still need better PCI approaches, particularly for distal disease
- SYNTAX randomized trial results coming


"Nobody else has complained about flies in the soup."

Consent For Bypass Surgery

I _____ authorize Dr Taggart and such other physicians as necessary to perform the following procedure, bypass surgery. I acknowledge the nature, purpose and risks of complications which include:

1. 53% chance that I will never be the same as I once was.
2. That I have a 40% chance of irreversible heart damage
3. That a stroke may occur (3%)
4. 40% of my grafts will fail in one year
5. I will experience cerebral microemboli – whatever that means

Surgeons are tall on enthusiasm but short on memory.

‘PCI used appropriately (including left main stem stenosis) can be a very effective and worthwhile intervention’

Taggart DP, Ann Thorac Surg 2006; 82:1966-75

Systematic Review
Data Synthesis and Analysis

- Random affects models
- Computation of risk differences and odds ratio
- Access heterogeneity of effects

Bravata: Ann Intern Med 147:703, 2007

Systematic Review
PCI vs CABG

Short Term and Procedural Outcome

1) **Survival at 30 days:** 98.9% PCI, 98.2% CABG

   Difference 0.2% (95% CI 0.3-0.6)

2) **Stroke:** 1.2% CABG, 0.6% PCI

   Difference 0.6% (95% CI 0.2-1)
   P=0.002

3) **Procedural MI:** NS

Bravata: Ann Intern Med 147:703, 2007

Systematic Review
PCI vs CABG

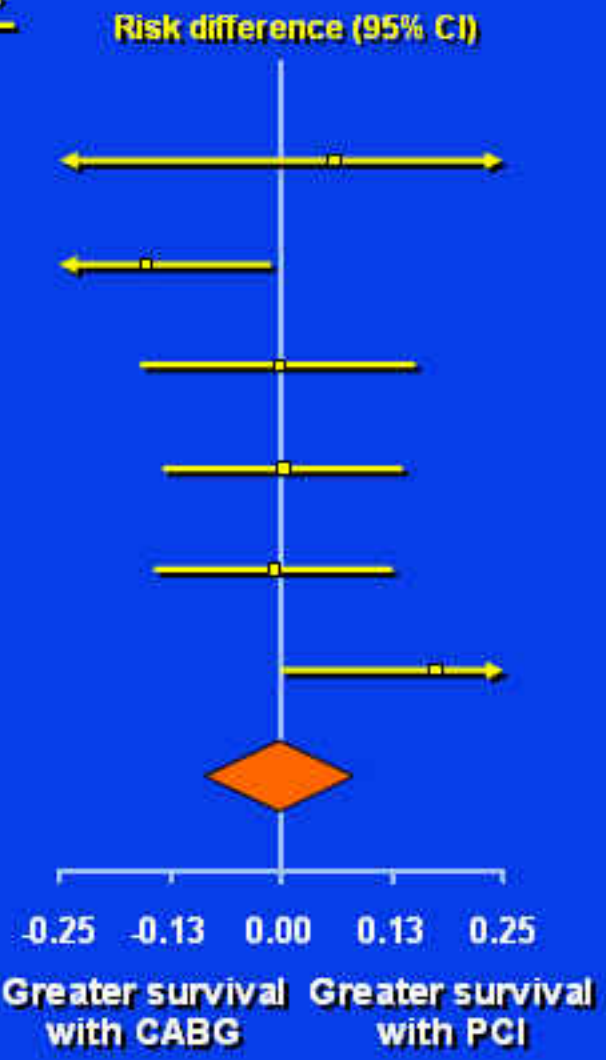
Long-Term Outcomes

- **1-year survival:** 96.4% CABG, 96.5% PCI
- **5-year survival:** 90.7% CABG, 89.7% PCI
- Survival did not differ when subdivided by SVD – prox LAD, or MVD

Bravata: Ann Intern Med 147:703, 2007

5-Year Survival in Diabetics

Study, year	Surviving patients/all patients: PCI	CABG
AWESOME, 2002	8/11	8/12
BARI, 1997; 1996	45/69	75/93
EAST, 2000	26/29	27/30
ERACI II, 2005	35/39	35/39
MASS II, 2006	47/56	50/59
RITA, 1998	27/29	25/33
Overall	188/233	220/266



Ann Int Med 147:708, 2007

Systematic Review
PCI vs CABG

Angina Relief

- 1 year, no angina: 75% PCI, 84% CABG
- 5 years, no angina: 79% PCI, 84% CABG
- PCI-CABG risk difference ranged from 5-8% between 1 and 5 years (P<0.001)

Bravata: Ann Intern Med 147:703, 2007

Systematic Review
PCI vs CABG

Diabetics

- **5-year survival:** Higher by 2%
  CABG but 95% bounds – 8.8%, 8.3%

Bravata: Ann Intern Med 147:703, 2007

?

PREVENT IV Trial
Angiographic Results

Event	Edifoligide No.	Edifoligide %	Placebo No.	Placebo %	OR (95% CI)	P
Per patient						
Vein graft failure	436/965	45.2	442/955	46.3	0.96 (0.80-1.14)	0.66
Vein graft occlu	403/964	41.8	397/951	41.7	1.00 (0.84-1.20)	0.97
Per vein graft						
Vein graft failure	650/2,303	28.5	671/2,254	29.7	0.94 (0.80-1.10)	0.44
Vein graft occlu	601/2,295	26.1	597/2,242	26.5	0.98 (0.83-1.15)	0.83
Internal thoracic artery graft closure	69/809	8.5	60/784	7.6	1.12 (0.78-1.61)	0.53

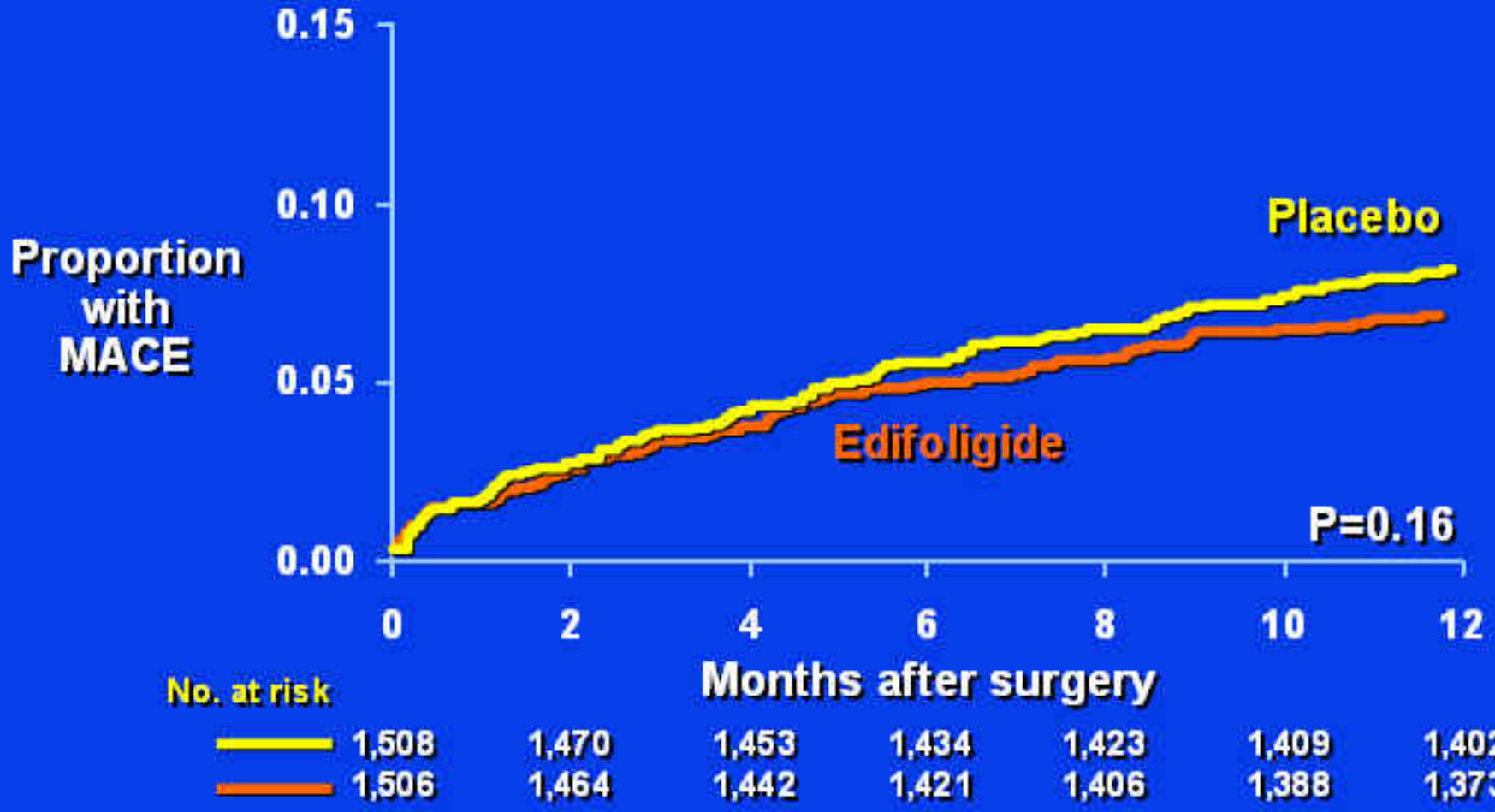
Alexander JH et al: JAMA 294:2446, 2005

PREVENT IV Trial
Clinical Events

Type of event	No. (Kaplan-Meier rate at 1 yr) Edifoligide n=1,508	Placebo n=1,506	HR (95% CI)	P
Death	52 (3.5)	43 (2.9)	1.21 (0.80-1.80)	0.37
Death or MI	63 (4.2)	72 (4.8)	0.87 (0.62-1.22)	0.42
Death, MI, or revasc	115 (7.6)	136 (9.1)	0.84 (0.65-1.08)	0.16
MACE	101 (6.7)	121 (8.1)	0.83 (0.64-1.08)	0.16

Alexander JH et al: JAMA 294:2446, 2005

PREVENT IV Trial
Kaplan-Meier Curves for Occurrence of Death, MI, or Revascularization with Vein Graft Failure



Alexander JH et al: JAMA 294:2446, 2005

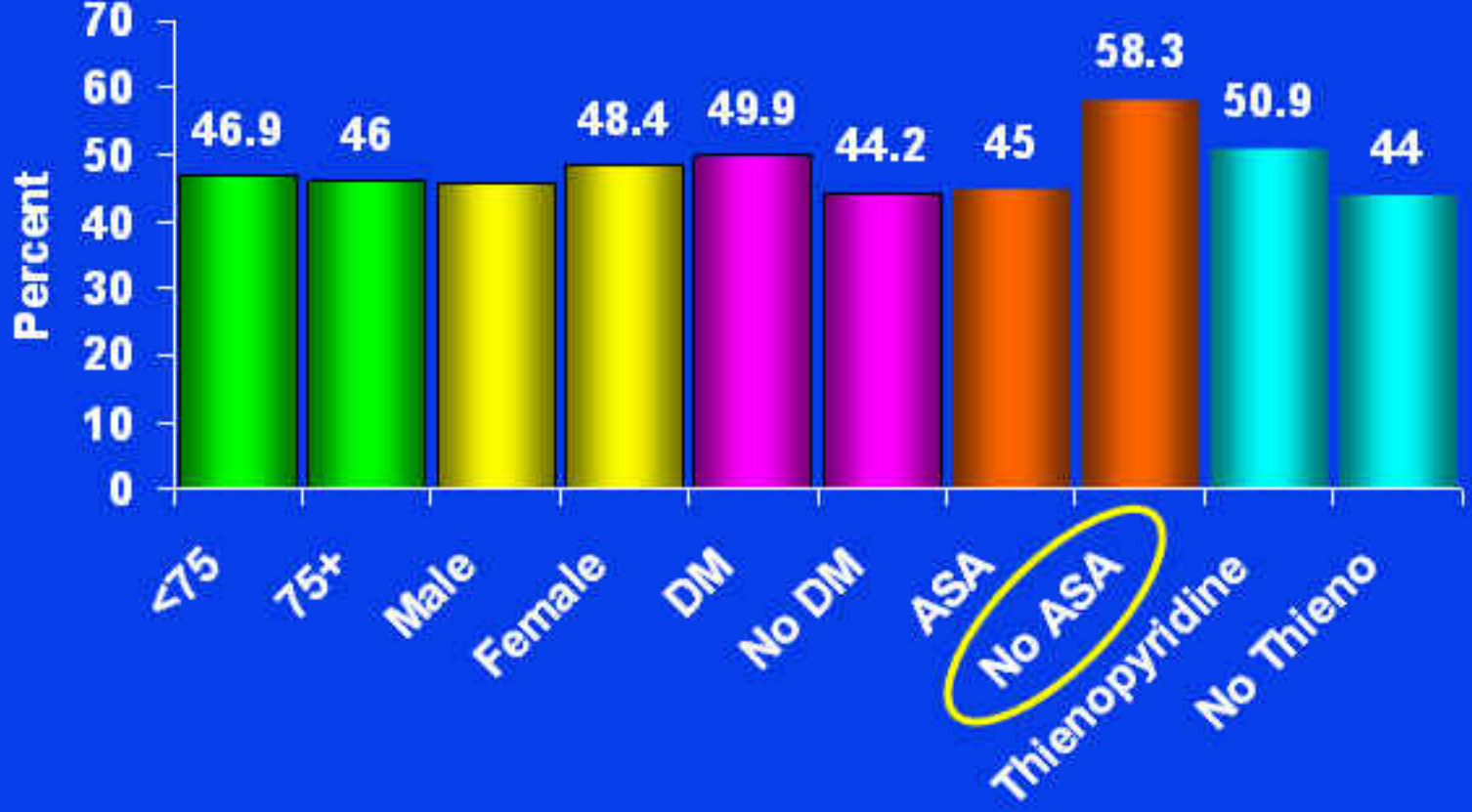
PREVENT IV Trial
Clinical Event in Patients by Vein Graft Failure Status

	Patients			
	Vein graft failure (n=878)		No vein graft failure (n=1,042)	
Type of event	No.	%	No.	%
Perioperative MI in CABG surgery	118	13.4	71	6.8
Death or MI	122	13.9	9	0.9
Death, MI, or revascularization	228	26.0	19	1.8

Alexander JH et al: JAMA 294:2446, 2005

12 Month Vein Graft Failure
PREVENT IV Placebo Cohort

12-18 Mo Angiography Follow-Up (80% of Eligible)



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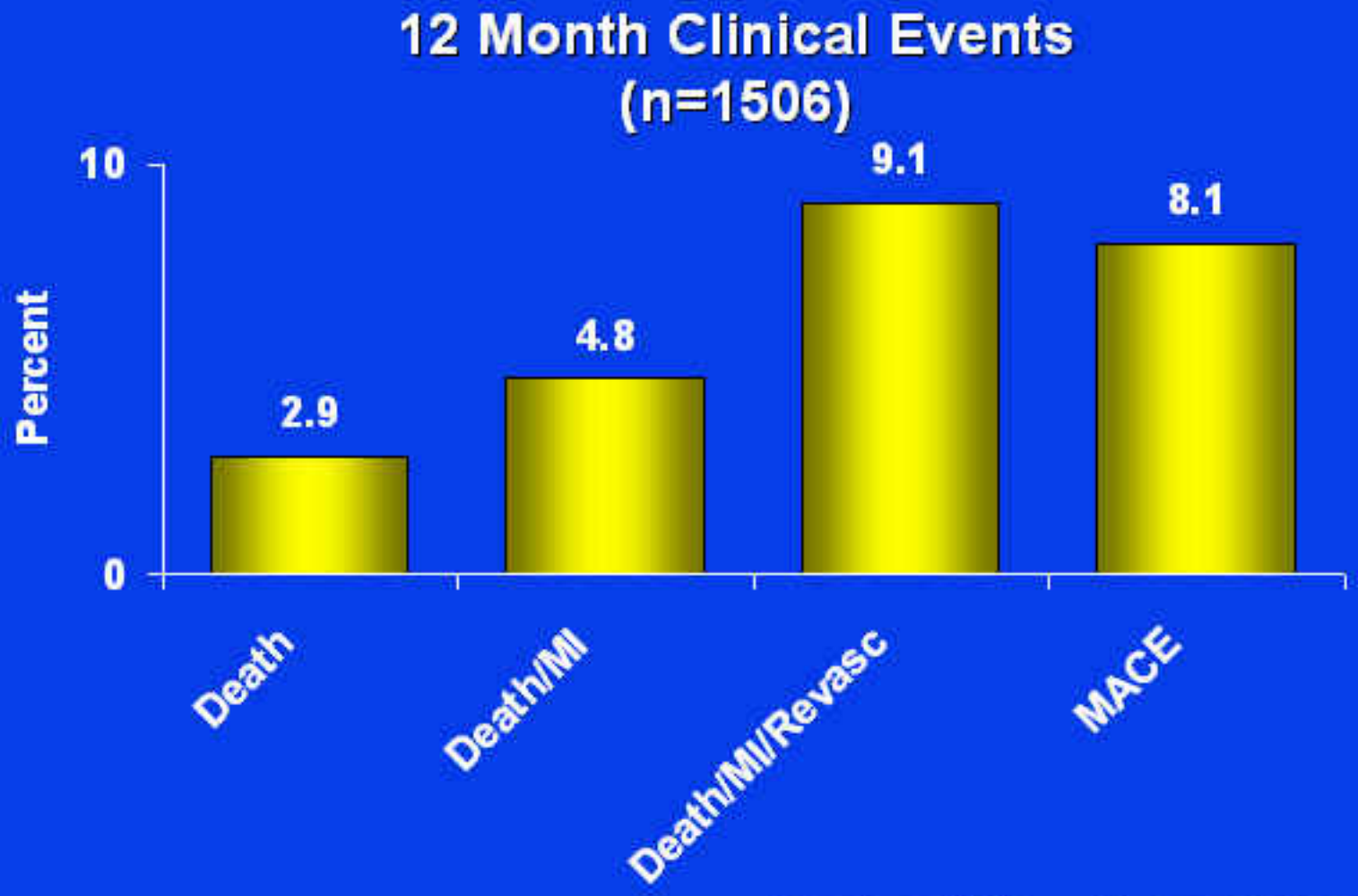
PREVENT IV Invest. *JAMA* 294:2446

12 Month Clinical Events After SVG
PREVENT IV Placebo Cohort



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PREVENT IV Invest. *JAMA* 294:2446

12 Month Clinical Events After SVG
PREVENT IV Randomized Cohort

Type of Event	SVG Failure (n=878)	No SVG Failure (n=1042)
CABG Peri-Op MI	13.4%	6.8%
Death or Non-Op MI	13.9%	0.9%
Death, Non-Op MI or Revascularization	26%	1.8%

PREVENT IV Invest. *JAMA* 294:2446

DES in LMS

			30 Day		
Author	N	EF	Death (%)	MI (%)	TLR (%)
DeLezo et al	52	57	0	4	0
Valgimigli et al	130	41	10	4	0
Price et al	50	>40	0	8	6
Chieffo et al	107	52	0	9	0
Lee et al	50	51	2	0	0
Kim et al	116	60	0	6	0
Palmerini et al	94	52	3.2	4.5	1
Weighted average	599		2.4	6	2.1

Taggart DP, JACC 2008; 51:885-92

DES in LMS

Author	N	F/U (mos)	Death (%)	MI (%)	TLR/TVR (%)
DeLezo et al	52	12	0	0	2
Valgimigli et al	130	18	14	4	6
Price et al	50	9	10	2	38
Chieffo et al	107	12	3	1	20
Lee et al	50	6	4		7
Kim et al	116	18	0	0	5
Palmerini et al	94	14	13.4	8.3	20
Weighted average	599	11	7	1.6	13

Taggart DP, JACC 2008; 51:885-92

Solid and Gaseous Microembolization After Cardiac Surgery

- 60 patients undergoing cardiac surgery
- Transcranial Doppler ultrasound during cardiac surgery
- Solid cerebral microemboli are detectable in the majority of such patients both 5 days and 3 months after surgery

Taggart DP et al, J Thorac Cardiovasc Surg 2008; 135:512-20

P.S. It is hard to imagine that 'solid cerebral microemboli' are a good thing – DRH

On-Pump vs Off-Pump CABG Graft Flow

- Mean graft flow higher for all grafts in the on-pump group
- Flow/pressure ratio significantly higher in on-pump
- Overall graft flow greater in saphenous vein than ITA ($p<.001$)

"In patients with UA or hemodynamic instability, potentially lower graft flow in arterial grafts should be considered"

Taggart DP et al, J Thorac Cardiovasc Surg 2008; 135:533-39

P.S. Does that mean more saphenous vein grafts? – DRH

‘Cognitive dysfunction and post operative hypoxia are common sequelae of coronary artery bypass grafting’

Taggart DP, J Thorac Cardiovasc Surg 2003; 126:1061-4

‘Cerebral injury is a major cause of morbidity and mortality of CABG. Stroke occurs in 3% of patients’

Taggart DP, Curr Opin Cardiol 2001; 16:271-6

‘Coenzyme Q10 may have a beneficial role in ischemia reperfusion injury’

Taggart DP, J Thorac Cardiovasc Surg 2003; 126:1061-4

Cerebral Function

'Cognitive dysfunction is common early after cardiac surgery'

'Patients undergoing….surgery have a significant reduction in pre frontal activation which correlates with cerebral microemboli'

'Microemboli load is an important mechanism of perioperative cerebral insult'

Taggart DP, J Thorac Cardiovasc Surg 2006; 132:1119-25

Off-Pump vs On-Pump CABG on Reversible and Irreversible Myocardial Injury

- Single center – small randomized trial – 60 patients undergoing CABG for MV disease
- MRI to evaluate myocardial injury

Findings: New IRREVERSIBLE myocardial injury seen in 36% on-pump and 44% of off-pump CABG patients

Taggart DP, Circ 2004; 109:345-50

‘Neurocognitive dysfunction remains a limitation of cardiac surgery’

Taggart DP, J Thorac Cardiovasc Surg 2004; 127:1759-65

‘Aprotinin should be considered routinely in patients undergoing total arterial grafting’

Taggart DP, J Thorac Cardiovasc Surg 2003; 126:1087-90

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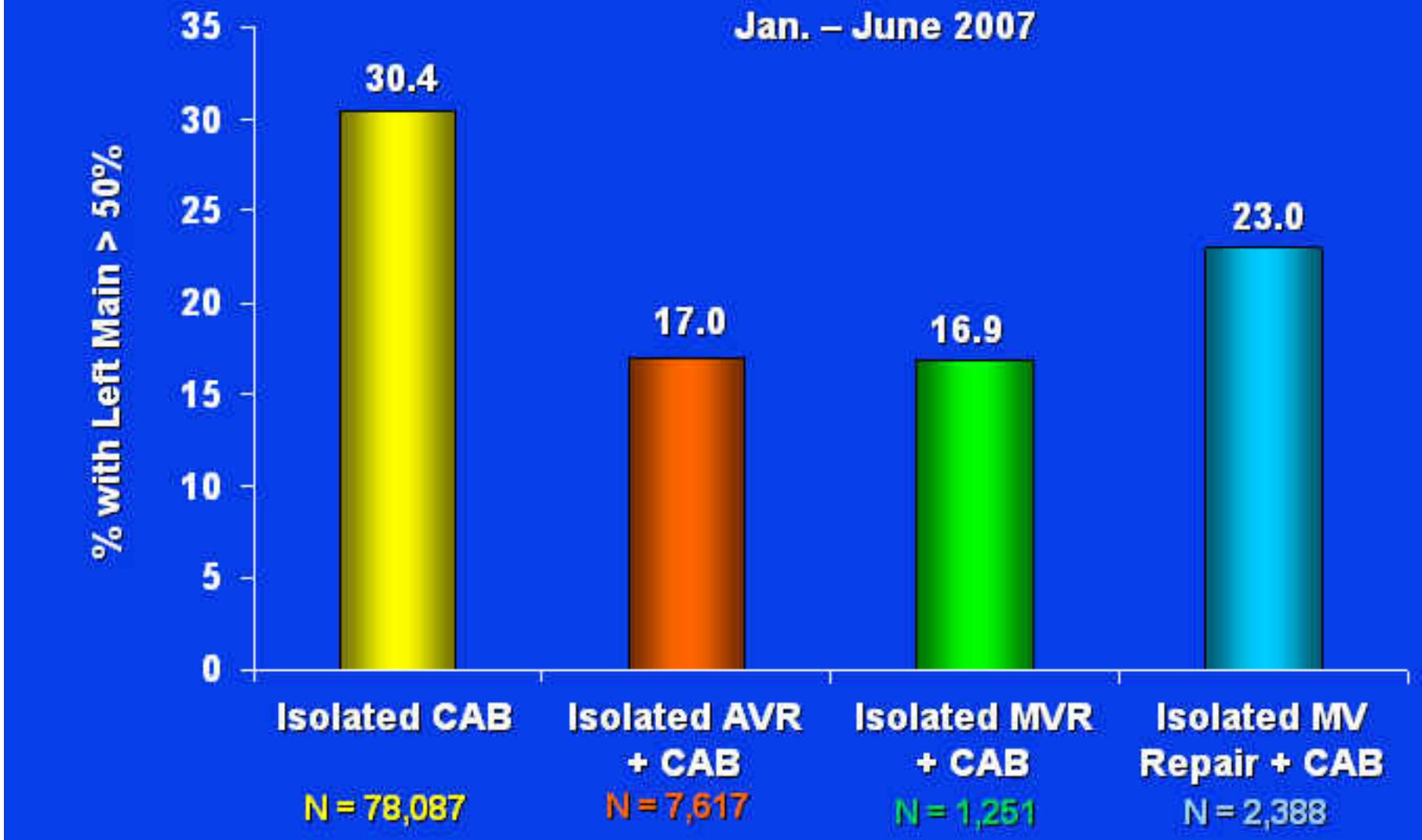
STS Data



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Data Analysis of the STS National Adult Cardiac Surgery Database

SAPPHIRE

- 334 patients with:
  - Symptomatic CAS ≥ 50%, or
  - Asymptomatic CAS ≥ 80%
- Pre specified major secondary endpoint:
  - Death, stroke or MI within 30 days, or
  - Death or ipsilateral at 3 years
- At 3 years, F/U available for 77.8% patients

Gurm HS et al: New Engl J Med 2008; 358:1572-9

SAPPHIRE

In patients with severe CAS at increased surgical risk, there is no significant difference in 3 year outcome between carotid artery stenting with EPD and CEA

Gurm HS et al: New Engl J Med 2008; 358:1572-9

The Main Compare Study

SCAI-ACCi2 LBCT Commentary

ACC, March 2008

David R. Holmes, Jr., M.D.
Mayo Clinic
Rochester, MN

MAYO CLINIC

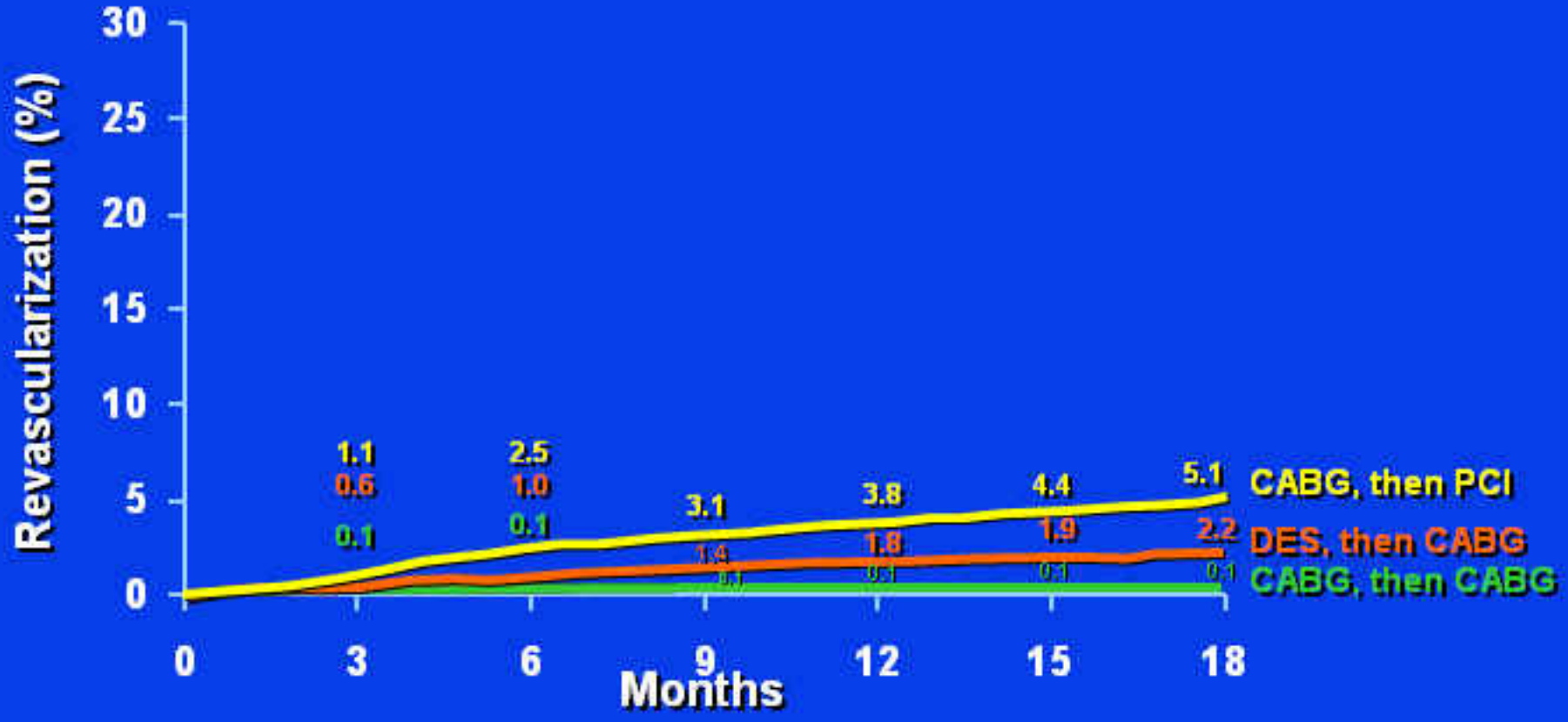
Reports that say that something hasn't happened are always interesting to me, because as we know, there are known knowns; there are things we know we know. We also know there are known unknowns; that is to say we know there are some things we do not know. But there are also unknown unknowns - - the ones we don't know we don't know.

