Evidence-Based Medicine: Good Medicine…? Good Value…?

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The Net Clinical Benefit of PCI in Patients with Stable CAD

- Are patients, physicians and payers getting optimal "bang for buck" for their health care dollar expenditure in stable CAD patients undergoing elective PCI?

- Is it important to define the "net clinical benefit" for any drug, device, intervention or surgery as the ultimate litmus test in defining a value-based system of health care delivery that is predicated on an evidence-based model of risks, benefits, outcomes, and costs?

The Role of PCI in Stable CAD

The Past, the Present and the Future:

- How did we get to where we are today?
- COURAGE—a Pivot Point for Change…
- Can/Should We Change the Future?

The Role of PCI in Stable CAD

The Past, the Present and the Future:

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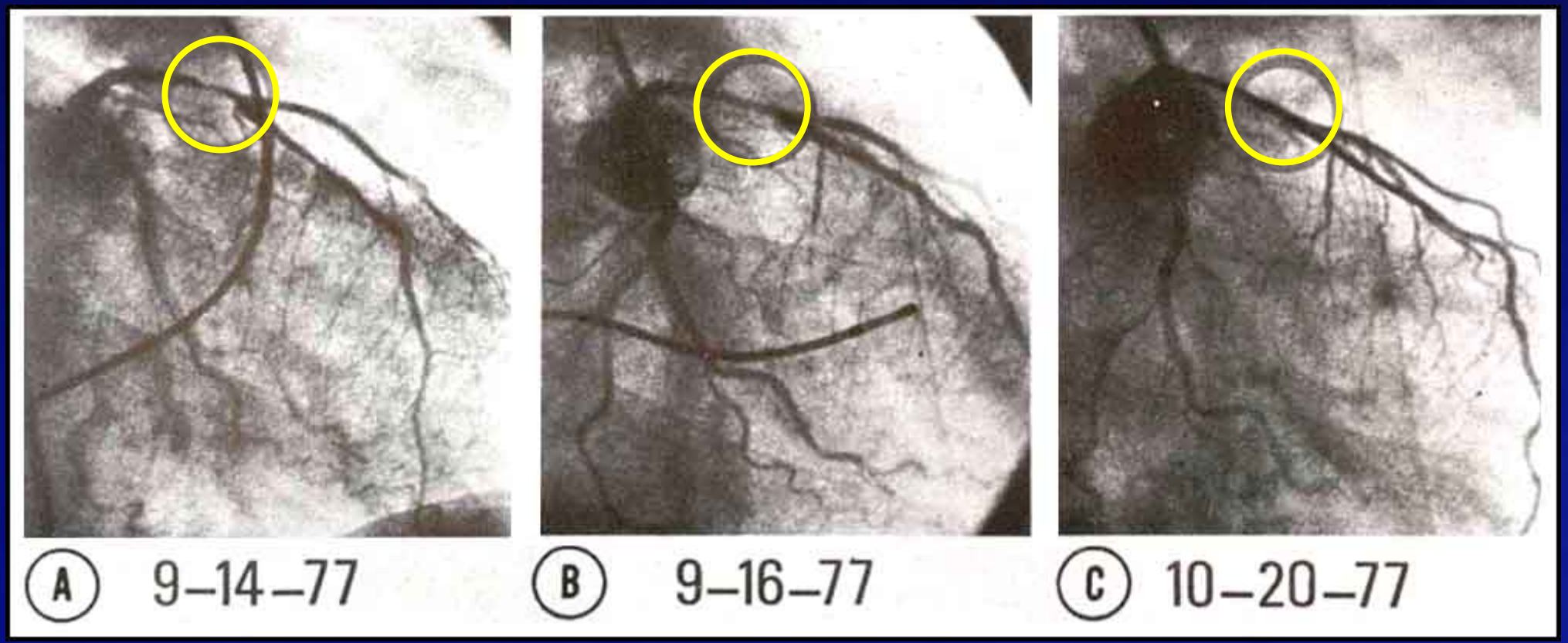
The 1st Coronary Angioplasty 30 Years Ago…



First coronary angioplasty lesion (circles) two days before (A), immediately after (B), and one month after (C) balloon dilation

Where The Clinical Role of PCI is Clearly Established…

In Patients with ACS:

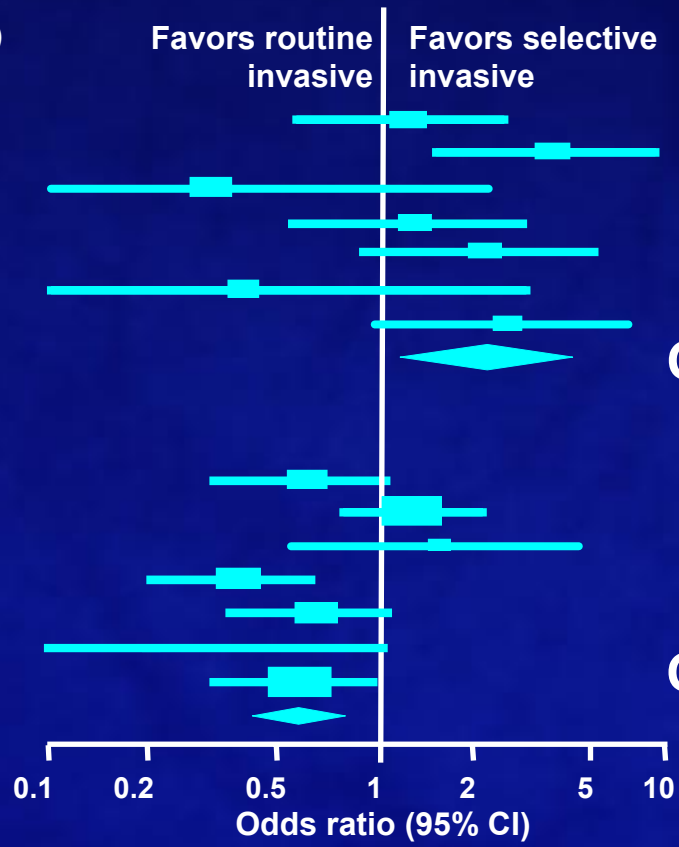
- For STEMI, primary PCI reduces mortality, MI and improves LV function compared to fibrinolytic therapy, although the optimal benefits associated with PCI are achieved in only ~ 35% of patients

- For NSTE ACS, PCI reduces late events in high-risk patients compared to a “conservative strategy”, but at the expense of an early excess of death and MI with no difference in overall late mortality

Routine Early Invasive Rx in ACS: Early vs. Late Mortality

7 trials, N = 9212

	Inv (%)	Cons (%)
Mortality during hospitalization		
TIMI 3B	2.2	1.9
VANQWISH	4.5	1.3
MATE	0.9	3.3
FRISC II	1.1	0.9
TACTICS	1.4	0.7
VINO	1.6	4.5
RITA 3	1.6	0.7
Subtotal	1.8	1.1
Mortality after discharge		
TIMI 3B	2.8	3.3
VANQWISH	13.4	11.7
MATE	10.0	6.9
FRISC II	1.2	3.0
TACTICS	1.9	2.8
VINO	1.6	9.4
RITA 3	5.2	7.3
Subtotal	3.8	4.9