Donald H. Rumsfeld

Department of Defense news briefing, February 12, 2002

US Secretary of Defense (1932 -)

Unadjusted Ejection Fraction
Rates of Revascularization within 18 Months After Initial Procedure



Hannan EL et al: NEJM 358:331, 2008

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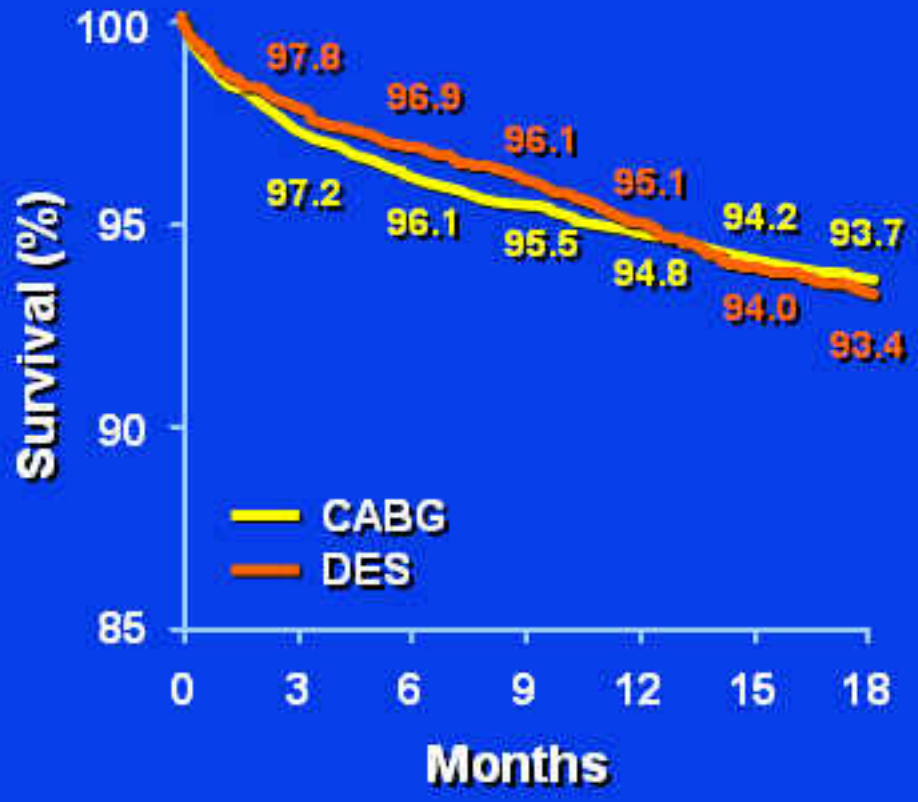
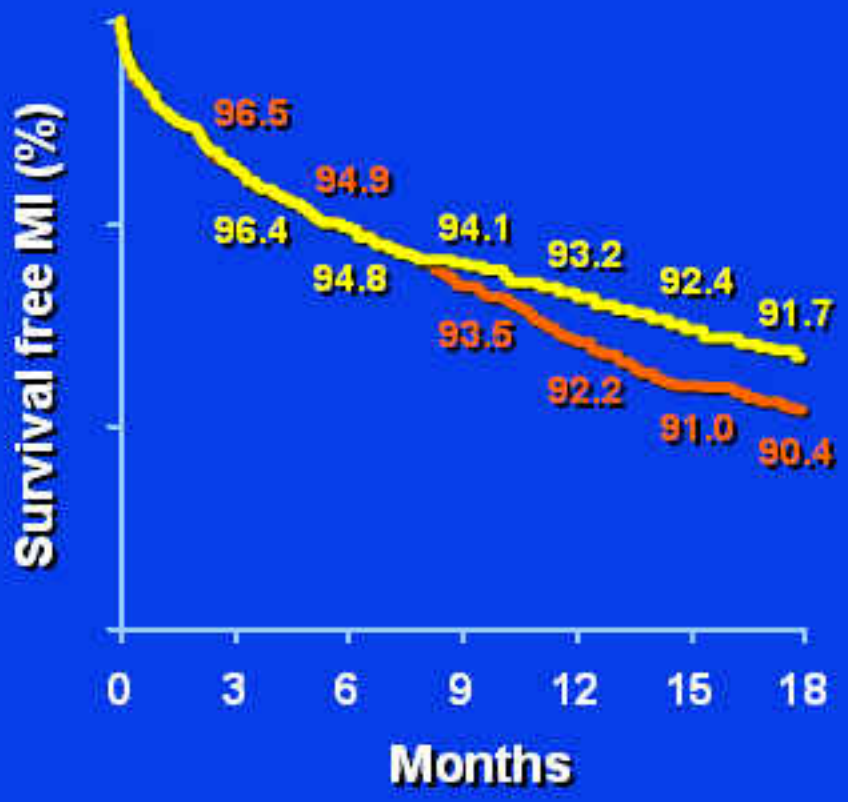
Unadjusted Ejection Fraction
3-Vessel Disease





CABG	5,202	5,058	5,001	4,967	4,931	4,083	3,139
DES	2,481	2,427	2,404	2,384	2,359	1,819	1,355

CABG	5,202	5,014	4,933	4,893	4,849	4,019	3,076
DES	2,481	2,393	2,355	2,320	2,287	1,761	1,313

Hannan EL et al: NEJM 358:331, 2008

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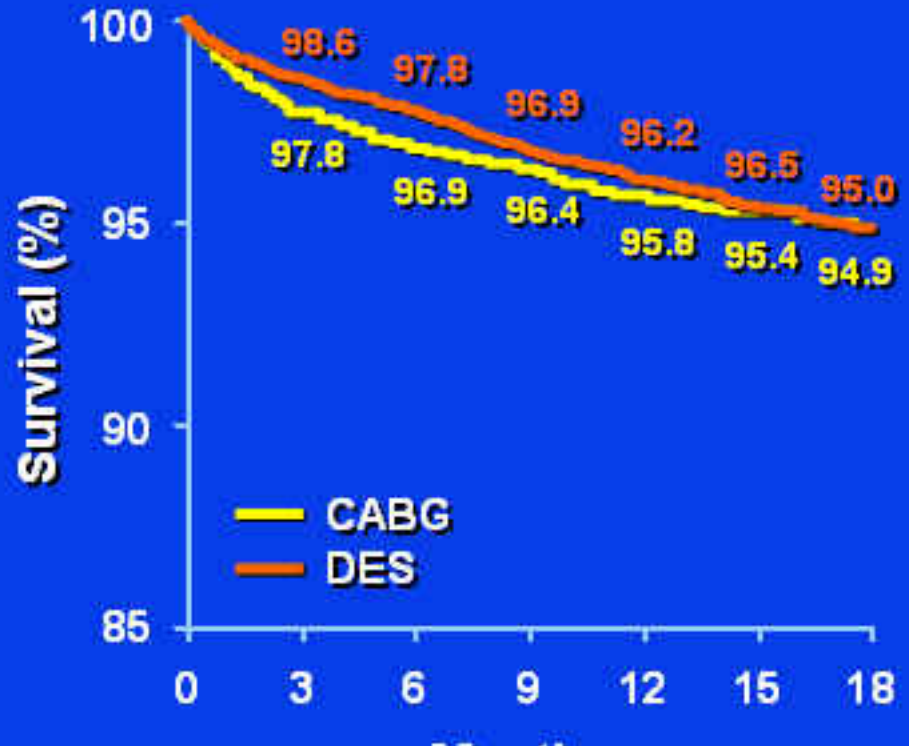
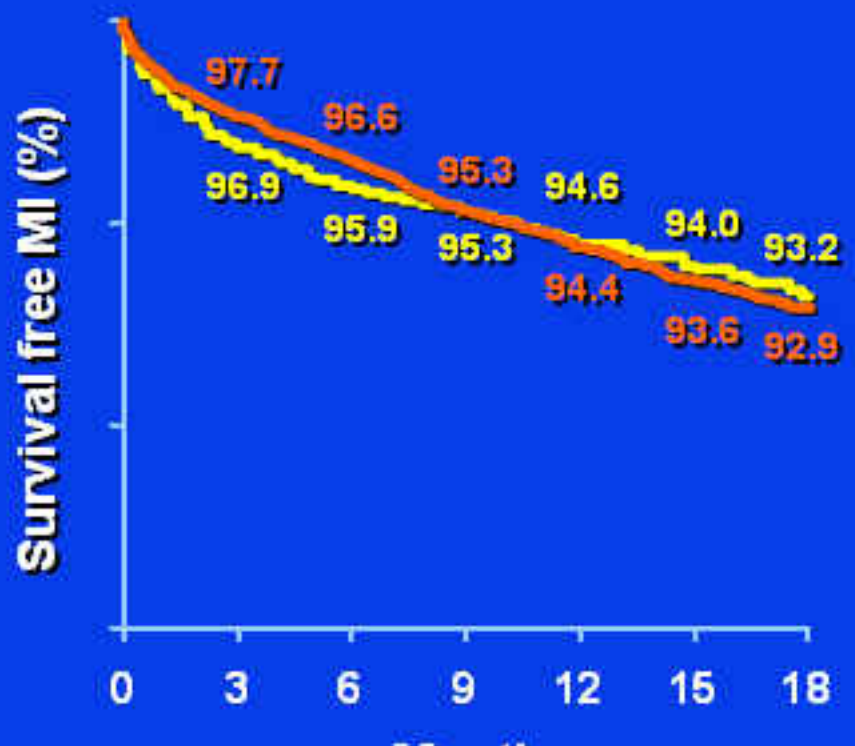
Unadjusted Ejection Fraction
2-Vessel Disease





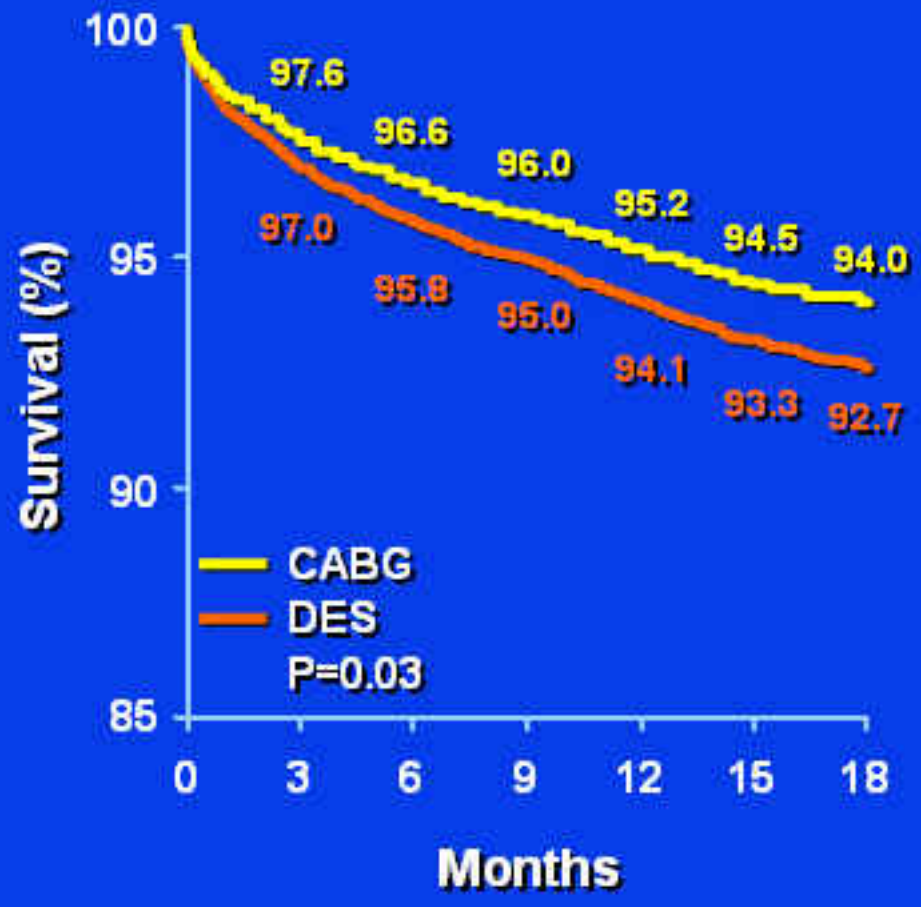
2,235	2,186	2,166	2,154	2,141	1,764	1,350
7,482	7,377	7,319	7,250	7,195	5,651	4,140

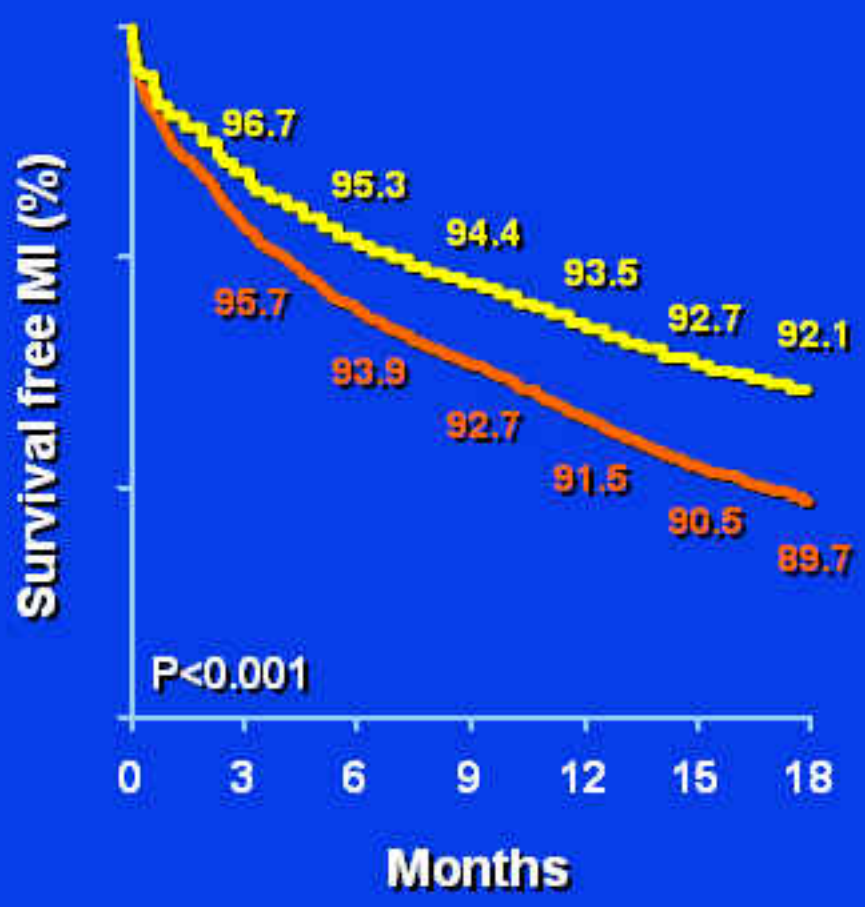
2,235	2,166	2,144	2,129	2,114	1,736	1,325
7,482	7,307	7,224	7,132	7,066	5,542	4,046

Hannan EL et al: NEJM 358:331, 2008

MAYO CLINIC

Adjusted Ejection Fraction
3-Vessel Disease

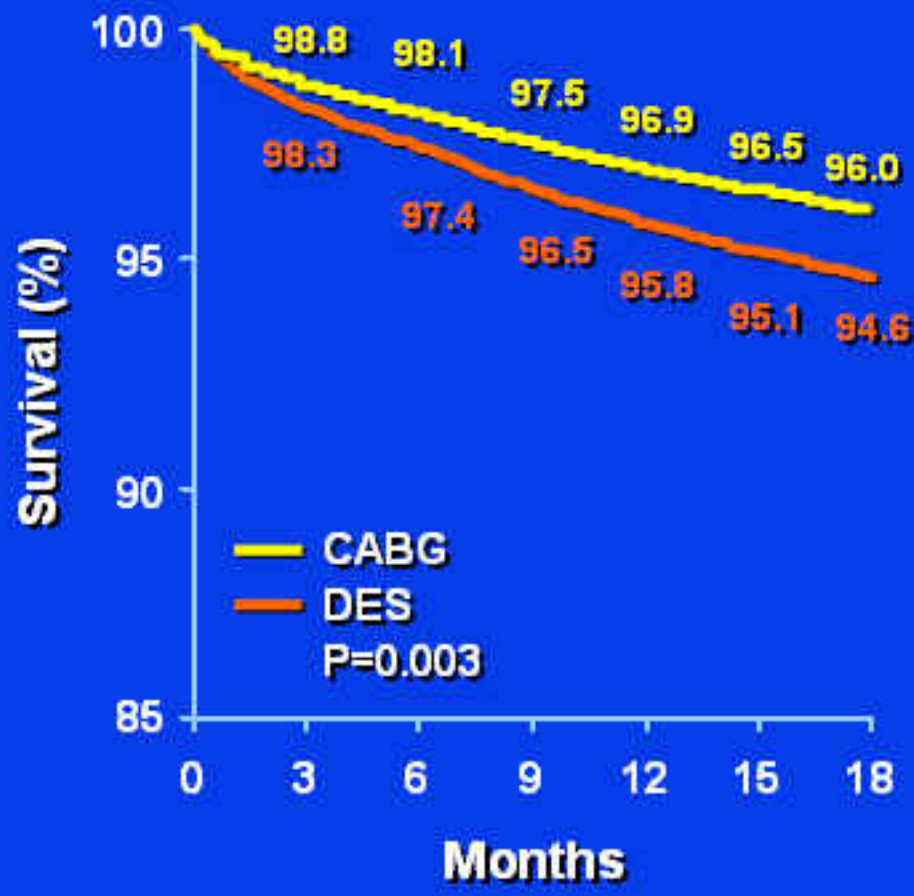


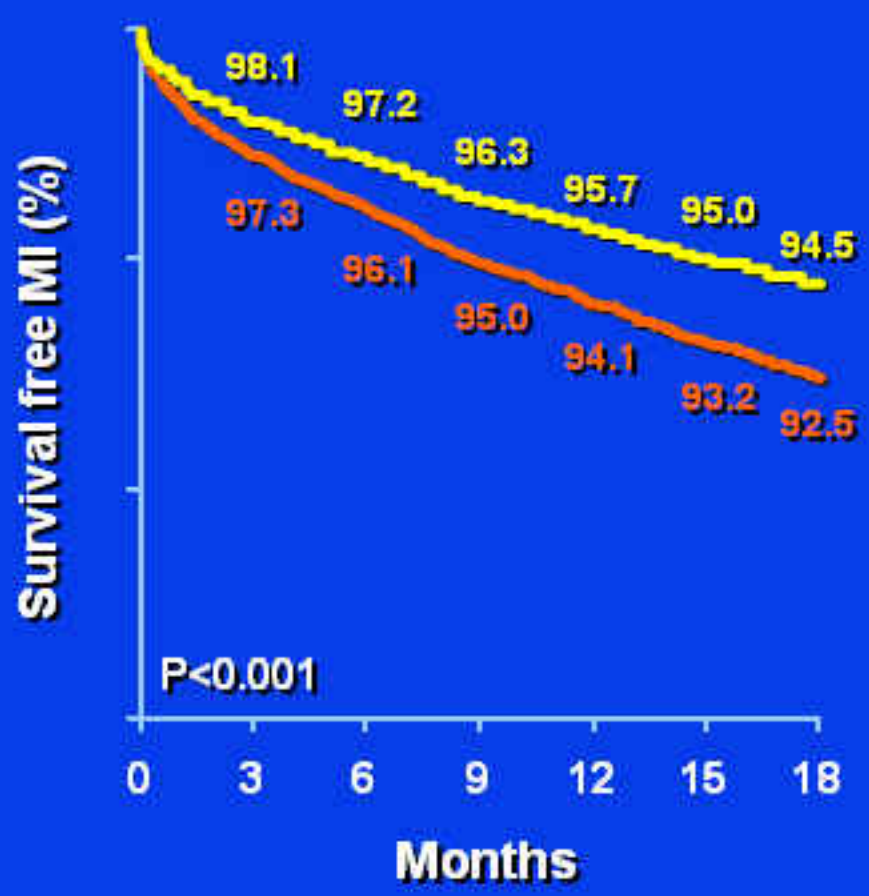


Hannan EL et al: NEJM 358:331, 2008

MAYO CLINIC

Adjusted Ejection Fraction
2-Vessel Disease

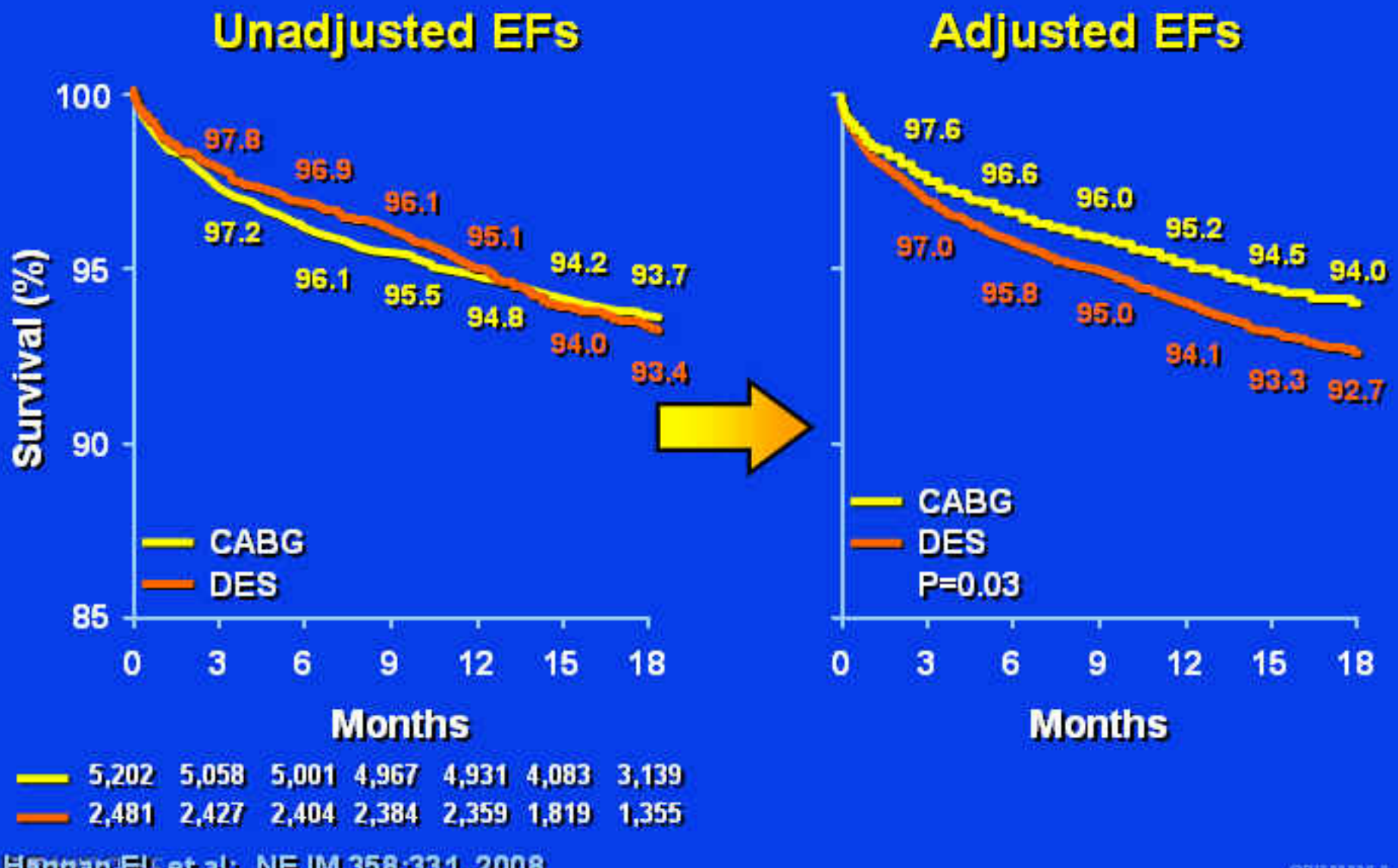




Hannan EL et al: NEJM 358:331, 2008

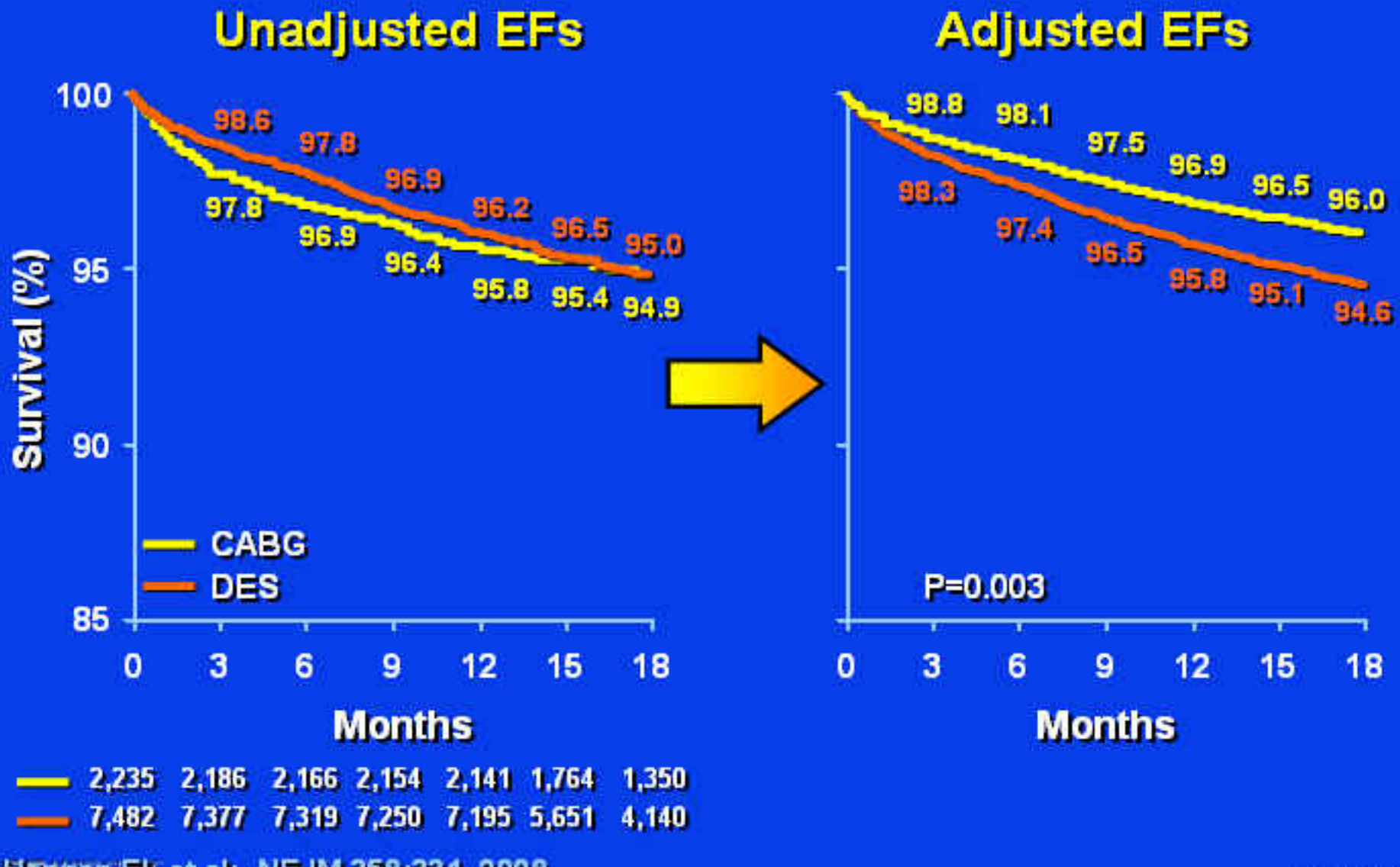
MAYO CLINIC

3-Vessel Disease



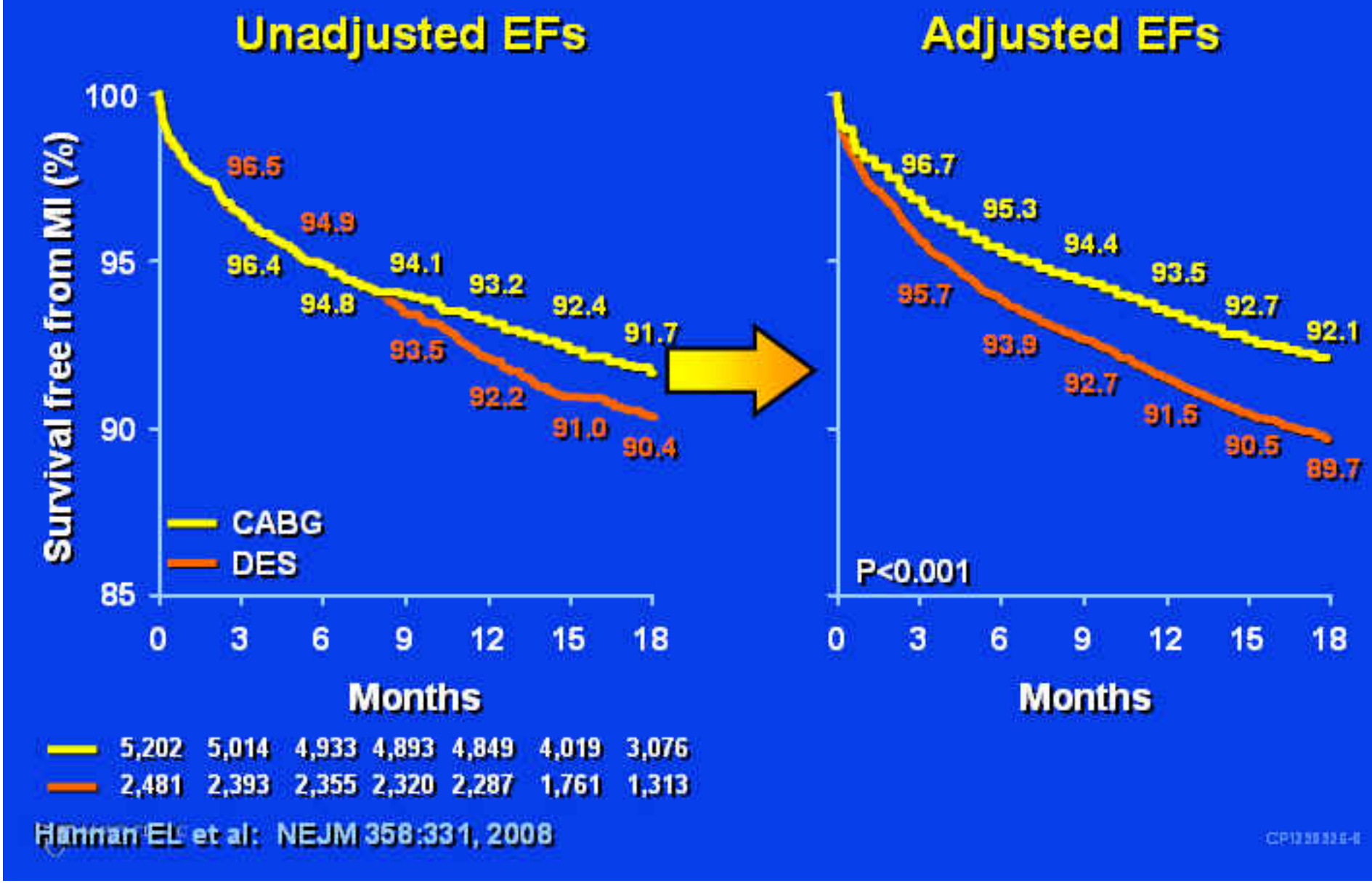
Hannan EL et al: NEJM 358:331, 2008

2-Vessel Disease



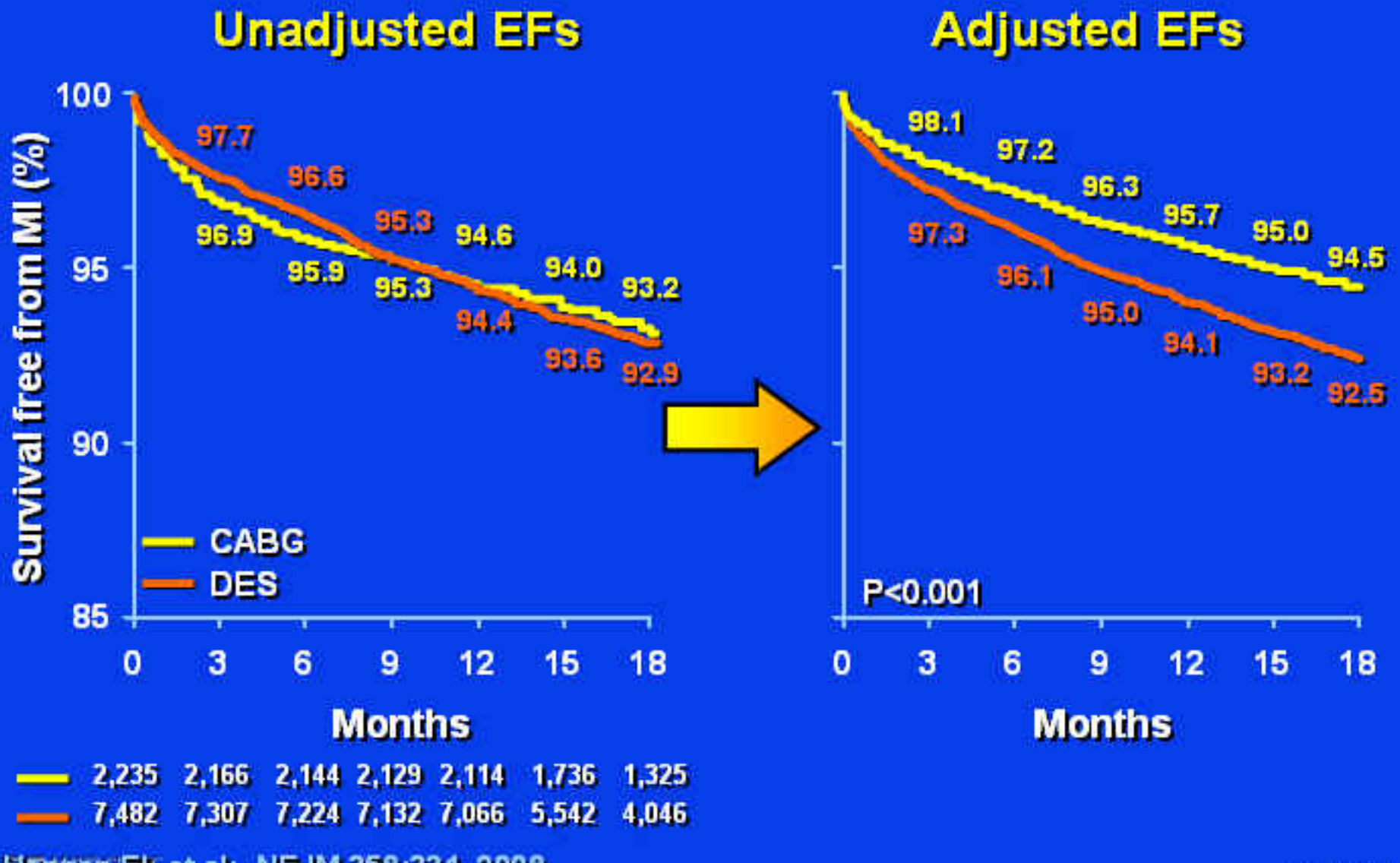
Hannan EL et al: NEJM 358:331, 2008

3-Vessel Disease



Hannan EL et al: NEJM 358:331, 2008

2-Vessel Disease



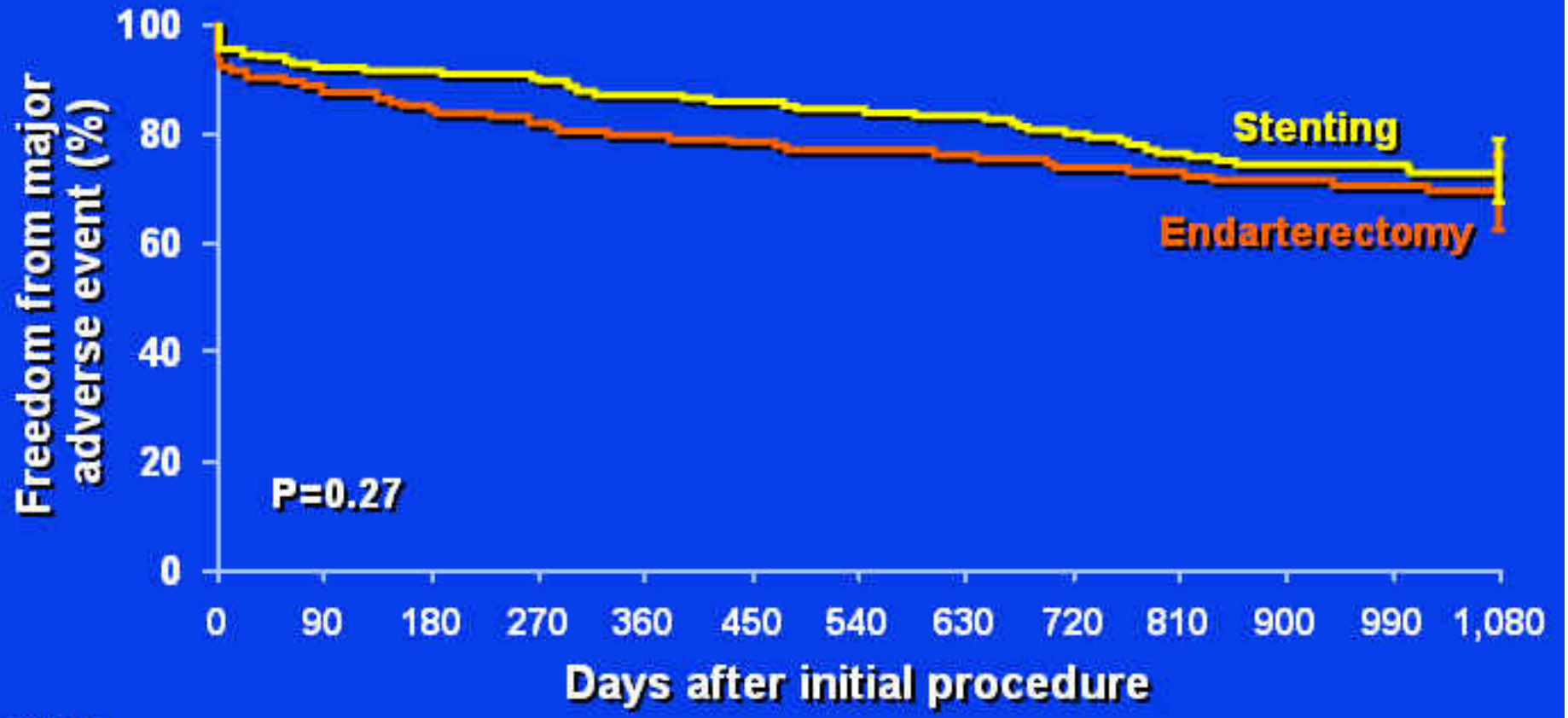
Hannan EL et al: NEJM 358:331, 2008

SAPPHIRE
MACE Through 1,080 Days

	Stenting (n=167)		Endarterectomy (n=167)	
Event	**No.**	**%**	**No.**	**%**
Death	31	18.6	35	21.0
Cardiac cause	15	9.0	15	9.0
Neurologic cause	3	1.8	4	2.4
Other cause	13	7.8	16	9.6
Stroke	15	9.0	15	9.0
Major ipsilateral	2	1.2	5	3.0
Major nonipsilateral	1	0.6	5	3.0
Minor ipsilateral	9	5.4	4	2.4
Minor nonipsilateral	4	2.4	4	2.4

Gurm HS et al: NEJM 358:1572, 2008

SAPPHIRE

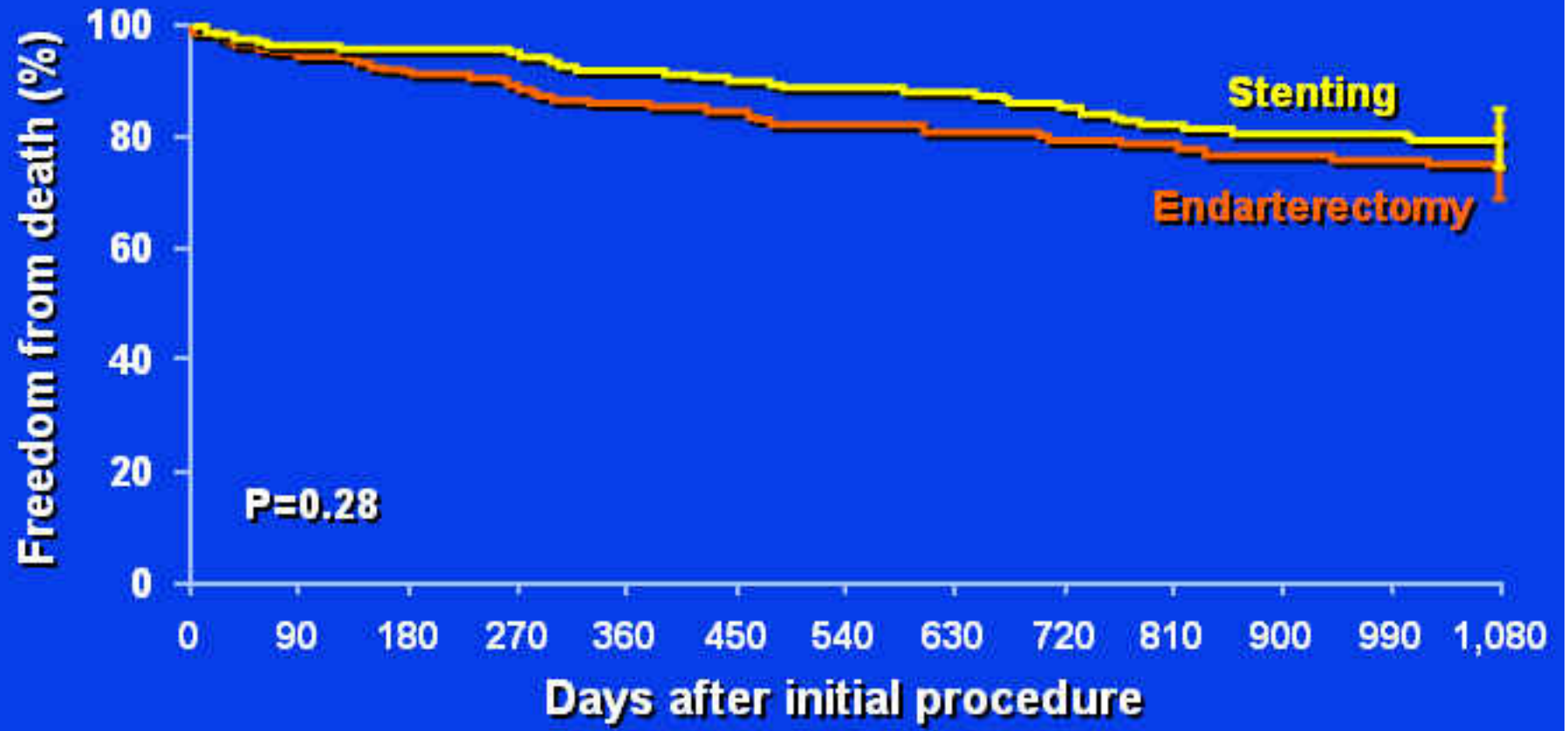


No. at risk							
Stenting	167	155	146	135	129	111	103
Endarterectomy	166	142	123	109	100	85	75

Gurm HS et al: NEJM 358:1572, 2008

MAYO CLINIC

SAPPHIRE

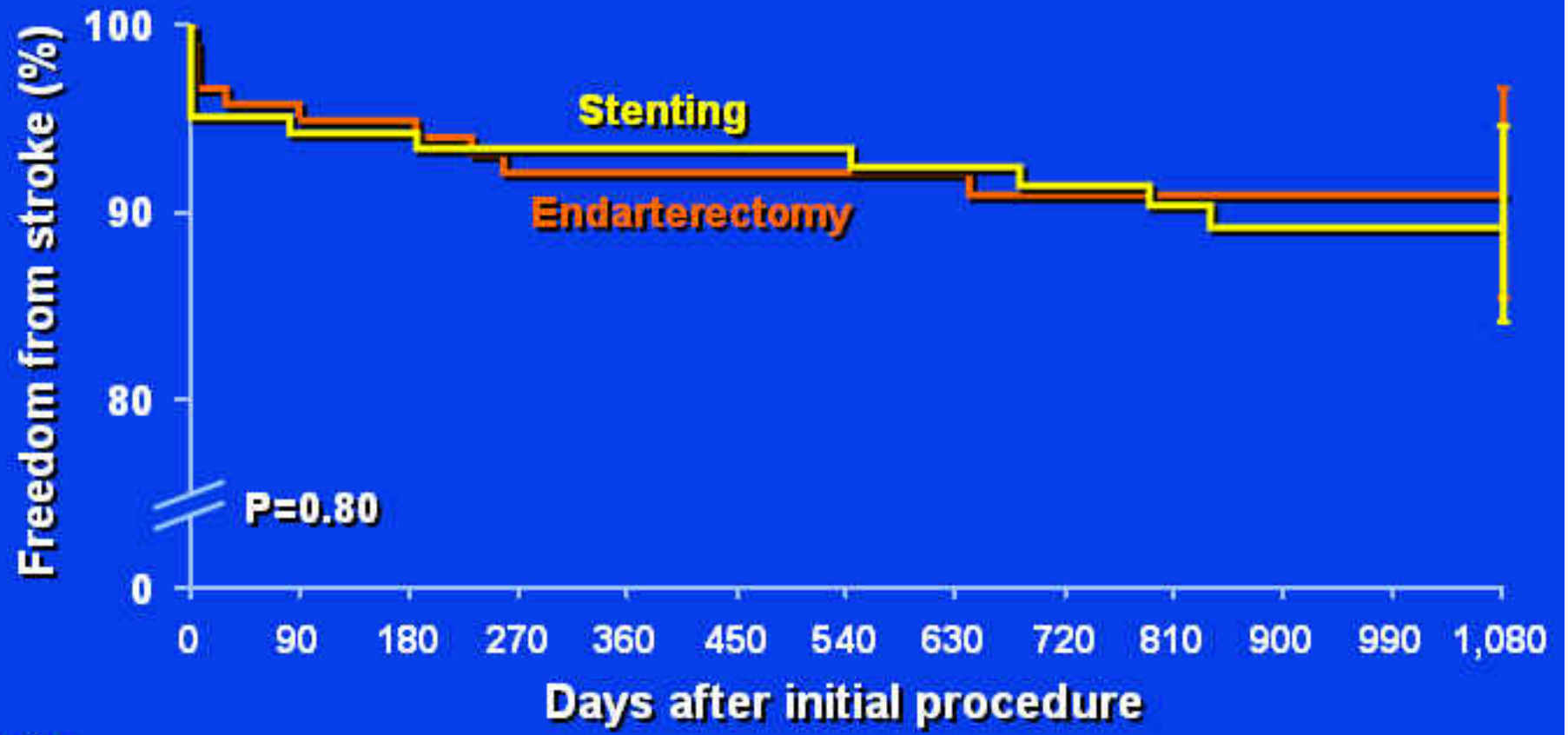


No. at risk							
Stenting	167	161	153	141	136	119	112
Endarterectomy	166	154	135	120	107	92	82

Gurm HS et al: NEJM 358:1572, 2008

MAYO CLINIC

SAPPHIRE

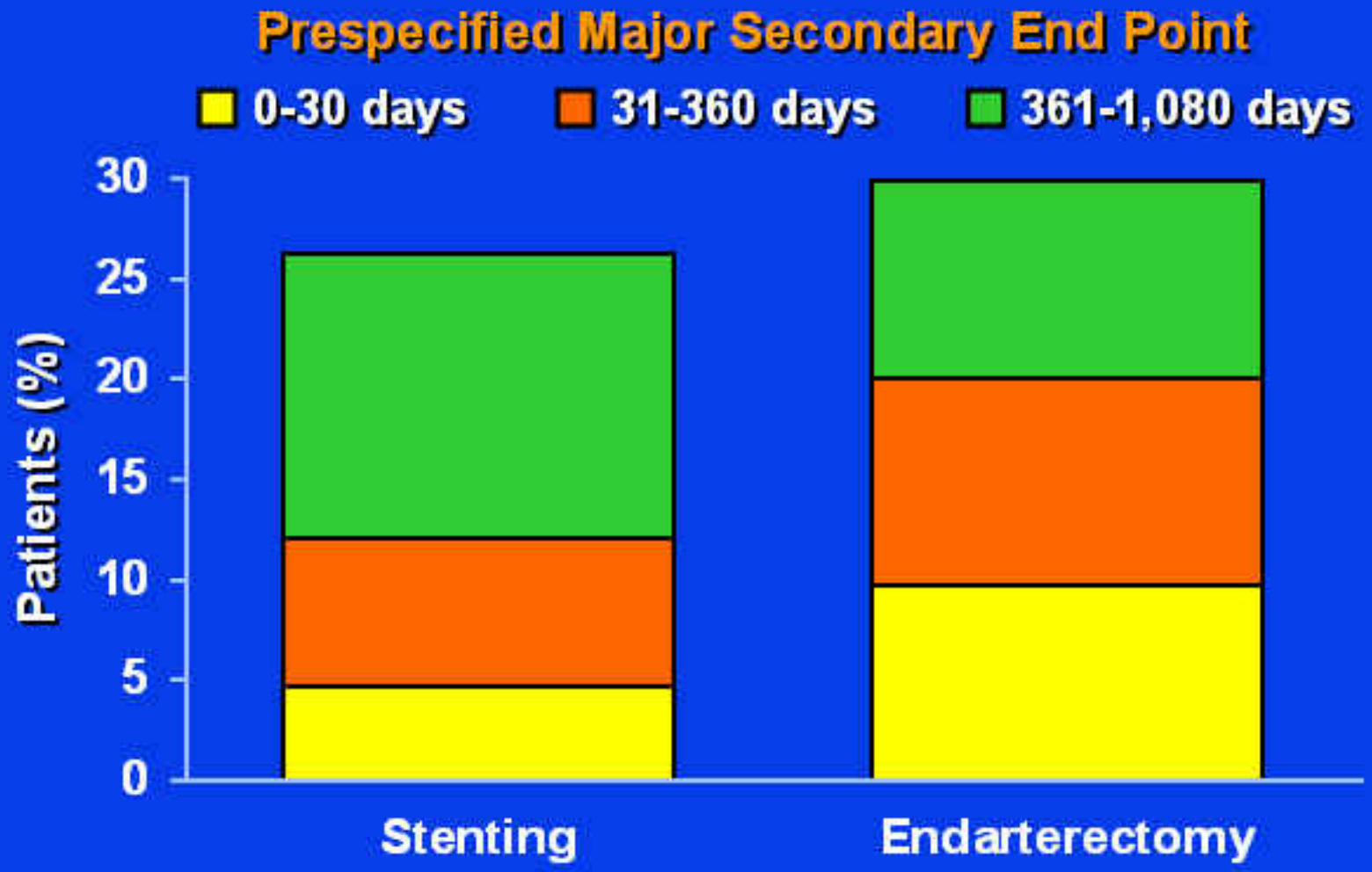


No. at risk							
Stenting	167	154	145	135	128	111	103
Endarterectomy	166	146	128	113	102	87	77

Gurm HS et al: NEJM 358:1572, 2008

MAYO CLINIC

SAPPHIRE



Gurm HS et al: NEJM 358:1572, 2008

SAPPHIRE

Gurm HS et al: NEJM 358:1572, 2008

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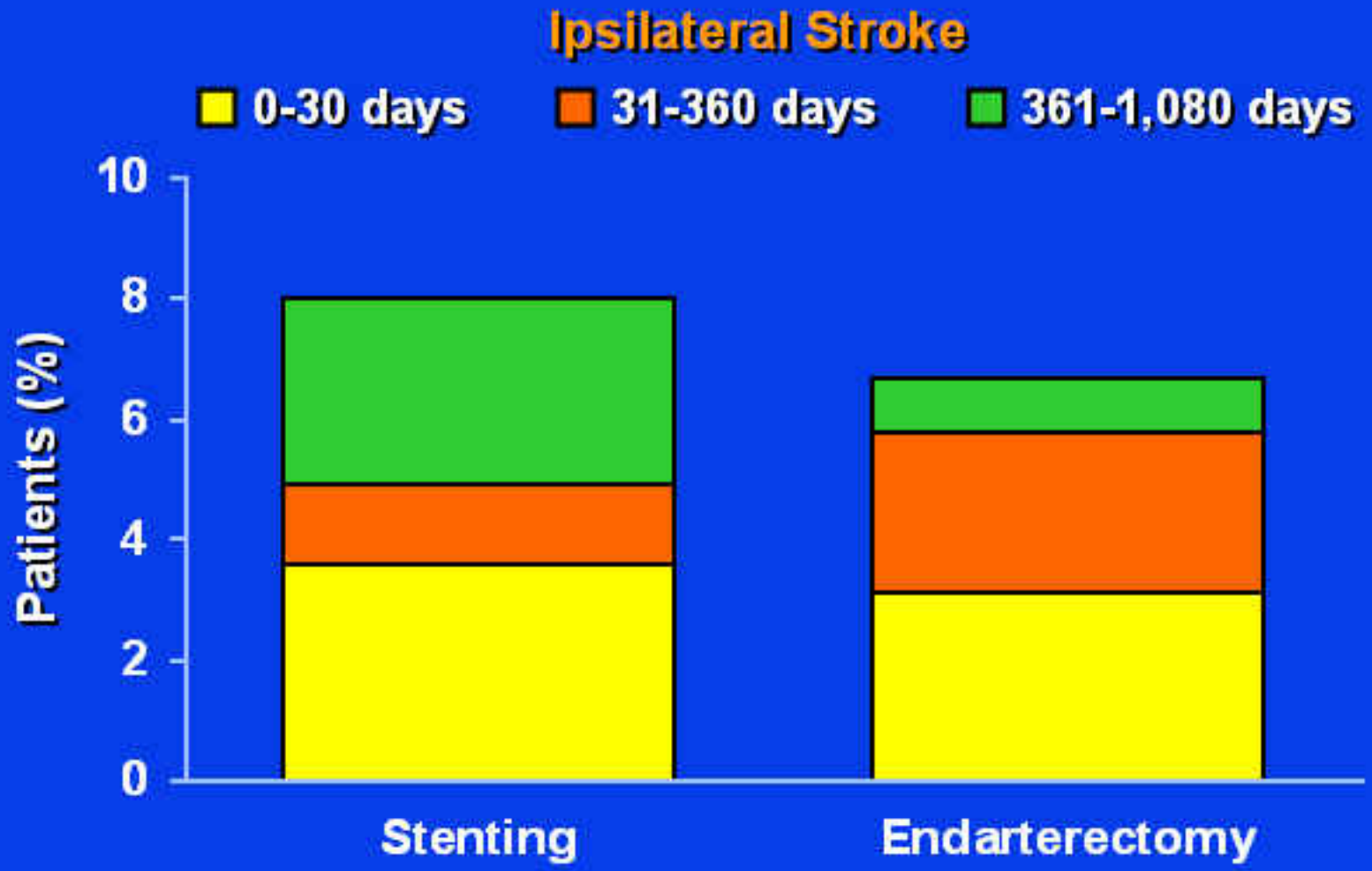
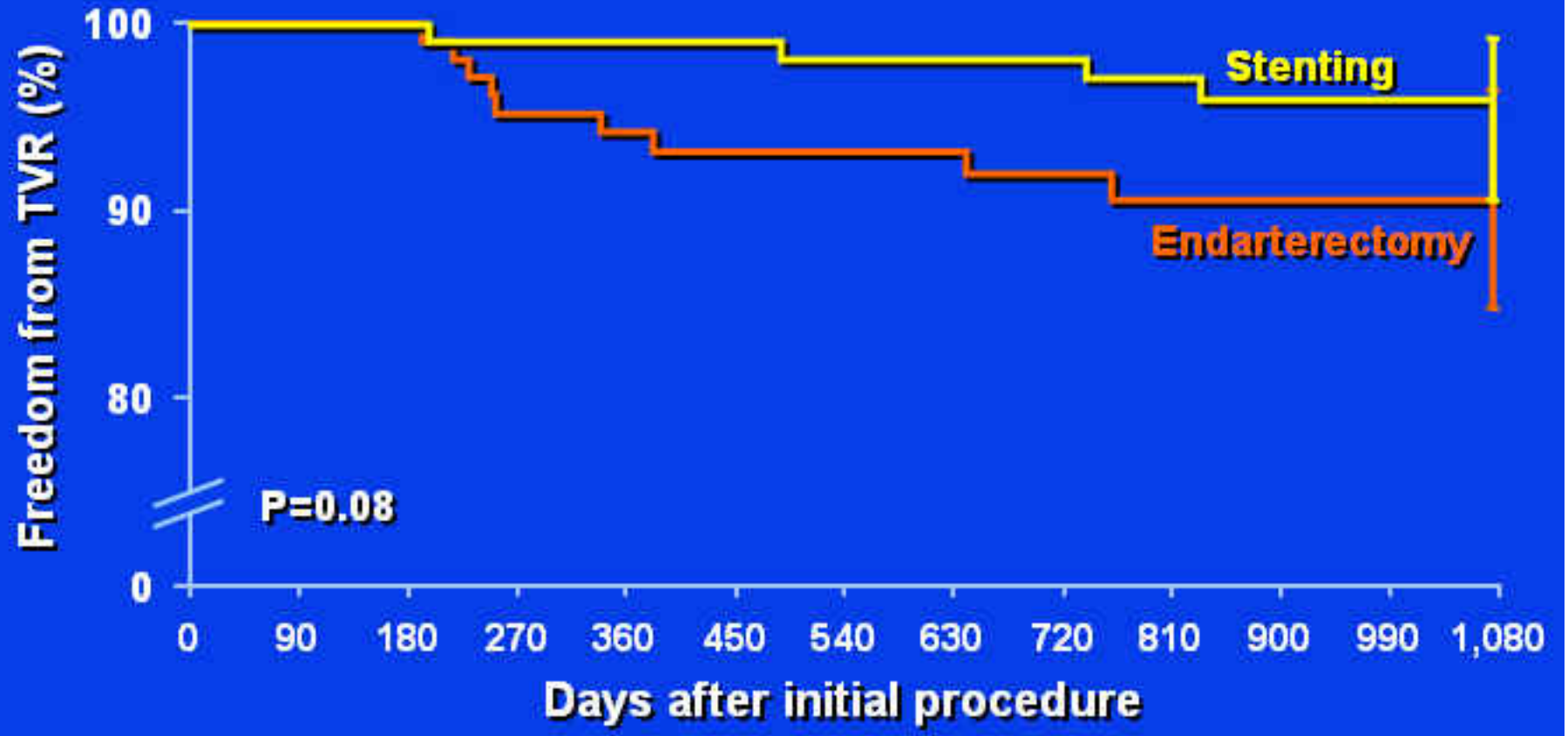


Gurm HS et al: NEJM 358:1572, 2008

SAPPHIRE
Freedom from TVR



No. at risk							
Stenting	167	157	151	140	133	116	108
Endarterectomy	166	147	128	112	100	83	74

Gurm HS et al: NEJM 358:1572, 2008

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LMCA Stenting
Issues

- Patient selection
  - High risk surgical vs good surgical candidates
- Lesion selection
  - Ostial, mid shaft, distal
  - Bifurcation, trifurcation
- Stent technique used and specific stent
- Effect of each of these on short and longer-term outcome


MAYO CLINIC

DES for LMCA Disease: Thar Be Dragons

ACC Lake Louise
March 2006

David R. Holmes, M.D.

Mayo Clinic, Rochester, MN

MAYO CLINIC

"Couldn't I do a couple of hundred hours of community service instead?"

- 55-year-old man was seized an hour after a moderately full meal with severe pain in the lower precordial region
- Chest was full of fine and coarse moist rales, a running feeble pulse of 140
- Urine scanty
- Condition remained up to the time of death 52 hours after pain onset

- Heart was of normal size
- Both coronary arteries were markedly sclerotic and calcareous
- A short distance from its origin, the left coronary artery was completely obliterated by a red thrombus that had formed at a point of great narrowing

Clinical Features of Sudden Obstruction of the Coronary Arteries

- James B. Herrick – Chicago
- JAMA – Dec. 7, 1912

Reports that say that something hasn't happened are always interesting to me, because as we know, there are known knowns; there are things we know we know. We also know there are known unknowns; that is to say we know there are some things we do not know. But there are also unknown unknowns - - the ones we don't know we don't know.

Donald H. Rumsfeld

Department of Defense news briefing, February 12, 2002

US Secretary of Defense (1932 -)

Does the Soul Live in the LMCA

- Medical Treatment:
  - 163 patients* with LMCA > 50%
    - 3-year survival 50%
    - LMCA > 70%
    - 3-year survival 41%
  - 1484 patients+ with LMCA
    - 3-year survival 69%

*Conley 1978
+CASS 1981

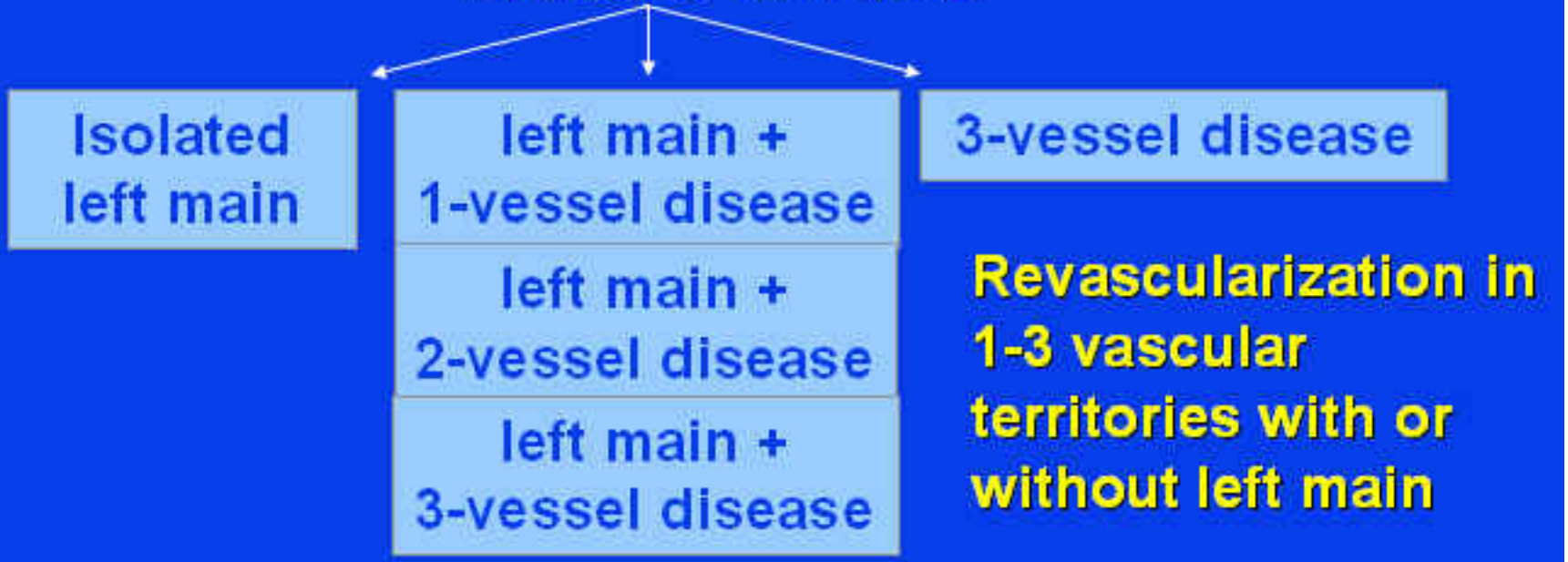
DES for LMCA Disease Wide Variation Worldwide

- Societal expectations
- Family expectations
- Availability of surgery
- Expertise of surgical team
- Expertise of interventional cardiology team

SYNTAX: Study Population

Question of optimal treatment approach?

Denovo disease



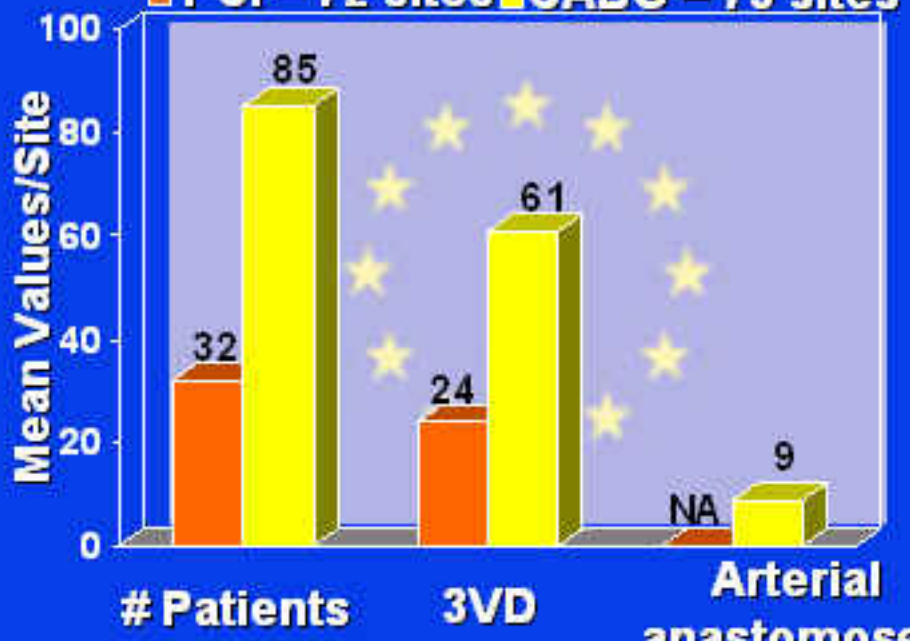
Revascularization in 1-3 vascular territories with or without left main

- Previous interventions (PCI or CABG) excluded
- Acute MI with CPK>2x
- Concomitant valve surgery

Run-in Phase Data

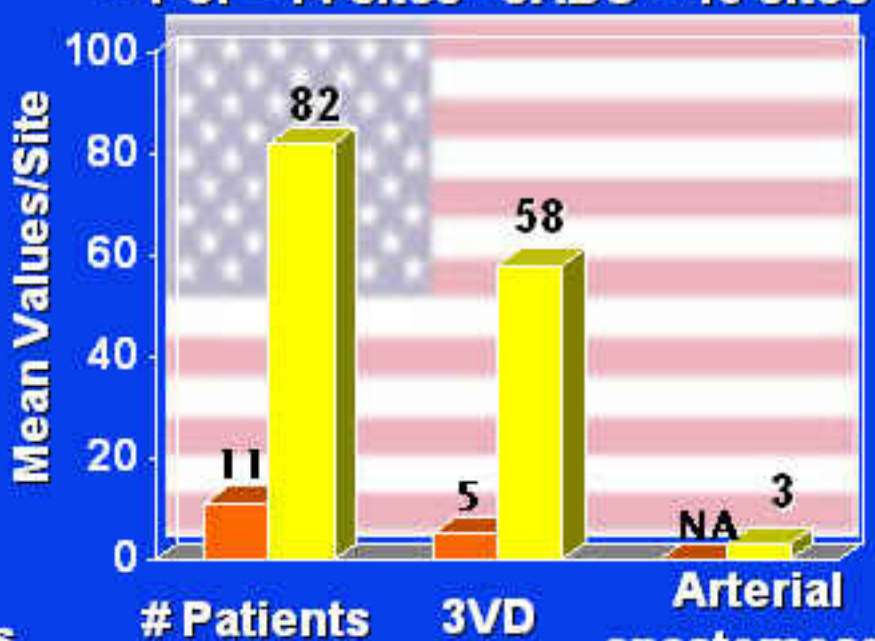
- Regional Results: Europe & USA -

Europe



	# Patients	3VD	Arterial anastomoses
Total PCI	2,424	1,785	NA
Total CABG	6,137	4,384	663

USA



	# Patients	3VD	Arterial anastomoses
Total PCI	182	90	NA
Total CABG	1,338	906	206

On average, Europe has 3X rate overall PCI , & 5X rate PCI for 3VD compared to USA.

Run-In Phase Data: Overall Results

	PCI	CABG
# of sites	81	80
# of pts. entered	2314	6486
Mean pts/site entered	29	81
Total 3VD	1701	4627
Mean 3VD/site	21	58
Total arterial anastomoses	NA	604
Mean arterial anastomoses/site	NA	8

PCI:CABG ratio for all pts entered is 1:3

PCI:CABG ratio for mean 3VD is 1:3

Run-In Phase Data: Overall Results

	PCI	CABG
Total LM	613	1859
Mean LM/site	8	23
Mean LM isolated/site	2	2
Mean LM + 1 VD/site	2	2
Mean LM + 2 VD/site	2	6
Mean LM + 3 VD/site	1.3	13
Mean LM protected/site	3	NA
Mean LM unprotected/site	5	NA

PCI:CABG ratio for overall LM is 1:3

PCI:CABG ratio for LM + 3VD is 1:3

Run-In Phase Data: Regional Results

	Europe		US/Canada	
	PCI	CABG	PCI	CABG
# of sites	66	66	15	14
# of pts. entered	2165	5406	149	1080
Mean pts/site entered	33	82	10	77
Total 3VD	1636	3873	65	754
Mean 3VD/site	25	59	4	54
Total arterial anastomoses	NA	556	NA	48
Mean arterial anastomoses/site	NA	8	NA	3

3X more PCI in Europe

6X more PCI for 3 vessel disease in Europe

Insight into North American Practice Pattern

Data for 3 vessel disease from 14 US/Canada sites show:

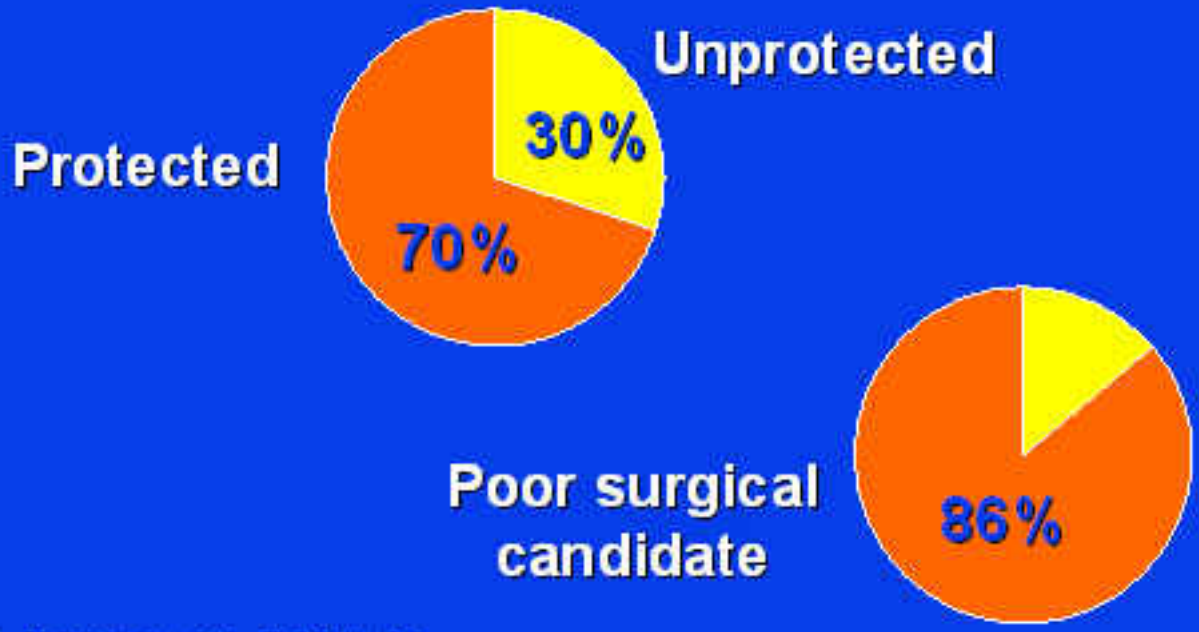
- Mean PCI treatment is 3X greater in Europe
- Mean CABG treatments is similar for the US/Canada & Europe
- However, ratio of PCI:CABG is
  - 1.5:10 in US/Canada
  - 2 : 5 (0.40) in Europe

DES for LMCA Disease Issues

- Patient demographics
  good surgical candidates, inoperable
- Prior CABG
  protected versus unprotected
- Specific anatomy
  ostial, shaft, distal RVD,
  calcification
- Associated degree and extent of CAD

One Year Outcome LMCA PCI

- Multi center observational study
- 142 consecutive patients - PCI of LMCA
- All cause mortality, MI, TLR, and MACE assessed at 1 year



Kelley, Eur Heart J 2003; 24:1554-59

One Year Outcomes

	Entire cohort (n=137)	Protected LMCA (n=94)	Unprotected LMCA (n=43)	P
Death	17 (12%)	5 (5%)	12 (28%)	<0.0001
MI	6 (4%)	3 (3%)	3 (7%)	0.4
TLR	27 (20%)	17 (18%)	10 (23%)	0.5
MACE	44 (32%)	23 (25%)	21 (49%)	0.005

Kelley, Eur Heart J 2003; 24:1554-59

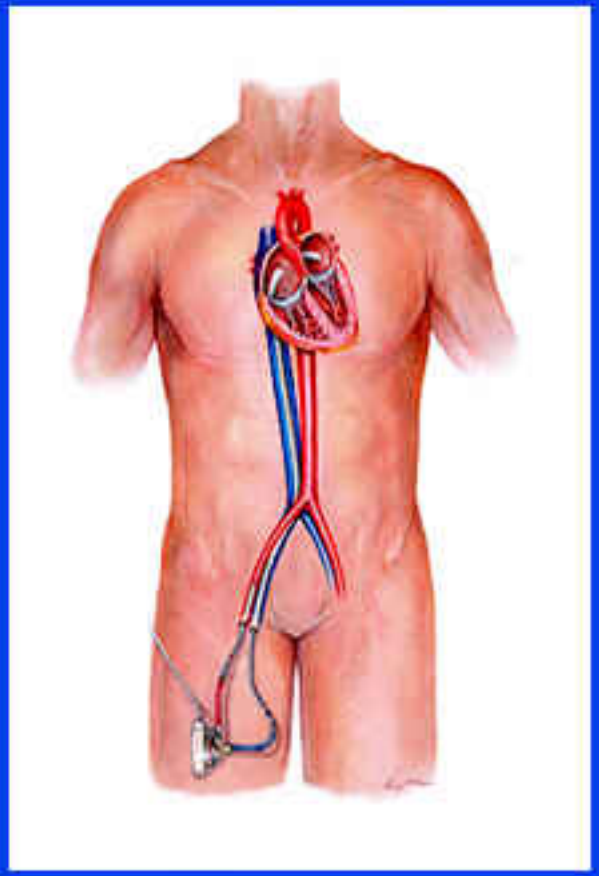
DES for LMCA Disease Issues

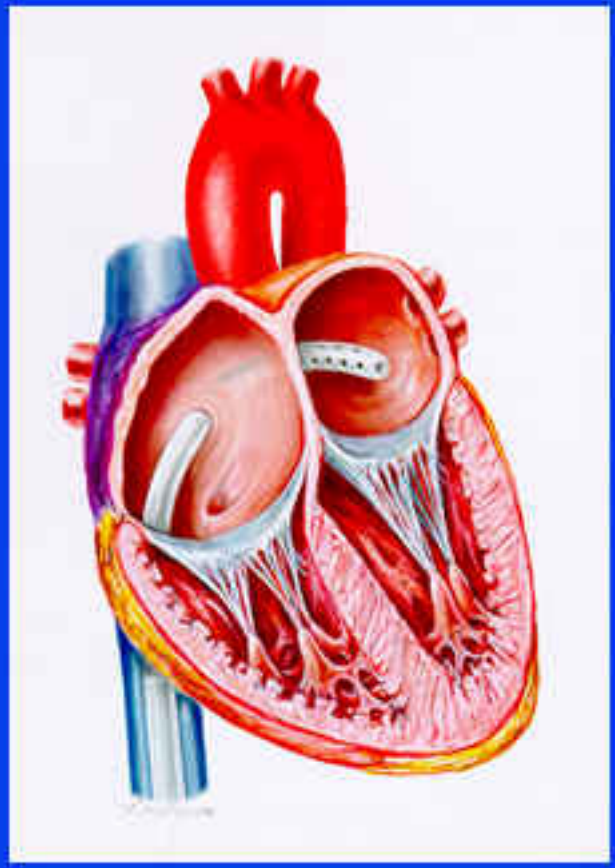
- Specific approach
  Hemodynamic support
  Stent approach
- In-hospital outcome
- Longer term outcome
  MACCE
  Restenosis
  SAT
- Clinical trials

Hemodynamic Support

- None
- Contra-lateral safety sheath
- IABP
- Circulatory support with LV assist

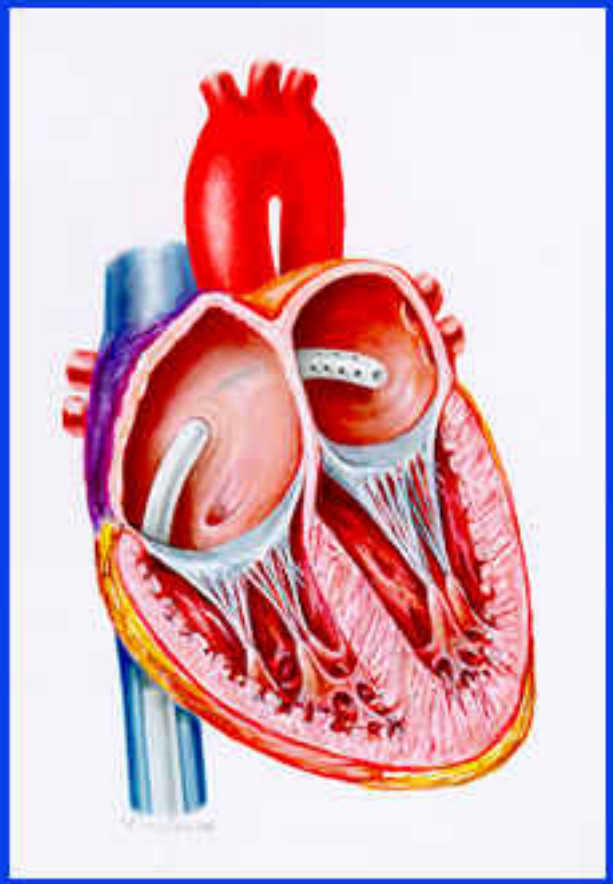
TandemHeart™ pVAD



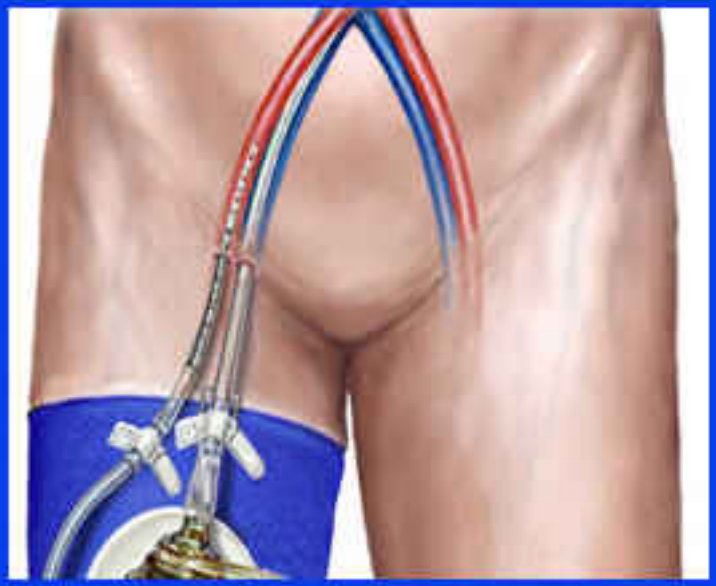


PTVA™ - Percutaneous Transseptal Ventricular Assistance

Percutaneous Left Ventricular Support



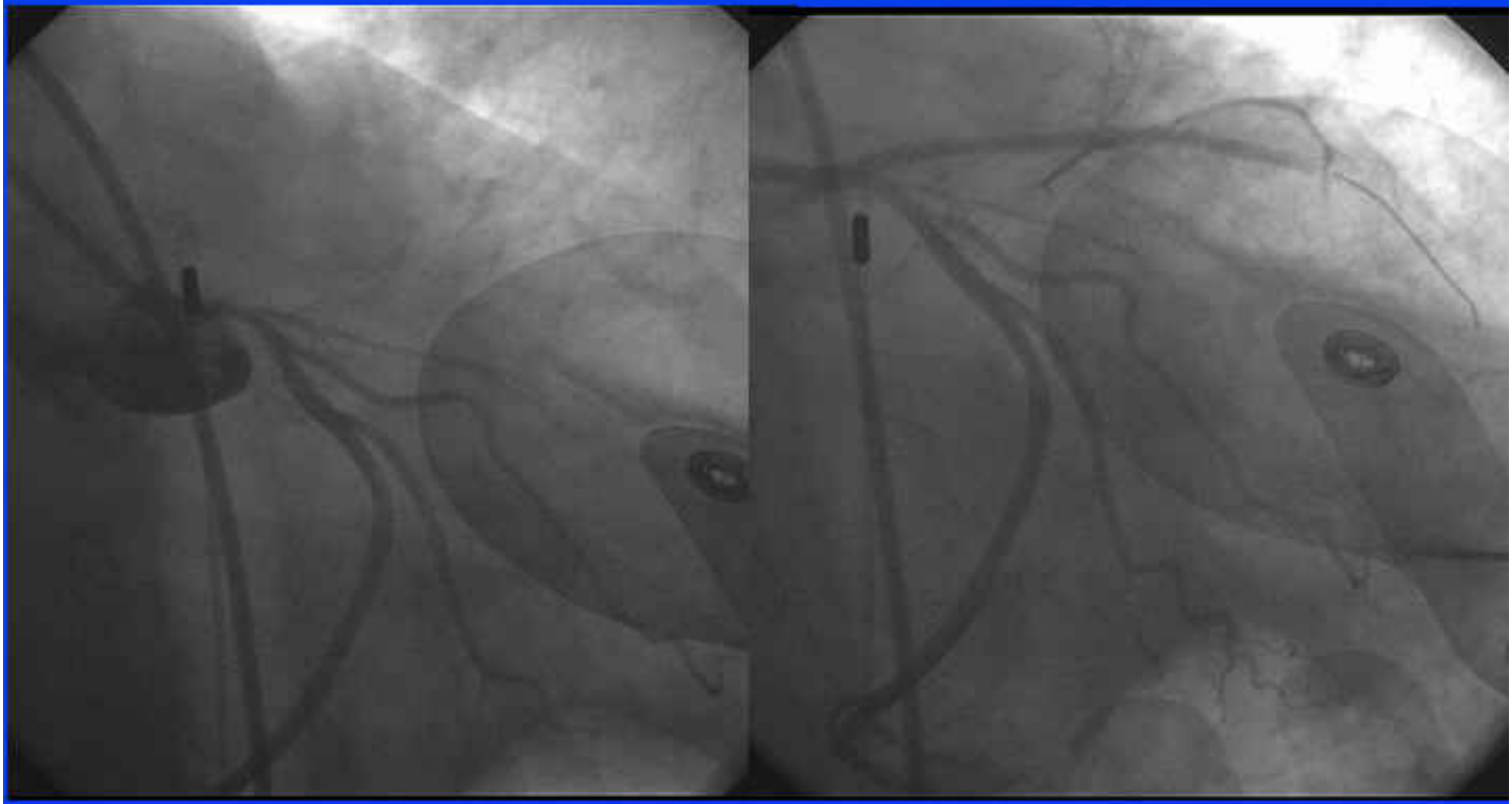
Up to 4.5 L/min flow achievable



TandemHeart pVAD

- Enables minimally invasive circulatory support
- Compact size, lightweight design suited to paracorporeal placement
- Continuous flow, very quiet
- Up to 4 LPM flow depending on cannulation
- Priming volume of only 7 ml
- Addresses a wide range of patient sizes
- Novel lubrication and anticoagulation system

CASE 53F
Ant MI. Shock, VT. TandemHeart -> Heartmate.



DES for LMCA Disease
Anatomic Considerations

- Ostial: recoil, calcification, stability of placement, failure to fully cover, avoidance of excess prolapse
- Approach: predilatation essential, optimize guide, multiple views and landmarks, optimal stent length, flare stent

DES for LMCA Disease
Anatomic considerations

- Shaft lesions: lesion calcification, RVD, lesion length, LMCA length
- Approach: pre-dilatation, gauge whether it is possible to deploy stent just in the shaft.

DES for LMCA Disease
Anatomic Considerations

- Distal disease: bifurcation or trifurcation lesions, angulation, size of branches, presence of stenosis
- Approach: Careful pre-procedure planning, adequate catheter size, safety wire, pre-dilatation and then reassessment. Alphabet soup.

LMCA Bifurcation Techniques

Technique	Angulation
• Crossover	• Wide range
• Kissing V-stent	• Narrow angle
• Crush-stenting	• Wide range
• T-stenting	• Ideally 90°
• Culotte-stenting	• Wide range


CAT

Problems

- Can't remember exactly how to do them all
- Take extra time, more resources
- Not very elegant or simple
- Restenosis rates and probably SAT are still increased

Advantages

Technique	Advantages
Crossover	• Technically straight forward • Better midterm outcome with BMS • No deformity of stent • Cheaper than double stenting
Kissing (V)-stenting	• Simple and quick • Easy access for both vessels
Crush-stenting	• Excellent lesion coverage • Easy access for main vessel • Relatively quick
T-stenting	• Easy access for main vessel • Less deformity of stent
Culotte-stenting	• Excellent lesion coverage • 6-Fr GC compatible

Disadvantages

Technique	Disadvantages
Crossover	• Rewiring side branch after stenting may be difficult • Result of side branch can be suboptimal
Kissing (V)-stenting	• Only for large vessels with narrow angulation • Metallic neocarina may trigger late thrombus formation and complicate future access to LAD/LCx Limited data
Crush-stenting	• Difficulty in recrossing lesion through crushed struts • Limited data • Large GC (8 Fr) needed (except reverse crush)
T-stenting	• Potential geographic miss to cover vessel ostium • Remaining high restenosis rate in a controlled randomized series
Culotte-stenting	• Rewiring main and side branch may be problematic • Limited data • Time-consuming


DO NOT TOUCH
DO NOT TOUCH


THE BEST
COMMERCIALS

DES for LMCA Disease Issues

- Specific approach
  Hemodynamic support
  Stent approach
- In-hospital outcome
- Longer term outcome
  MACCE
  Restenosis
  SAT
- Clinical trials

PCI vs CABG in LMD
ACC/AHA/SCAI 2005 Guideline Recommendations

Class IIa

- Use of PCI is reasonable in pt with asymptomatic ischemia or CCS class I, II, or III angina, or with UA/NSTEMI with significant left main CAD (>50% DS) who are candidates for revascularization but are not eligible for CABG (level of evidence B)
- It is reasonable that pt undergoing PCI to unprotected left main coronary obstructions be followed up with coronary angiography between 2 and 6 mo after PCI (level of evidence C)

Class III

- PCI is not recommended in pt with asymptomatic ischemia or CCS class I, II, or III angina, left main disease and eligibility for CABG (level of evidence C)
- In absence of high-risk features associated with UA/NSTEMI, PCI is not recommended for pt with UA/NSTEMI, and significant left main CAD and candidacy for CABG (level of evidence B)

Smith et al: ACC/AHA/SCAI 2005 Guideline Update for PCI

Experiences with PCI for ULMD (1)

First author, year	Device used	No.	In-hosp mortality (%)	Mortality (%) (F-U)	Re-stenosis (%)	TVR (%)	Comments
Ellis, 1994-1996	50% BMS	107	20.6	66.0±4.7 (9 mo)	20.8	NA	Survival to hospital discharge 31% in acute MI pt; in elective pt, in-hosp mortality 5.9% in good candidates for CABG 30.4% in poor CABG candidates; in-hosp survival strongly correlated with LVEF
Silvestri, 1993-1998	100% BMS	140	9% high CABG risk; 0% low CABG risk	2% high CABG risk; 2.6% low CABG risk (6 mo)	23	17.4	Good immediate results of PCI in ULM stenosis, especially in good CABG candidates
Black, 1994-1998	100% BMS	92	4.3	10.8 (8.3±5.8 mo)	NA	7.3	PCI to ULM appears better in candidates for CABG than in pt in whom CABG is contraindicated; trend toward cardiac mortality with 3-VD and low LVEF; low final stent lumen diameter only significant predictor of cardiac mortality
ULTIMA, 1993-1998	68.6% BMS	279	13.7	24.2 (1 yr)	NA	33.6	46% of pt were deemed inoperable or at high risk for CABG; in pt <65 yr old with LVEF >30% and no shock, 0% periprocedural deaths and 1-yr mortality 3.4%; 2%/mo death rate among hospital survivors over 6 mo after discharge; careful surveillance with coronary angio recommended

SES and Unprotected LMCA

- Single center observational study
- 52 patients with LM stenosis
  47 de-novo
  5 ISR

EF 57%
DM 35%
UA 83%

de Lezo; Am Heart J, 2004;148:481-5

SES and Unprotected LMCA

Primary Success 96%

Periprocedural NSTEMI 4%

Mean FU 12 ± 4 mos

96% - asymptomatic

No late death or SAT

2 patients became symptomatic

1 restenosis at remote site

1 ISR

de Lezo; Am Heart J, 2004;148:481-5

DES for LMCA Disease

- Single center observational study
- Patients undergoing PCR of unprotected LMCA disease
- 102 – SES
- 121 – BMS

	SES	BMS	P
Age	60.3	57.6	.08
DM	28.4	21.5	.23
UA	50.0	61.2	.23
LVEF	60.4	61.8	.15
≥ 2VD	58.4	10.7	<.001

Park, JACC 2005; 45:351-6

DES and LMCA Disease
Outcome

	SES	BMS
Procedural Success	100%	100%
Death	0	0
QMI	0	0
Emer CABG	0	0

Park, JACC 2005; 45:351-6

DES and LMCA Disease
1 Year Outcome

	SES	BMS	P
Restenosis	7%	30.3%	<0.001
Ostium Circ	4.7	13.1	.07
Death	0	0	
QMI	0	0	
TLR	2%	17.4%	<.001

Park, JACC 2005; 45:351-6

DES for LMCA Disease

SES in patients with unprotected LMCA and normal LV function is safe with no episodes of death or stent thrombosis

Restenosis rates are low

Park, JACC 2005; 45:351-6

French LMCA TAXUS Pilot
291 patients

• Prior MI	11.5%
• Prior PCI	20.1%
• Prior CABG	1.0%
• UA	37.4%
• Recent MI	6.6%
• TVD	25.8%
• EF	60 +/- 13%

Left Main TAXUS Pilot
291 patients

- RVD: 3.71mm
- Distal lesion 78%
- Angio Success 99.6%
- In hosp MACCE 3.8%
- In hosp death .7%

French TAXUS Pilot Study
Distal lesion in 77.9%

• Provisional SB T-Stent	91.5%
• Systematic T-Stent	8.0%
• Side Branch stented	40.6%
• V-Stent	.5%
• Final kissing balloon	96.8%

Left Main TAXUS Pilot
6-8 Month Follow up

• MACCE	11.6%
• Death	3.4%
• TVR	5.2%
• Stroke	.7%
• SAT	1.0%
• Restenosis	9.5%

LMCA Disease
CABG vs DES

- Single center consecutive patient registry
- Patients with unprotected LMCA stenosis
  - 50 – PCI with DES
  - 123 – CABG

Lee MS et al: JACC, 47:864-70, 2006

LMCA Disease
PCI Performance

Location	
Ostial	42%
Mid	20%
Distal	60%

Single stent over LCX	33%
Crush	40%
T	10%
Simul Kiss	17%
IABP	64%
IIb/IIIa	14%

Lee MS et al: JACC, 47:864-70, 2006

LMCA Disease
Procedural Performance

PCI

2.5 ± 1.4 stents/pt

PCI of other lesions – 66%

CABG

3.0 ± .8 grafts/pt

LIMA to LAD – 96%

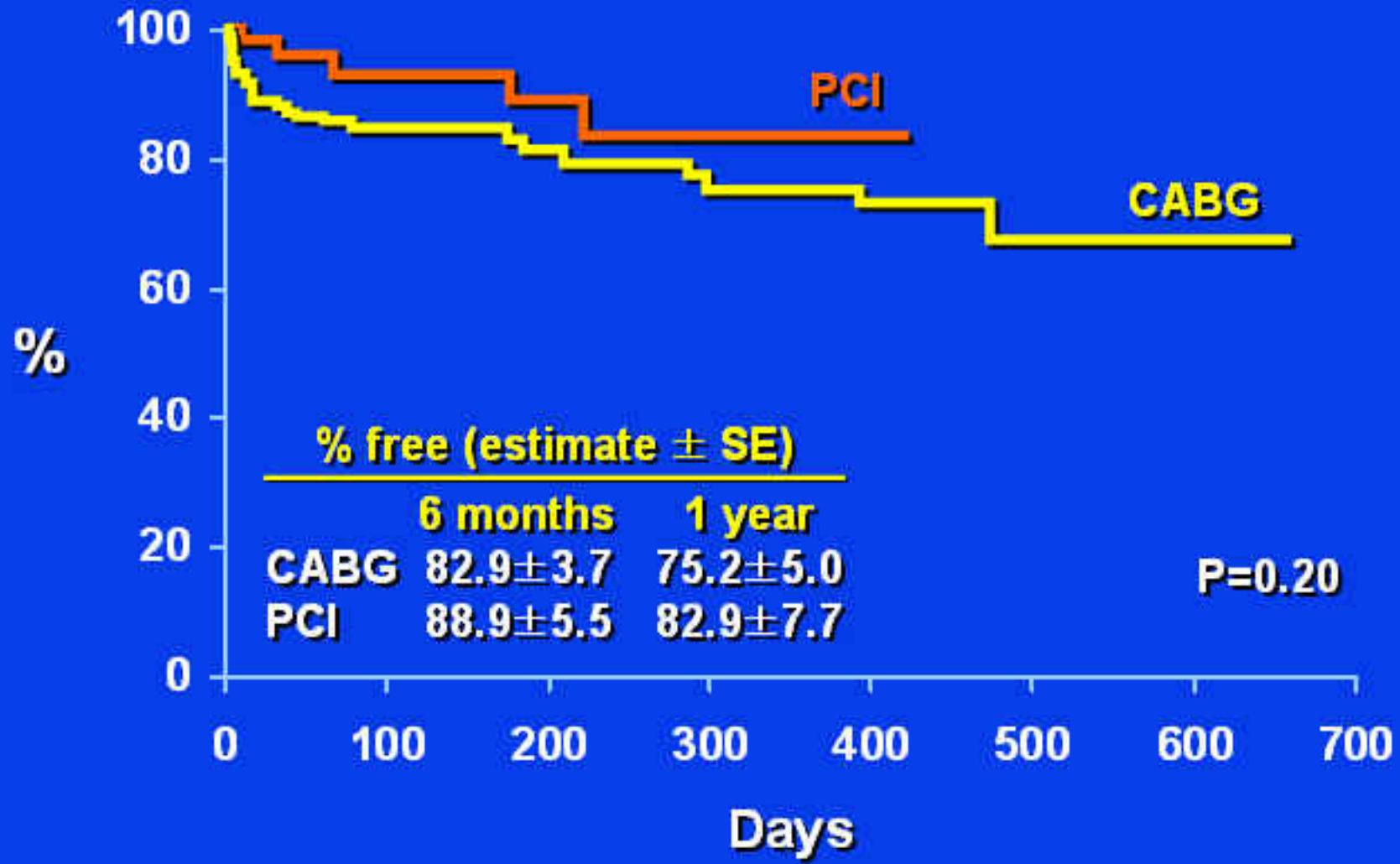
Lee MS et al: JACC, 47:864-70, 2006

Cox Proportional Hazard Model Results

Variables	P	Hazard Ratio (95% CI)
Univariate analysis		
MI	<0.01	
Parsonnet score	<0.01	
DM	<0.01	
Multivariate analysis		
Parsonnet score	<0.01	1.1 (1.0-1.1)
DM	0.03	2.2 (1.1-4.6)
CABG (vs. PCI)	0.04	2.8 (1.0-7.4)

Lee MS et al: JACC, 47:864, 2006

MACCE-Free Survival

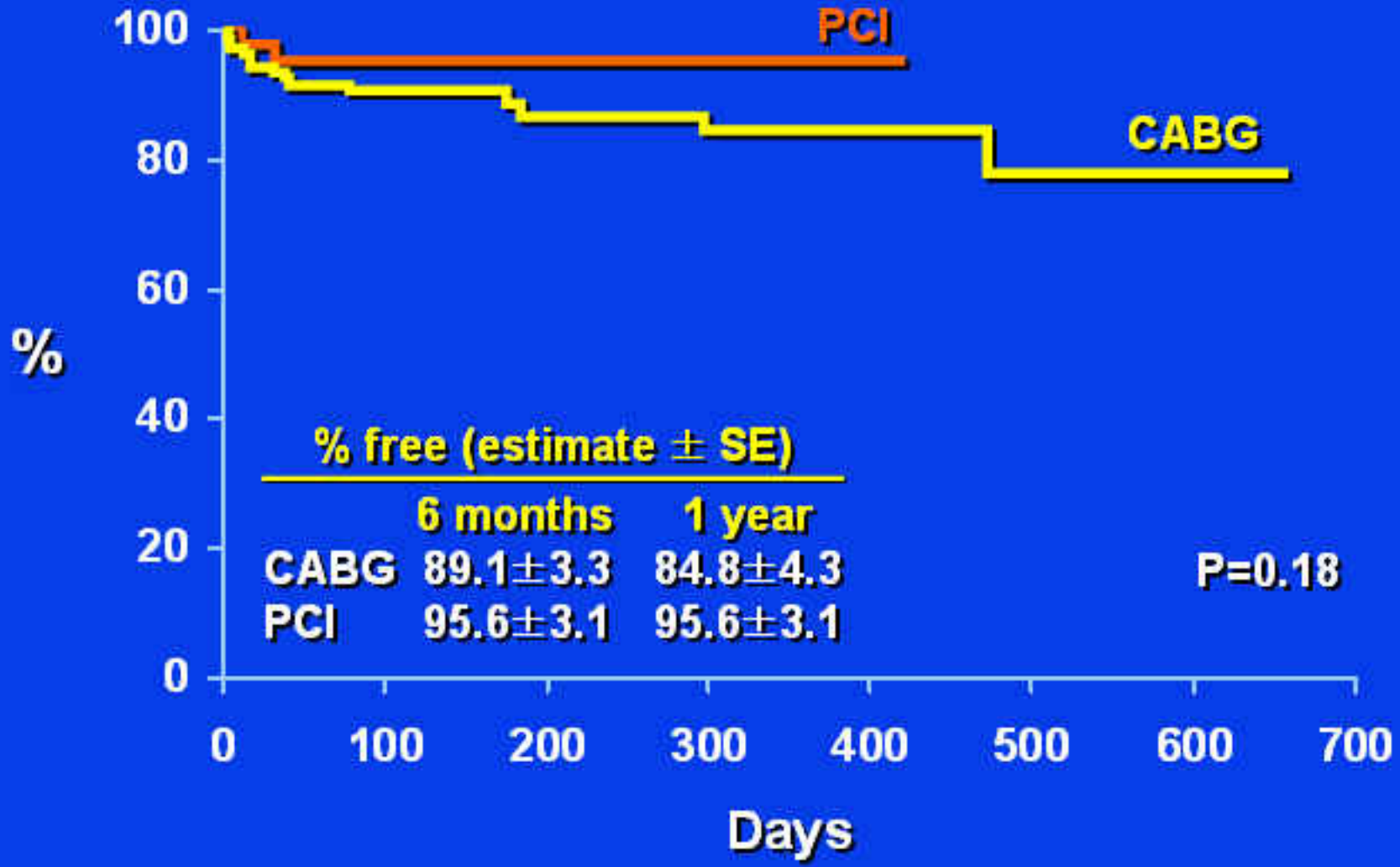


Lee MS et al: JACC, 47:864, 2006

MAYO CLINIC

CP122562-1

Freedom from Death

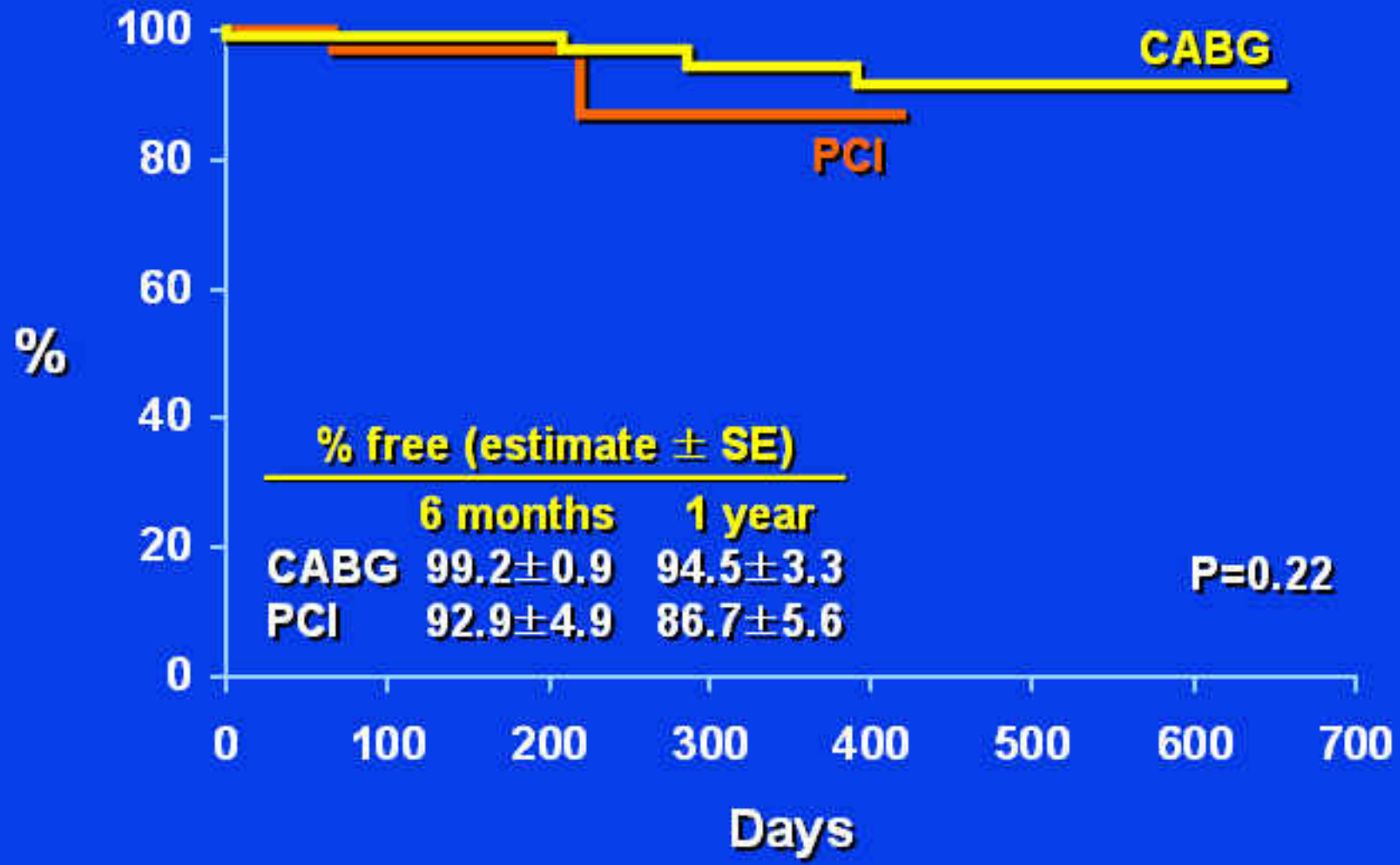


Lee MS et al: JACC, 47:864, 2006

MAYO CLINIC

CP122562-2

Freedom from Target Vessel Revascularization

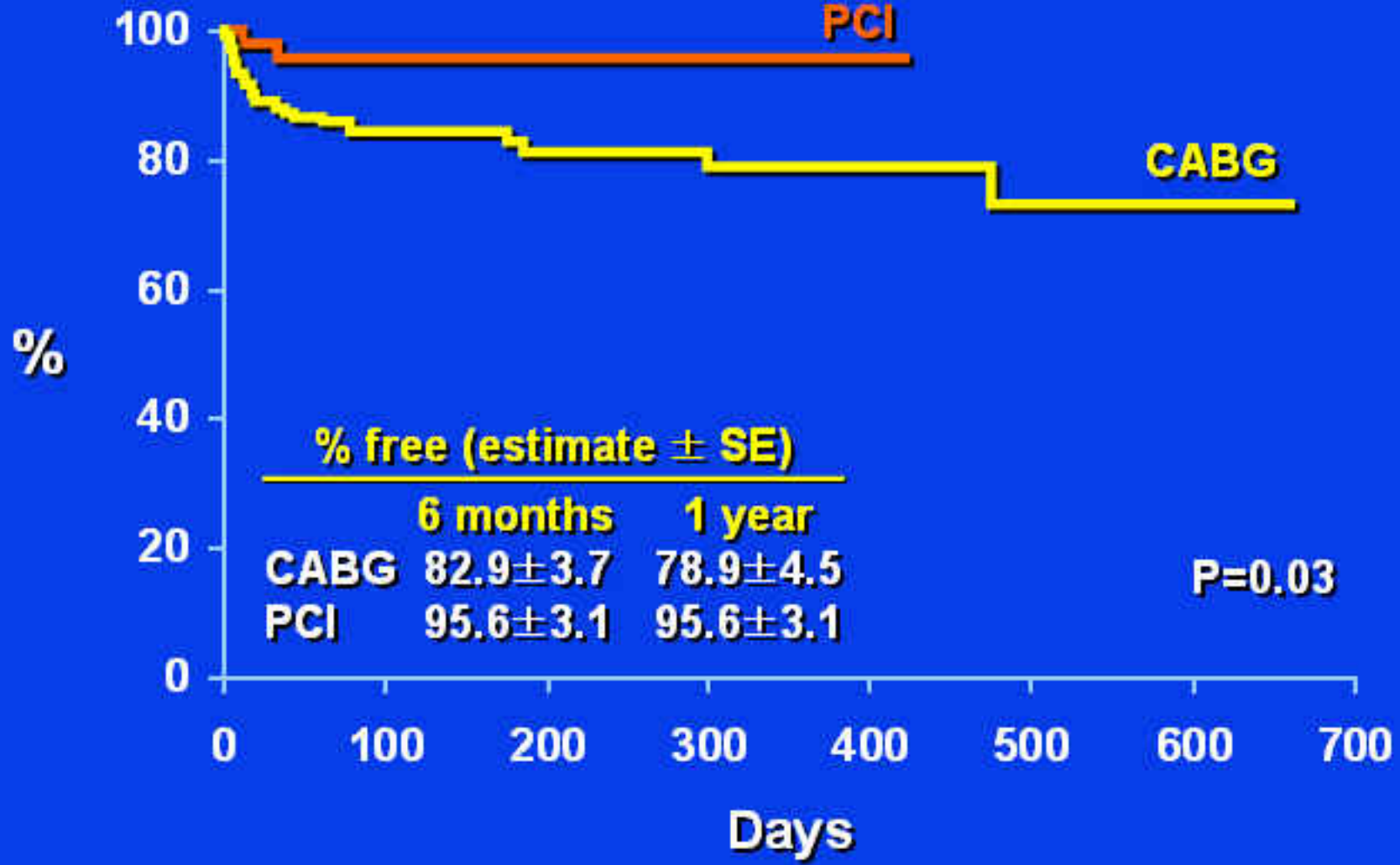


Lee MS et al: JACC, 47:864, 2006

MAYO CLINIC

CP122282-3

Freedom from D, MI, Cerebrovascular Events



Lee MS et al: JACC, 47:864, 2006

MAYO CLINIC

CP122362-4

Procedural and 30-Day Outcomes

%	CABG	PCI	P
MAACE	17	2	<0.01
Death	5	2	0.34
MI	2	0	>0.9
Urgent TVR	1	0	>0.9
CVA events	8	0	0.03
VT/VF	9	0	0.03
Renal failure requiring dialysis	2	0	>0.9
Cardiac tamponade	1	2	>0.9
Vasc. hematoma requiring vascular repair	0	0	>0.9
Repeat surgery for bleeding	7	NA	
In-hospital length of stay (days ± SD)	7.6 ± 4.9	3.9 ± 4.5	<0.01

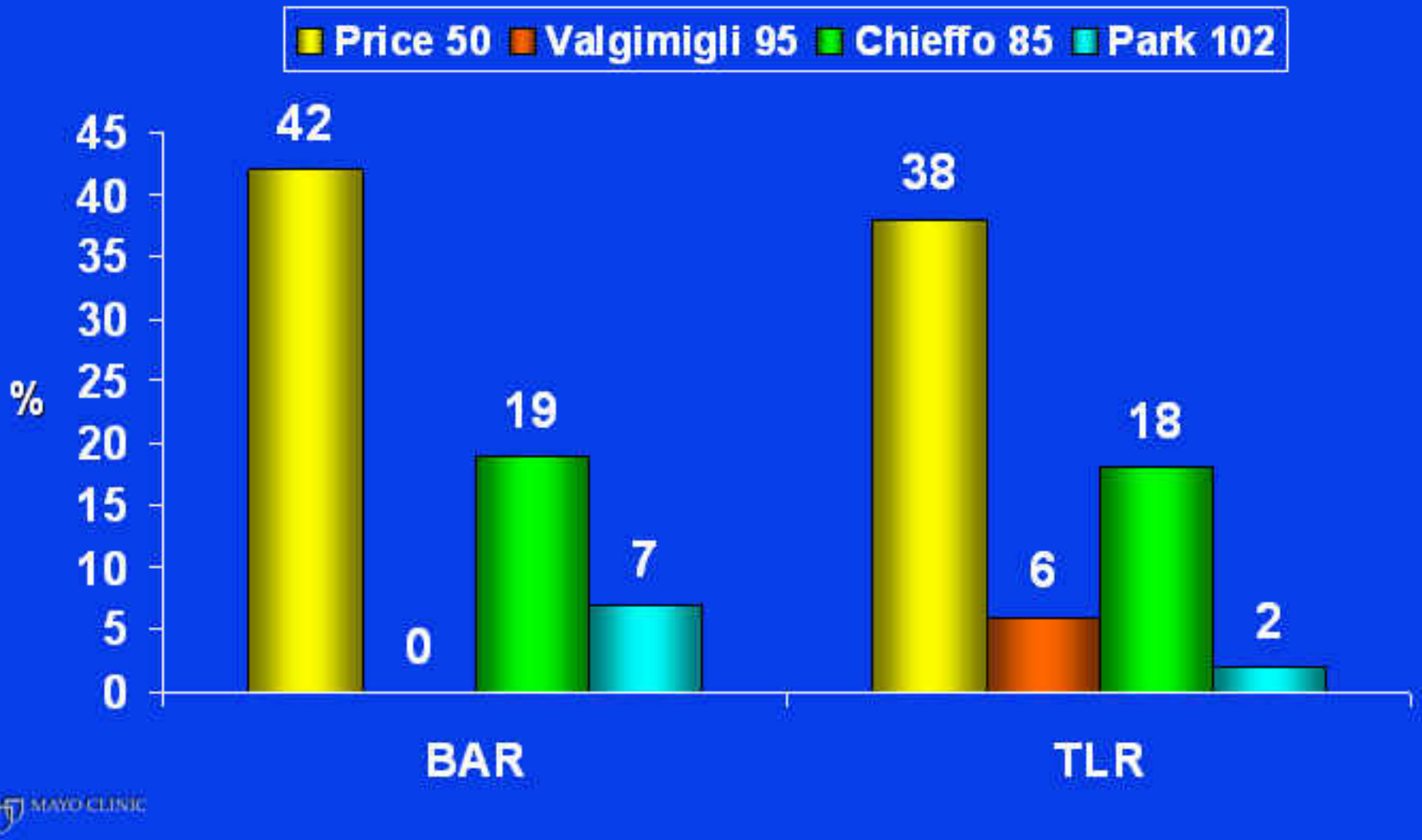
Lee MS et al: JACC, 47:864, 2006

LMCA Disease
CABG vs DES
Conclusions

PCI with DES for unprotected LMCA disease was not associated with an increase in immediate or medium term complications compared with CABG

Lee MS et al: JACC, 47:864-70, 2006

LMCA



SES for LMCA Disease

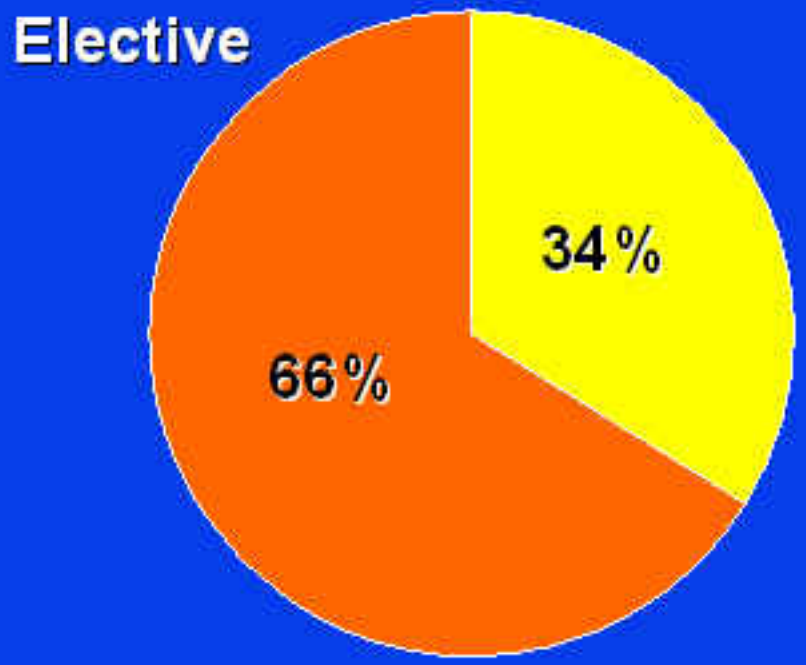
- Registry experience of patients undergoing elective, urgent or emergent placement of SES for ULMCA disease
- Surveillance angiography at 3 and 9 months

Price MJ et al: JACC 47:871-7, 2006

SES for LMCA Disease

Lesion Characteristics

- De novo 86%
- Distal LMCA 94%



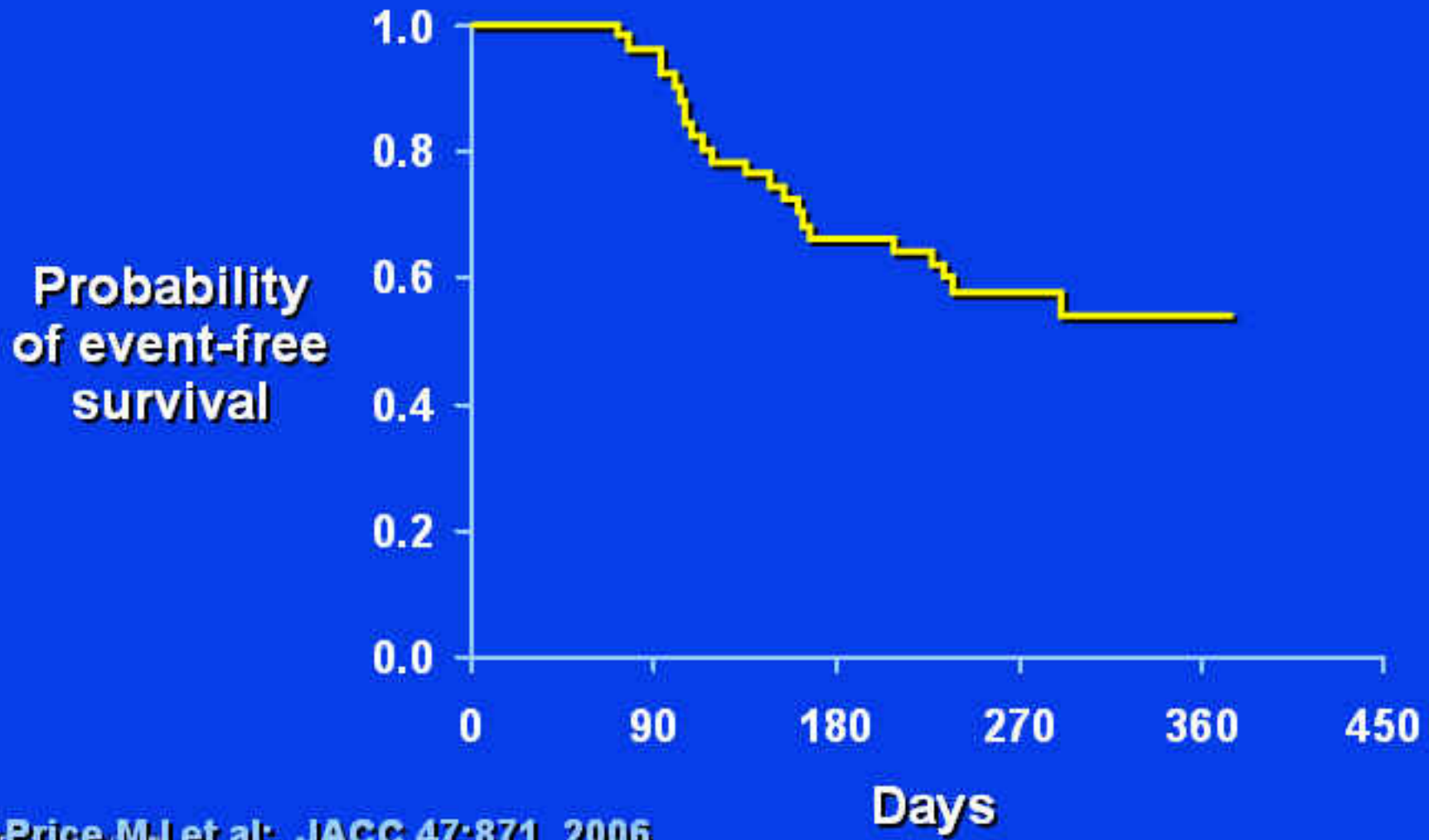
Price MJ et al: JACC 47:871-7, 2006

SES for LMCA Disease
Techniques Used

Both branches stented	84%
Kissing	68%
Crush	16%
Post crush kiss	8%
Single SES across ostium	8%
Single SES only in LMCA	8%

Price MJ et al: JACC 47:871-7, 2006

SES for LMCA Disease



Price MJ et al: JACC 47:871, 2006

CP12230B-1

SES for LMCA Disease
Early and Late Clinical Events

	(n = 50)
In-hospital events	
Death	0
MI	4 (8%)
Non-Q-wave	3 (6%)
Q-wave	1 (2%)
Acute thrombosis	2 (4%)
TLR	3 (6%)
Death, any MI, TLR, or thrombosis	5 (10%)
Events out-of-hospital over F/U	
Death	5 (10%)
Cardiac death	1 (2%)
Non-cardiac death	4 (8%)
Subacute thrombosis	0
MI	1 (2%)
TLR	19 (38%)
TLR; ischemic driven	7 (14%)
Death, any MI, TLR, or thrombosis	22 (44%)

Price MJ et al: JACC 47:871-7, 2006

SES for LMCA Disease
QCA

	LMCA – LAD	LCX
Restenosis		
3 months	13%	28%
9 months	23%	35%

TLR – 38%
Clinical TLR – 14%
Overall restenosis – 44%

Price MJ et al: JACC 47:871-7, 2006

SES for LMCA Disease
Distribution of Angiographic In-Stent Restenosis

Site	N = 21
LMCA ± branch ostia	4 (19%)
LAD ostium only	2 (9.5%)
LCX ostium only	10 (48%)
Both LAD, LCX ostia	5 (24%)

Price MJ et al: JACC 47:871-7, 2006

Patterns of Restenosis

- Chieffo: 12 restenotic lesions with DES. All occurred with treatment of distal LMCA. 7/12 (58%) involved ostium of LAD or circ
- Price: 21 restenotic lesions with DES
  - 10 – LCX ostium alone
  - 5 – LCX + LAD ostium
  - 2 – LAD ostium alone
- Park: 6 restenotic lesions with DES. All occurred with treatment of distal LMCA. 4 – LCX ostium alone

DES for LMCA Disease
Optimization of outcome

- Optimal equipment size
- Pre treatment planning, 'plan for success, prepare for failure Plan B'
- Post stent deployment dilatation
- IVUS guidance
- Dual anti-platelet therapy
- Surveillance angiography

SYNTAX: Study Design

All Patients with 3VD/LM

Heart Team (surgeon and interventionalist)

amenable for both treatments options

amenable for one treatment approach

Randomized Arm

N=1500 (1:1)

TAXUS *vs* **CABG**

- reasonable doubt
- follow-up: 30d, 6m, 1-5 yrs
- Goal: to define the most appropriate treatment through randomized trial methods

Two Registry Arms

CABG
2750 captured
(750 followed)

PCI
All captured and followed

- consensus exists that only one treatment option (CABG vs PCI) is appropriate
- Goal: to profile larger pool of non randomizable patients and their subsequent outcomes

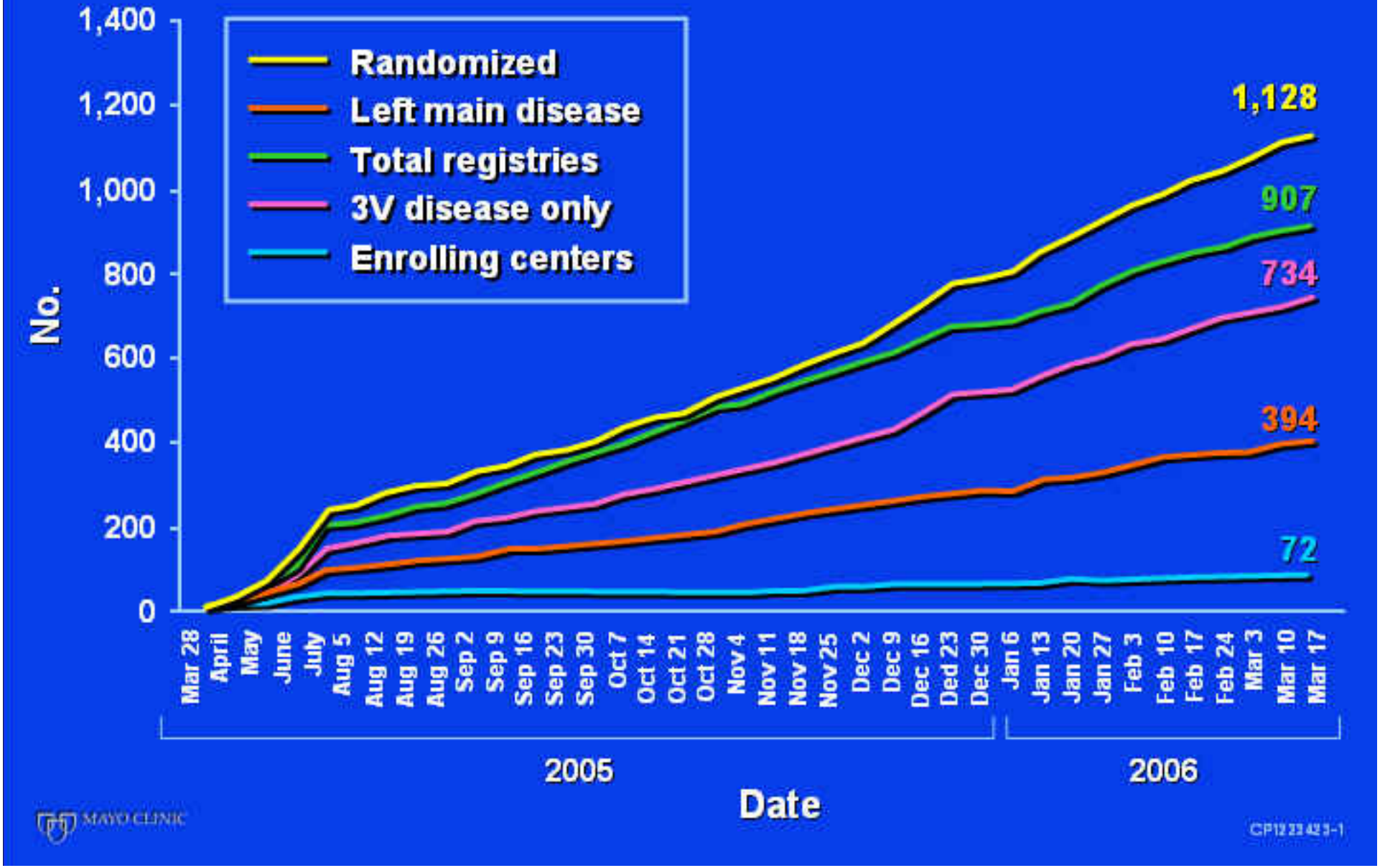
SYNTAX:
Primary endpoint

•TEST	•de novo 3VD/LM pts treated with paclitaxel-eluting TAXUS SR stents
•CONTROL	•de novo 3VD/LM pts treated with current standard of care CABG

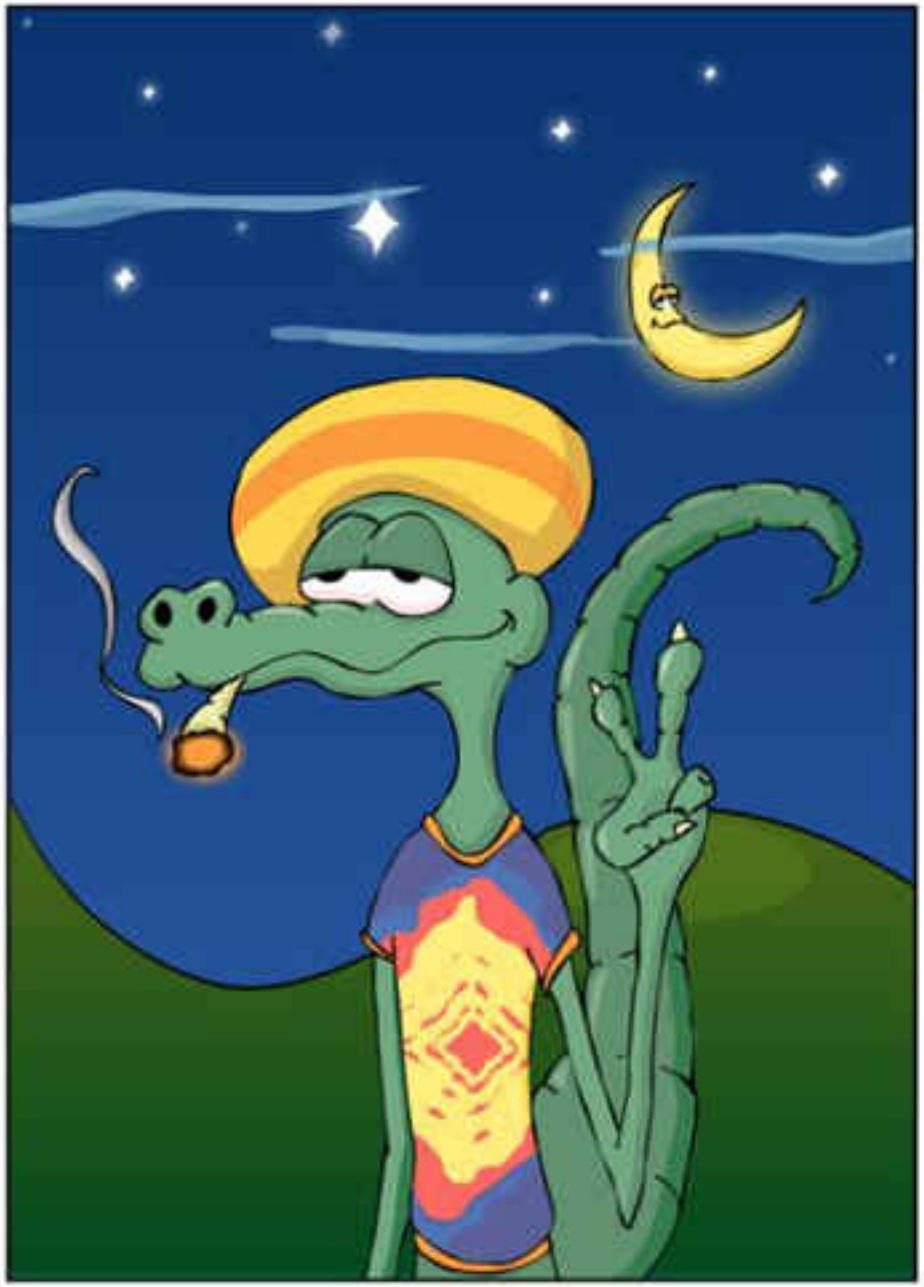
Compare 12 month MACCE (Major Adverse Cardiac and Cerebrovascular Events):

- all cause death
- myocardial infarction
- cerebrovascular events (CVA only)
- repeat revascularization (CABG or/and PCI)

Syntax Enrollment



MAYO CLINIC



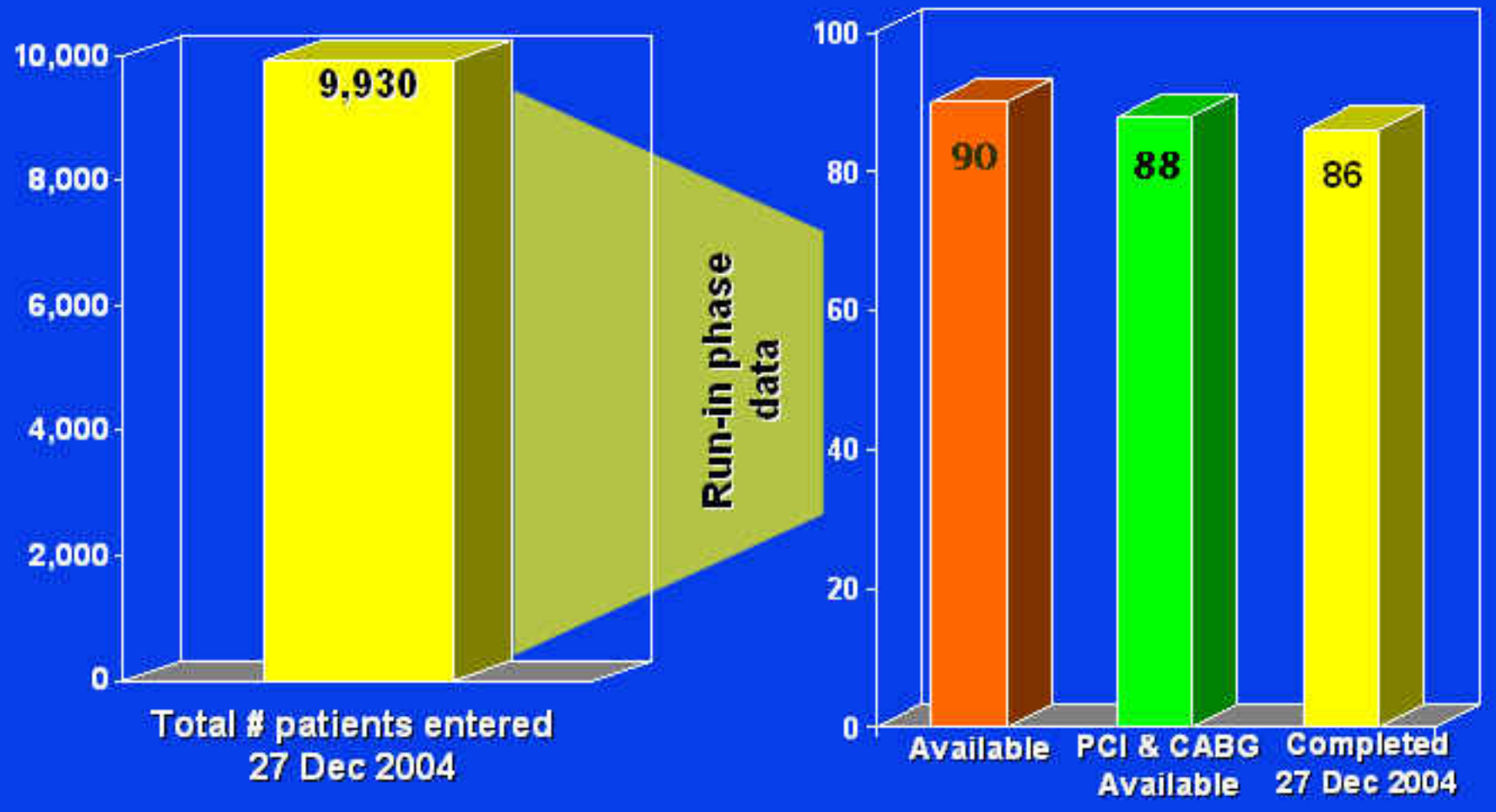
MAYO CLINIC

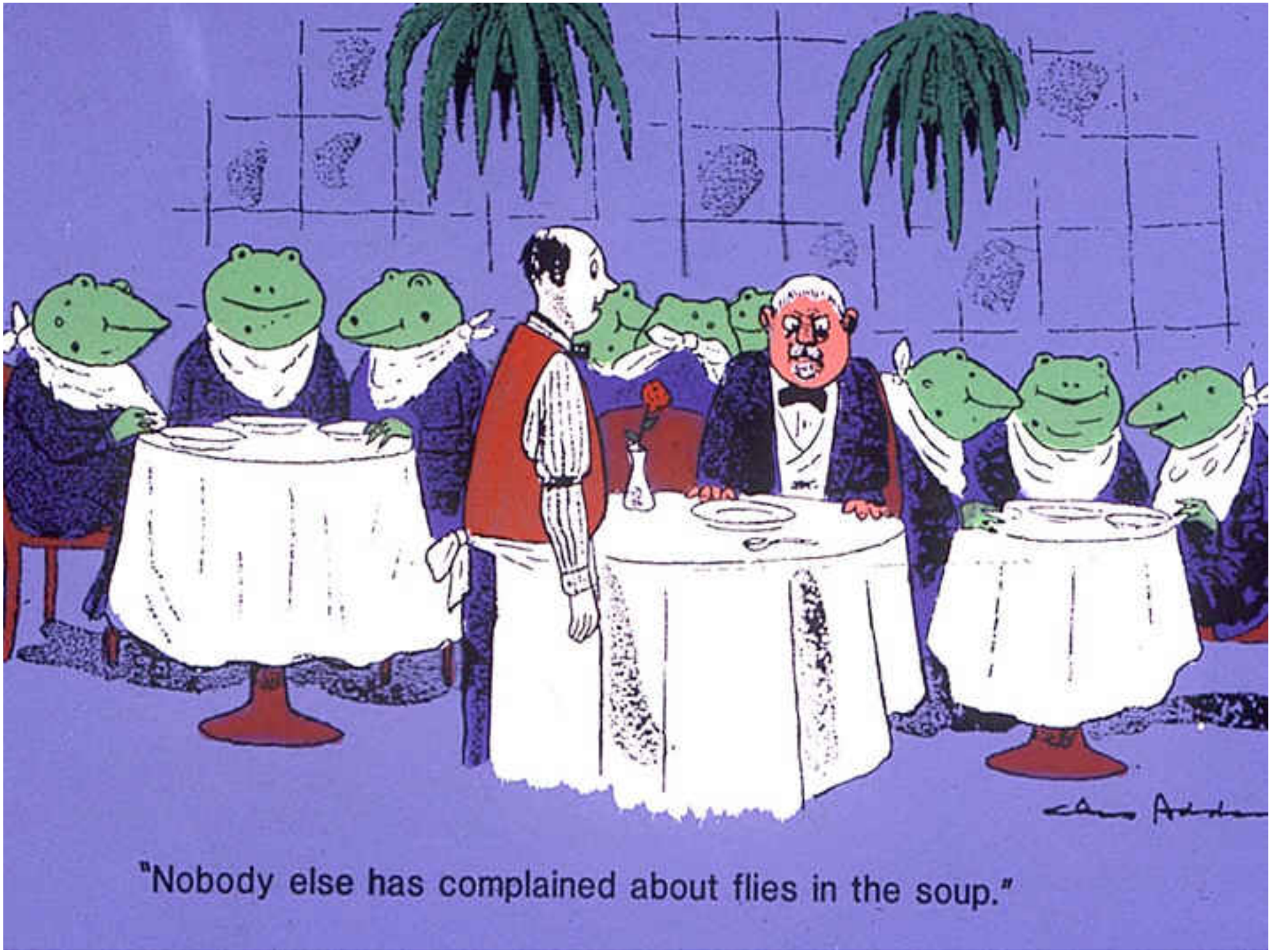

Warning: Cardiologists
are closer than you think

What is the Lexicon

- V or Kissing Stent
- Crush, mini-crush, reverse crush
- Inverted crush, step crush
- T stent
- Modified T stent
- Provisional stent

Run-in Phase Data
- Overall Results -

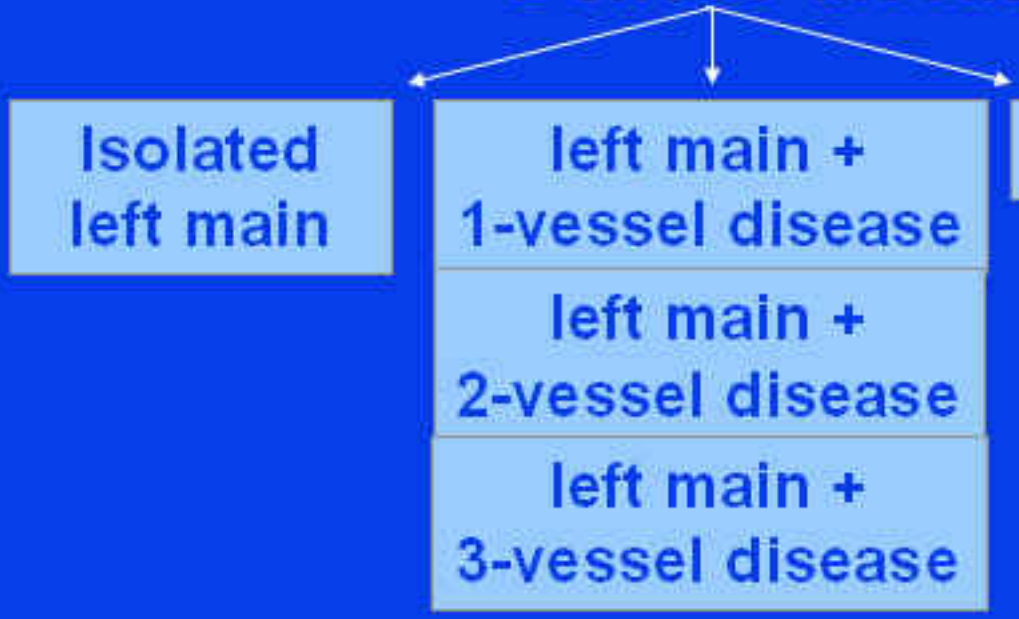



"Nobody else has complained about flies in the soup."

SYNTAX:
Study Population

Question of optimal treatment approach?

Denovo disease



Revascularization in 1-3 vascular territories with or without left main

- Previous interventions (PCI or CABG) excluded
- Acute MI with CPK>2x
- Concomitant valve surgery


Warning: A pathologist
is closer than you think

SYNTAX:
Primary endpoint

•TEST	•de novo 3VD/LM pts treated with paclitaxel-eluting TAXUS SR stents
•CONTROL	•de novo 3VD/LM pts treated with current standard of care CABG

Compare 12 month MACCE (Major Adverse Cardiac and Cerebrovascular Events):

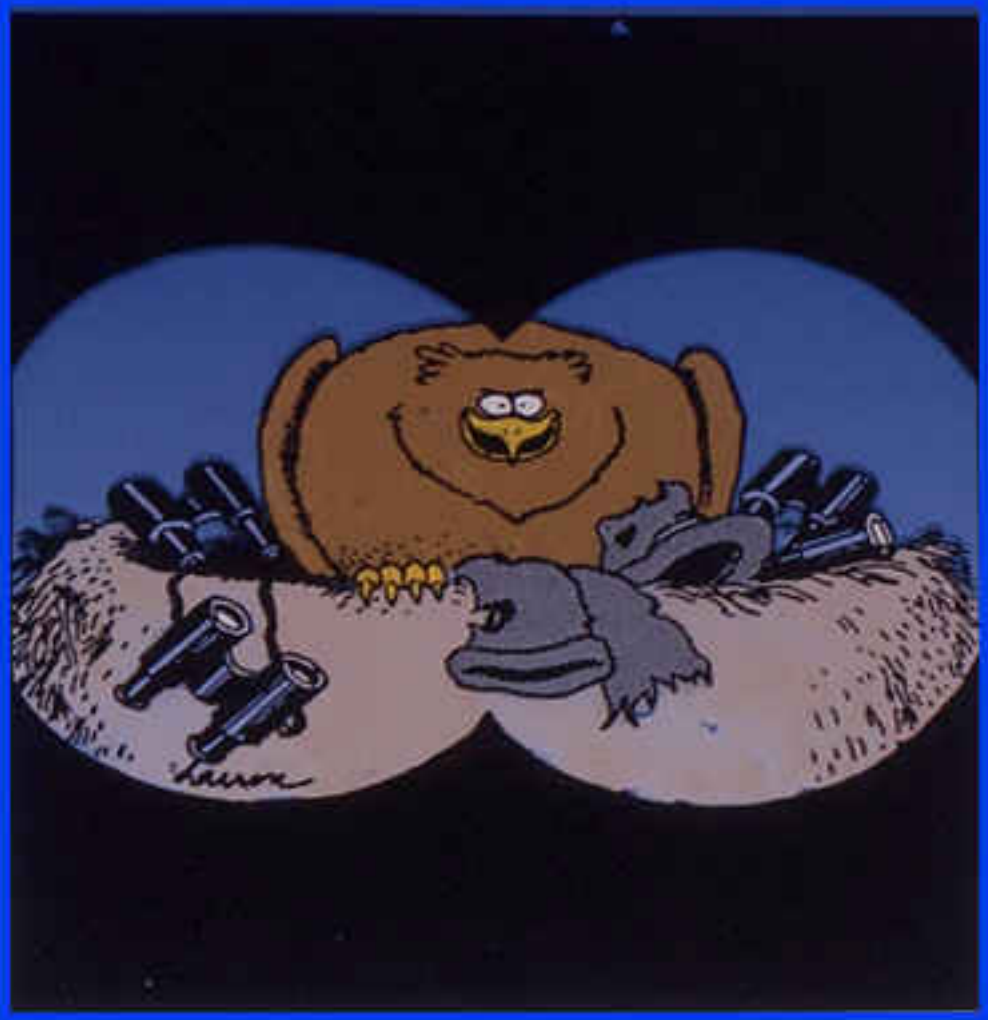
- all cause death
- myocardial infarction
- cerebrovascular events (CVA only)
- repeat revascularization (CABG or/and PCI)

You Can't Get it Back

"Reason for returning it?"

Patients with significant MVD CAD being treated for a mid (but large) LAD stenosis, which results in a long dissection extending almost to the apex

Maybe But Shouldn't



Significant left main coronary artery stenosis and undilatable dominant RCA disease. Preserved LV function

Title/drp–author: WT/BK – Holmes, D
Sub/drp–Job#: YW105/BK – CP1219570

Subject: LMCA Disease

Background: BU3

Banner/brdr: BU2/BU41

Side title: YW105

• /colhdgs: YW105

Text: WT/BK

Highlight: YO114

Subdue: BU31

Footnotes: BU41

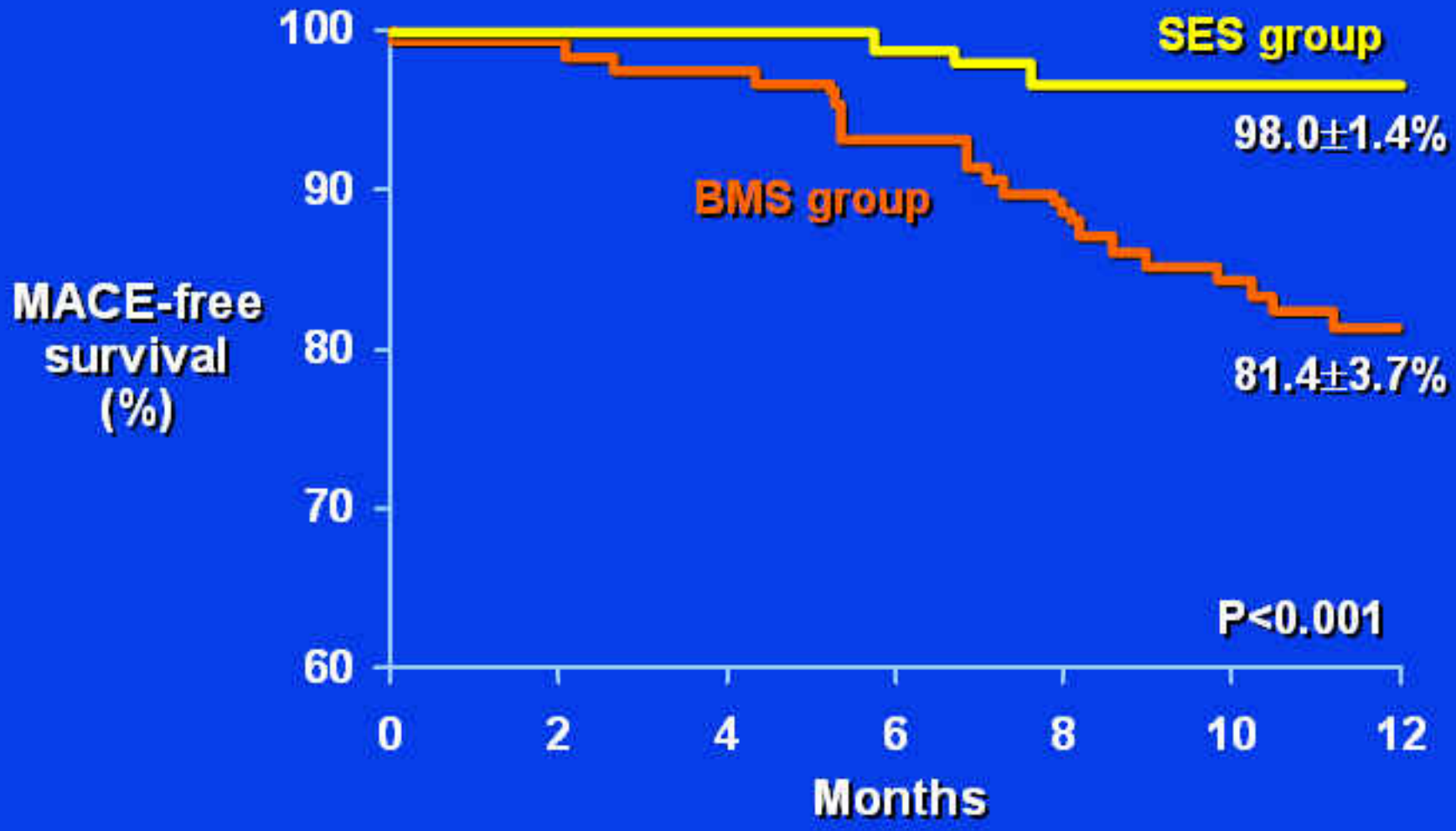
Plot/brdr: open/BU41
x, y only

PPT shooting instructions
PPT File to Server
(1 image)

COLOR REFERENCE ONLY

Match: Mayo2BU (CP1111378)

LMCA Disease



Ng MKC et al: Rev Cardiovasc Med 6:187, 2005

What Does the Soul Look Like and Where Does it Live?


MAYO CLINIC

Title/drp–author: WT/BK– Holmes, D

Sub/drp–Job#: YW8/BK–CP1221098

Subject: Various slides

Background: 6,61,232

Banner/brdr: BU4/BU41

Side title: YW105

• /colhdgs: YW105

Text: WT/BK

Highlight: YO114

Subdue: BU31

Footnotes: BU41

Plot/brdr: open/BU31
x, y only

PPT shooting instructions
1 PPT to server
(24 images)

COLOR REFERENCE ONLY

Match: CG-Mayo2bu (2002).pot

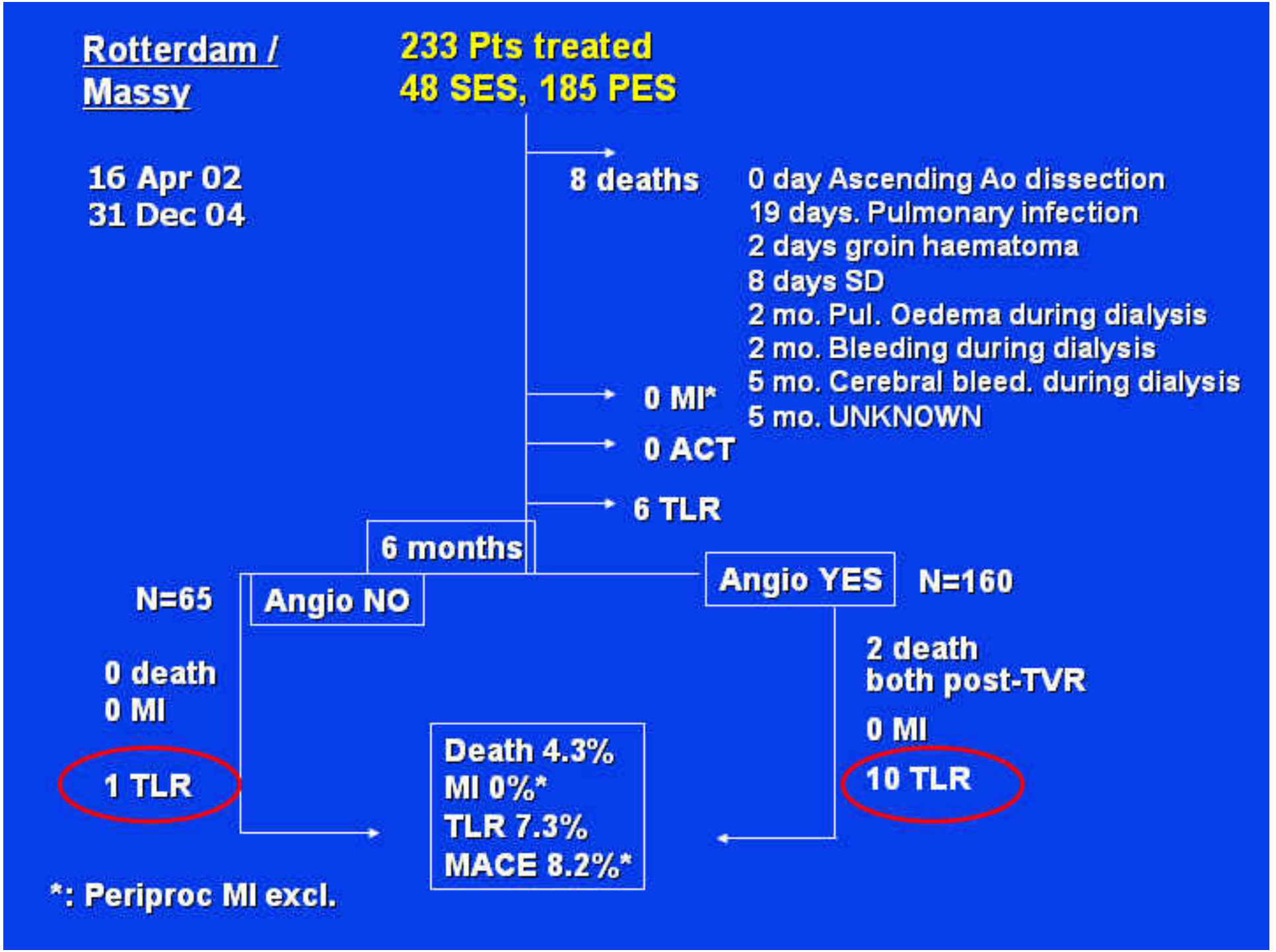
PCI vs CABG: Clinical Trials

- Unprotected left main disease
- Multivessel disease in diabetics

Left Main Disease (LMD)

- CABG is the "gold standard" for revascularization of lesions in the ULM coronary artery*†
- DES have shown encouraging short-term outcomes, but long-term follow-up is needed†
- The use of PCI for patients with significant ULM stenosis who care candidates for revascularization but not suitable for CABG can improve CV outcomes†

*Eagle et al: ACC/AHA 2004 Guideline Update for CABG
†Smith et al: ACC/AHA/SCAI 2005 Guideline Update for PCI

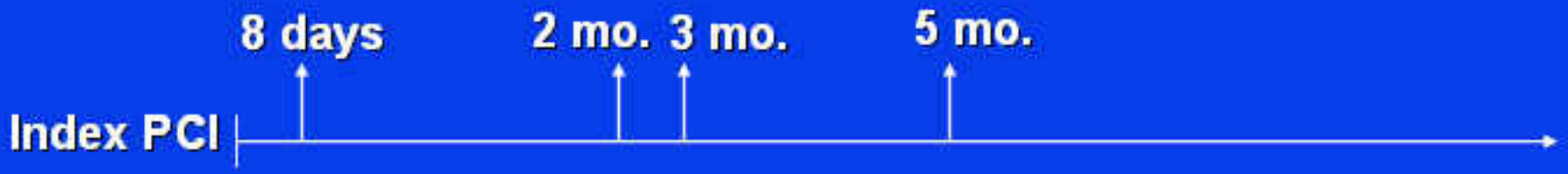

Rotterdam / Massy
233 Pts treated
48 SES, 185 PES
16 Apr 02
31 Dec 04
8 deaths
0 day Ascending Ao dissection
19 days. Pulmonary infection
2 days groin haematoma
8 days SD
2 mo. Pul. Oedema during dialysis
2 mo. Bleeding during dialysis
5 mo. Cerebral bleed. during dialysis
5 mo. UNKNOWN
0 MI*
0 ACT
6 TLR
6 months
N=65
Angio NO
Angio YES
N=160
0 death
0 MI
1 TLR
2 death
both post-TVR
0 MI
10 TLR
Death 4.3%
MI 0%*
TLR 7.3%
MACE 8.2%*
*: Periproc MI excl.

Le Mans sub study: Sudden death rate

- 4 episodes of confirmed or possible SD out of 340 pts treated.

1.2%

No confirmed or suspected episodes in the group not receiving angio-follow-up



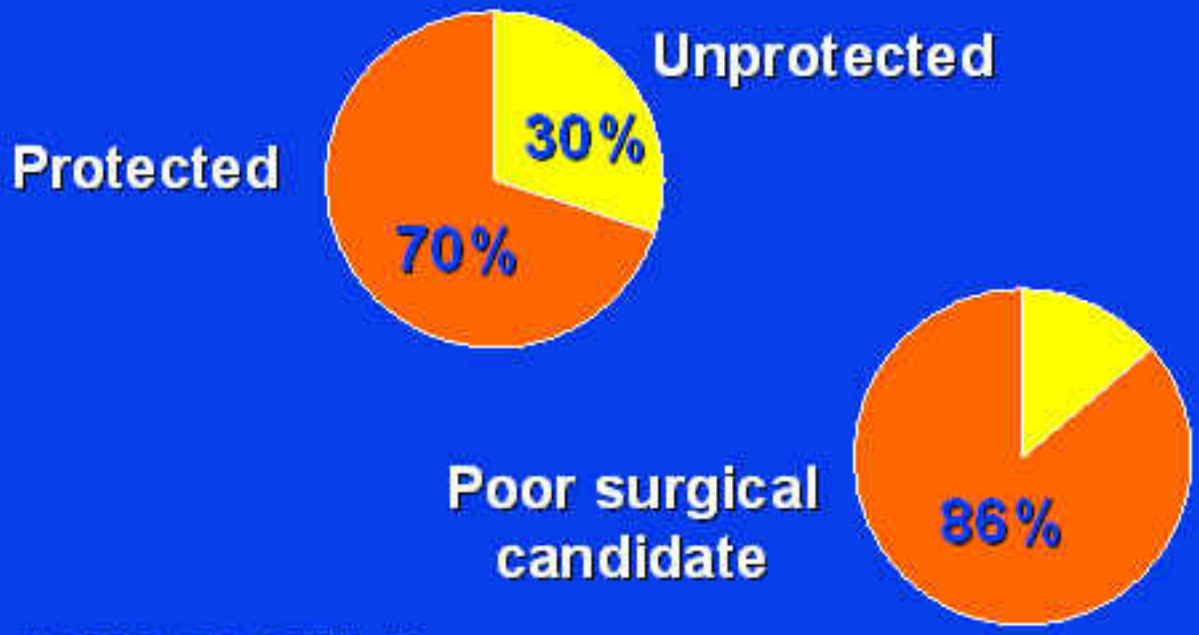
Le Mans sub study: Cumulative MACE rate

- Death rate: 3.8% (13/340)
- MI rate: 0.3% (1/340)*
- TLR rate: 10% (34/340)
- MACE rate 13.5% (46/340)

*: Periproc MI excl.

One Year Outcome LMCA PCI

- Multi center observational study
- 142 consecutive patients - PCI of LMCA
- All cause mortality, MI, TLR, and MACE assessed at 1 year



Kelley, Eur Heart J 2003; 24:1554-59

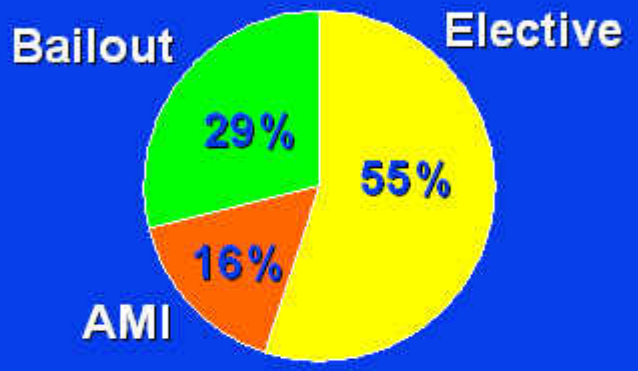
One Year Outcomes

	Entire cohort (n=137)	Protected LMCA (n=94)	Unprotected LMCA (n=43)	P
Death	17 (12%)	5 (5%)	12 (28%)	<0.0001
MI	6 (4%)	3 (3%)	3 (7%)	0.4
TLR	27 (20%)	17 (18%)	10 (23%)	0.5
MACE	44 (32%)	23 (25%)	21 (49%)	0.005

Kelley, Eur Heart J 2003; 24:1554-59

SES for LMCA Disease

N = 31



- 3.0 mm SES
- ASA + Plavix - 6 months
- 2.8-4.5 stents/patient
- Bifurcation 50%

Arampatzis, Am J Cardiol 2003; 92:327-329

SES for LMCA Disease

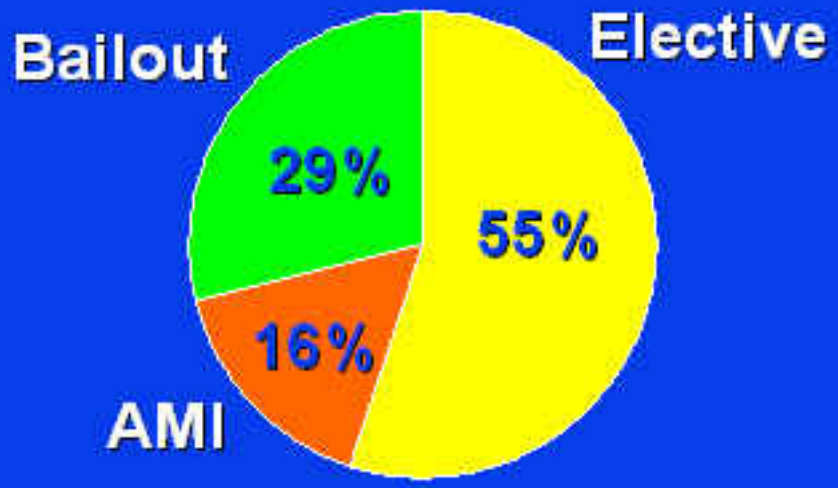
N = 31

	AMI 5	Bailout 9	Elective 17
In-hospital			
D	3 (60%)	0	1 (6%)
MI	--	0	2 (12%)
CABG	0	1 (11%)	0
Follow-up (5.1±1.8)	2 pts.	9 pts.	16 pts.
D	0	0	0
MI	0	0	0
CABG	0	1 (11%)	0

Arampatzis, Am J Cardiol 2003; 92:327-329

SES for LMCA Disease

N = 31



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SES for LMCA Disease

N = 31

	AMI 5	Bailout 9	Elective 17
In-hospital			
D	3 (60%)	0	1 (6%)
MI	--	0	2 (12%)
CABG	0	1 (11%)	0
Follow-up (5.1±1.8)	2 pts.	9 pts.	16 pts.
D	0	0	0
MI	0	0	0
CABG	0	1 (11%)	0

Arampatzis, Am J Cardiol 2003; 92:327-329

Outcomes of TAXUS Stenting in High Risk Lesions/patients (Real World)

	WISDOM	MILES TONE II	ARRIVE I	T-SEARCH	TRUE	Colombo ULM (DES)	Mann et al DES
Left Main (n=pts)	7	98	72	88	65	85	61
Major Cardiac Events 6M	0.0% (0/7)	5.2% (5/96)	12.5% (9/72)	9.1% (8/88)	13.8% (9/65)	20%	16% @ 9 mos
TVR	0.0% (0/7)	NA	3.8% (3/79)	NA	NA	18.8%	9.8%
Death	0.0% (0/7)	NA	11.1% (8/72)	NA	NA	3.5%	1.6%
MI	0.0% (0/7)	NA	2.8% (2/72)	NA	NA	0%	4.9%

ULM stenting with DES

Authors	FU (mth)	N @ FU	Death	MI	TLR
Colombo	6	39	5%	2.5%	23%
RESEARCH	5	16	0%	0%	0%
T-SEARCH	6	29	3%	3%	10%
Zanuttini	6	34	0%	0%	5.9%
Park	6	45	0%	0%	5%
Lefevre	6	21	4.5%	_	0%
De Lezo	12±4	50	0	4%	2%
		245	0 - 5%	0 - 4%	0-23%

*AHA 2004: abstracts not reported

Conclusions

- EPC titer directly correlates with angiographic and IVUS outcome and identifies patients likely to respond to EPC capture stenting.
- HEALING II suggested that patients with a normal EPC count responded favorably to EPC capture stenting (late loss index 0.19; late luminal loss 0.48 mm)
- TLR/TVR events were restricted to the low EPC group.
- Patients without statin therapy at the time of implant were generally restricted to the low EPC group.
- Low EPC count was associated with a significant late luminal loss, high TVR/TLR incidence and a lack of statin therapy.
- Since statin therapy has been shown to augment EPC number (and function), it may enhance the outcome of EPC capture stenting (Vasa *et al.* Circ 2001, Landmesser *et al.* Circ 2005).

The practice of medicine is a thinker's art.

The practice of surgery is a plumber's.

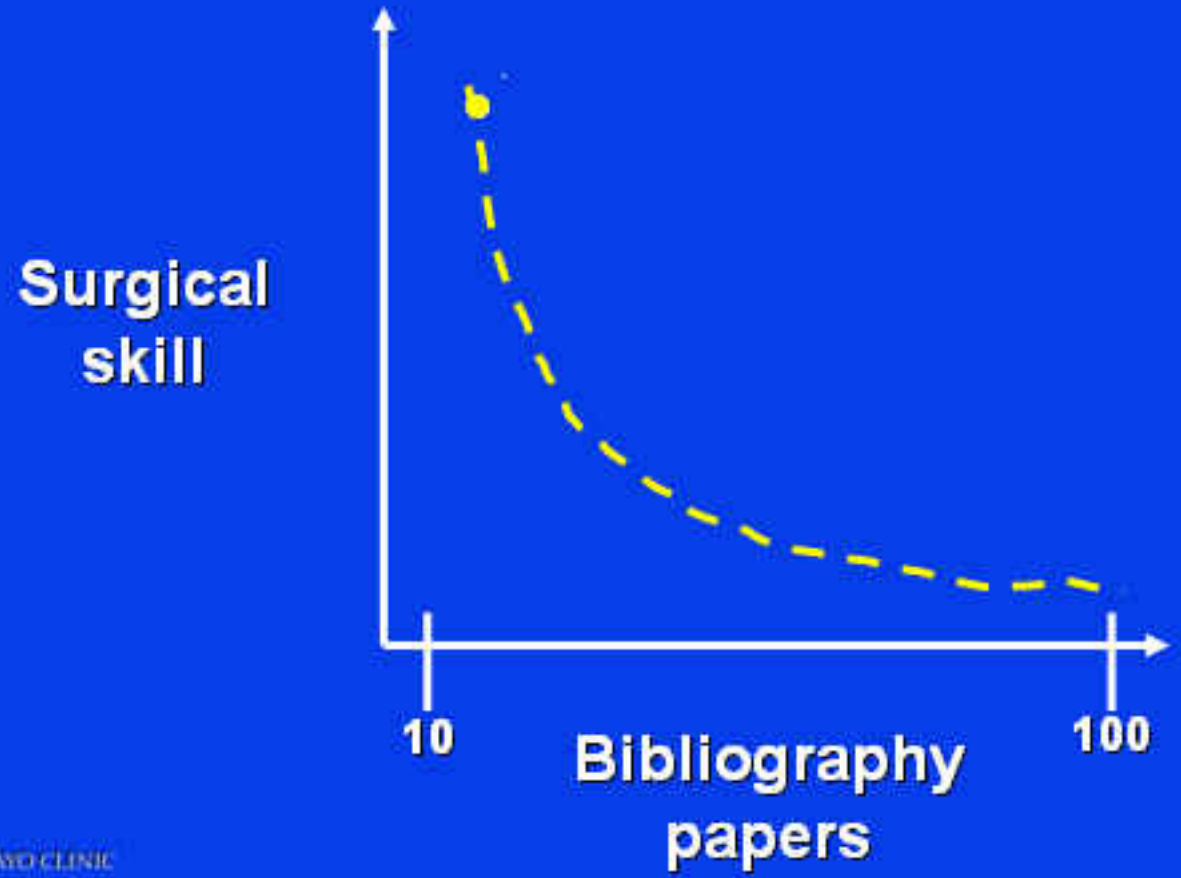
Martin Fischer

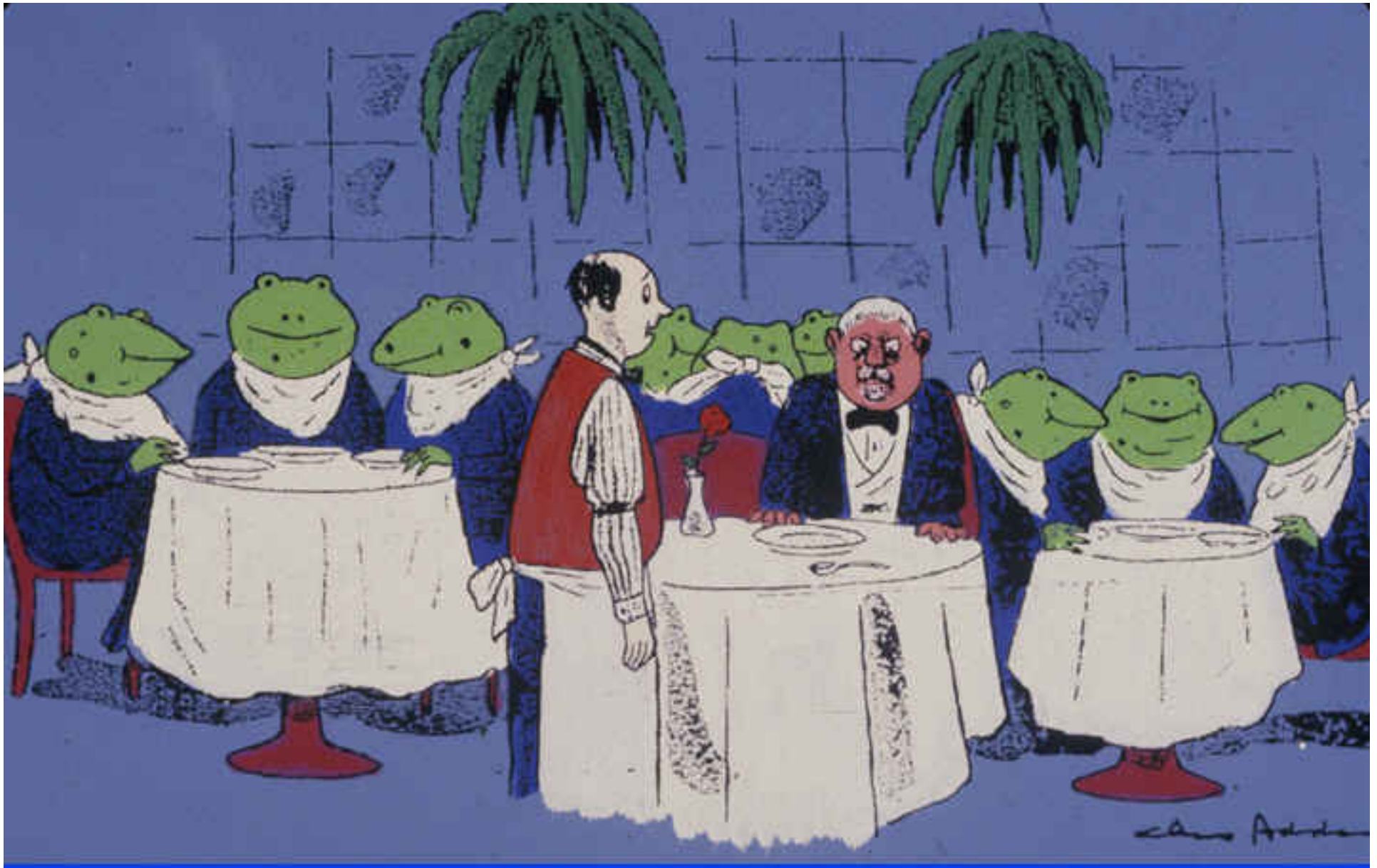
Most medical students are attracted to surgery, yet few of these admiring students become surgeons. The very best minds in the class seldom lean to surgery. This is a sad admission but true.

J. Chalmers Da Costa
1863-1933

Surgical Aphorism

Academic productivity $\propto \frac{1}{\text{surgical skill}}$





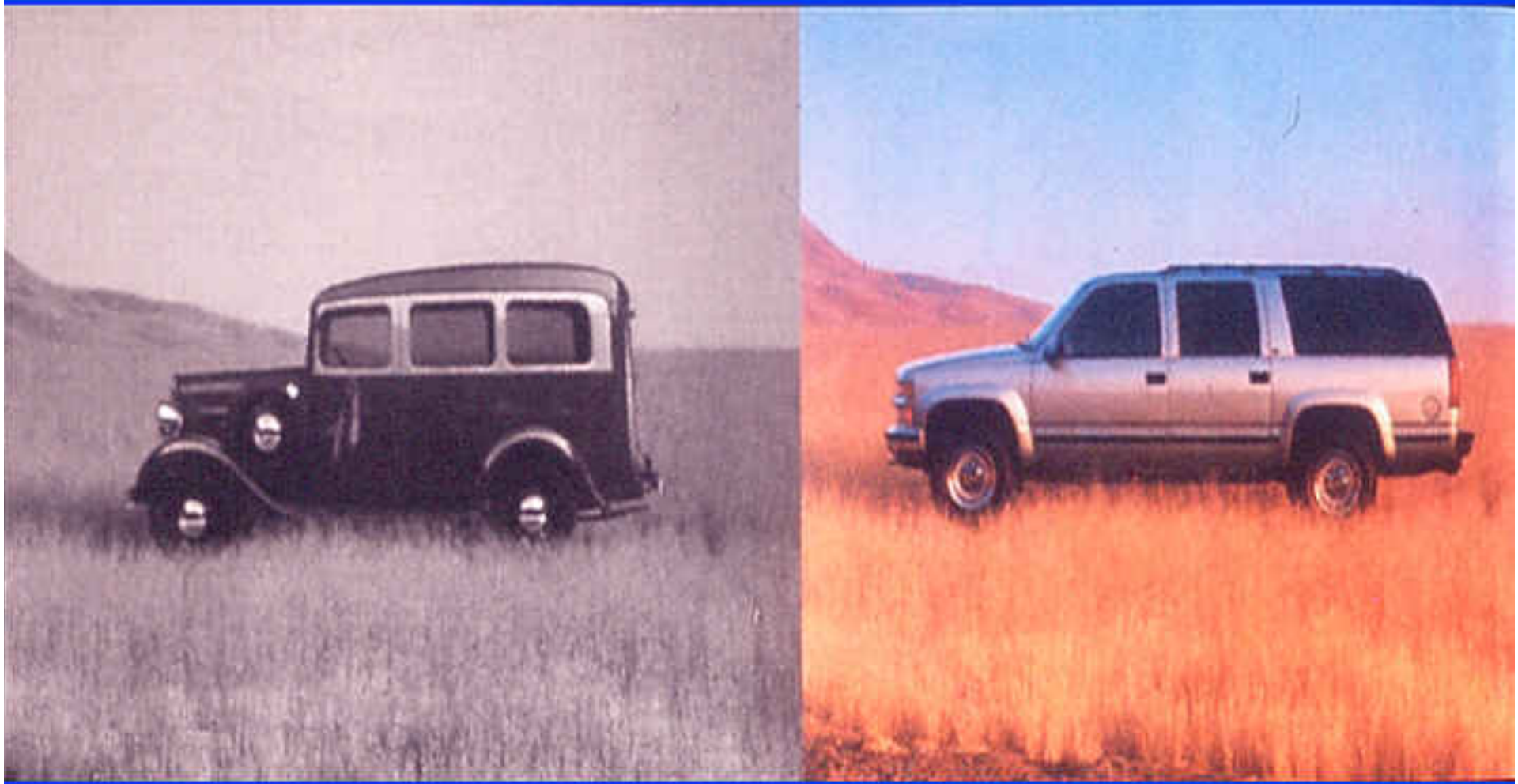
"Nobody else has complained about flies in the soup."

MAYO CLINIC

Interventional Cardiology

Goals of Therapy

- Improve symptoms/signs of ischemic coronary artery disease by percutaneous coronary intervention
- Reduce morbidity and mortality
- Avoid the need for surgery



MAYO CLINIC

Major 'Milestones'

Cardiac Surgery

1932 - Injection of carbon particles into cor artery
Hudson, Moritz, Wearn

1935 - Omental implantation on myocardium
Beck

1936 - Cardio-omentopexy with aleuronate paste
O'Shaughnessy

Talc in pericardium, pericardial poudrage, mammary artery ligation.

Minimally invasive cardiac surgery

Euphemism

- From Greek euphemisms - sounding good
- The substitution of an inoffensive expression for one that may suggest something unpleasant

Interventional Cardiology

'A small bruise'

'You'll have to lie flat for a little while'

'You might be a little sick to your stomach'

'There may be some renarrowing'

You Are Never Quite The Same

The hidden risk of CABG

Meta analysis of 12 cohort and 11 intervention studies of CABG.
Pooled analysis of comparable studies - - 22.5% (18.7% - 26.4%) have a measurable cognitive deficit in ≥ 2/9 tests at 2 months post surgery

Van Dyk
J Th CV Surg 120:632-9, 2000

Neuropsychological Dysfunction

MIDCAB

	MIDCAB	SVCABG	MVCABG	Control
Test interval (D)	7.6	7.6	7.9	----
Peg L	9.6	11.4	11.2	12.3*
Peg R	8.7	8.3	9.2	10.1*
TMT	108.9	131.2	119.2	85.4*
Dig Symb	39.0	32.4	36.3	43.0*

P<0.05

Andrew, Ann Thorac Surgery
1998;66:1611-7

Neuropsychological Dysfunction

Elimination of cardiopulmonary bypass does not prevent neuropsychological dysfunction as patients undergoing MIDCAB and single graft procedures experience similar deterioration.

Andrew, Ann Thorac Surgery 1998;66:1611-7

?

FACT

One's technical accomplishment relates directly to one's professional accomplishment as evidenced, for example, by one's publication history.

Surgeon's Definition of Stent

- A small hollow piece of metal that when successfully deployed makes the surgeon unhappy except:

  a) during AMI at 3:00 a.m.

  b) when patient weighs more than 150 kg

  c) when creatinine is > 5mgm

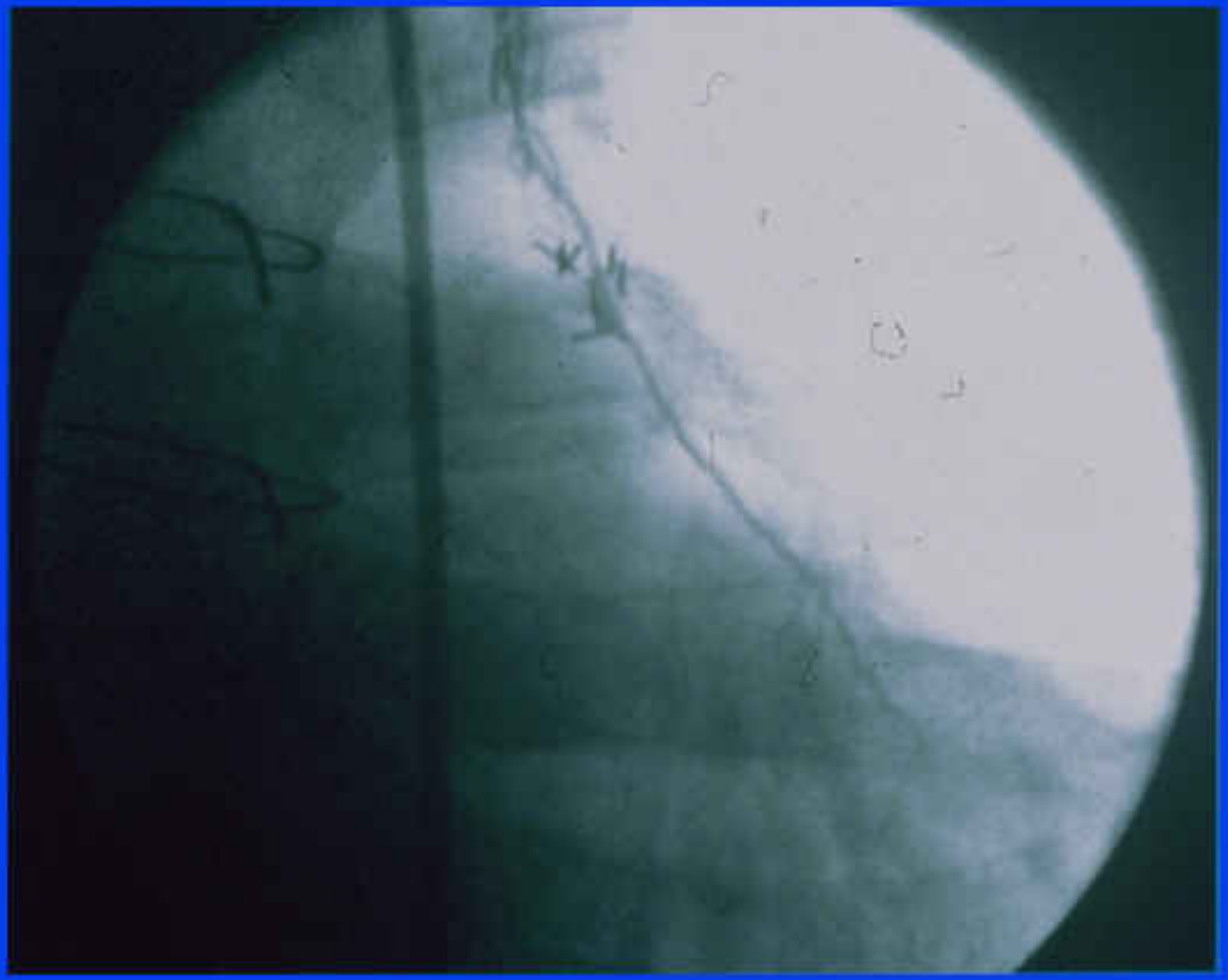
  d) when the patient is the surgeon

Potential End Points

Comparing Revascularization Strategies

- Death
- Myocardial infarction
- Stroke or other CNS event
- Return to work
- Need for repeated procedures
- Quality of life
- Functional class
- Functional/stress testing
- Economic cost
- Repeated hospitalization
- Need for crossover procedures

Goy



IF AN EAR
THERMOMETER
SOUNDS PECULIAR,
IMAGINE THE
REACTION TO THE
FIRST RECTAL
THERMOMETER.

Percutaneous Coronary Intervention

Goals

Acute	Long-term
• Safe effective relief of ischemia	• Safe effective relief of ischemia • Prevent development of m/m

Bypass the Bypass

A good surgeon is a medical man who can cut.

An interventional cardiologist is a surgeon who can think.

Martin Fischer 1879-62
Modified by DRH

The feasibility of a procedure is not the best indication for its performance

Heart Surgery Unplugged

- Patients on the heart-lung machine have a 2-4% risk of stroke, a 25% risk of transitory retinal damage and 30-35% experience the pump head syndrome
- Memory loss, inability to concentrate, inability to perform basic calculations, difficulties in recognizing patterns, this usually goes away

Heart Surgery Unplugged

'I went straight to Stop and Shop and bought myself a bunch of soup ladles… After a few hours, I had something I thought might work. After several attempts it worked well enough to be tried on a human being. It was gorgeous.'

Cohn Cardiac Stabilizer

Heart Surgery Unplugged

'A two-pronged salad fork that rides with the heart muscle like a cowboy on a bronco.'

'Hot damn this is great'

Critical Balanced View of Surgery

Advantages

- Decreased need for subsequent procedures for at least a while
- Complete revascularization for awhile

Disadvantages

- Major surgery
- Draining leg incisions
- 40% incidence of cognitive impairment
- Sternal infection
- Single ticket plan
- Long recovery

Critical Balanced View of PCI

Advantages

- Short recovery
- CNS problems very rare
- Can be repeated

Disadvantages

- May need to be repeated
- Incomplete revascularization

To a man with a hammer, everything looks like a nail to be pounded

To a man with a blade, everything looks like something to be cut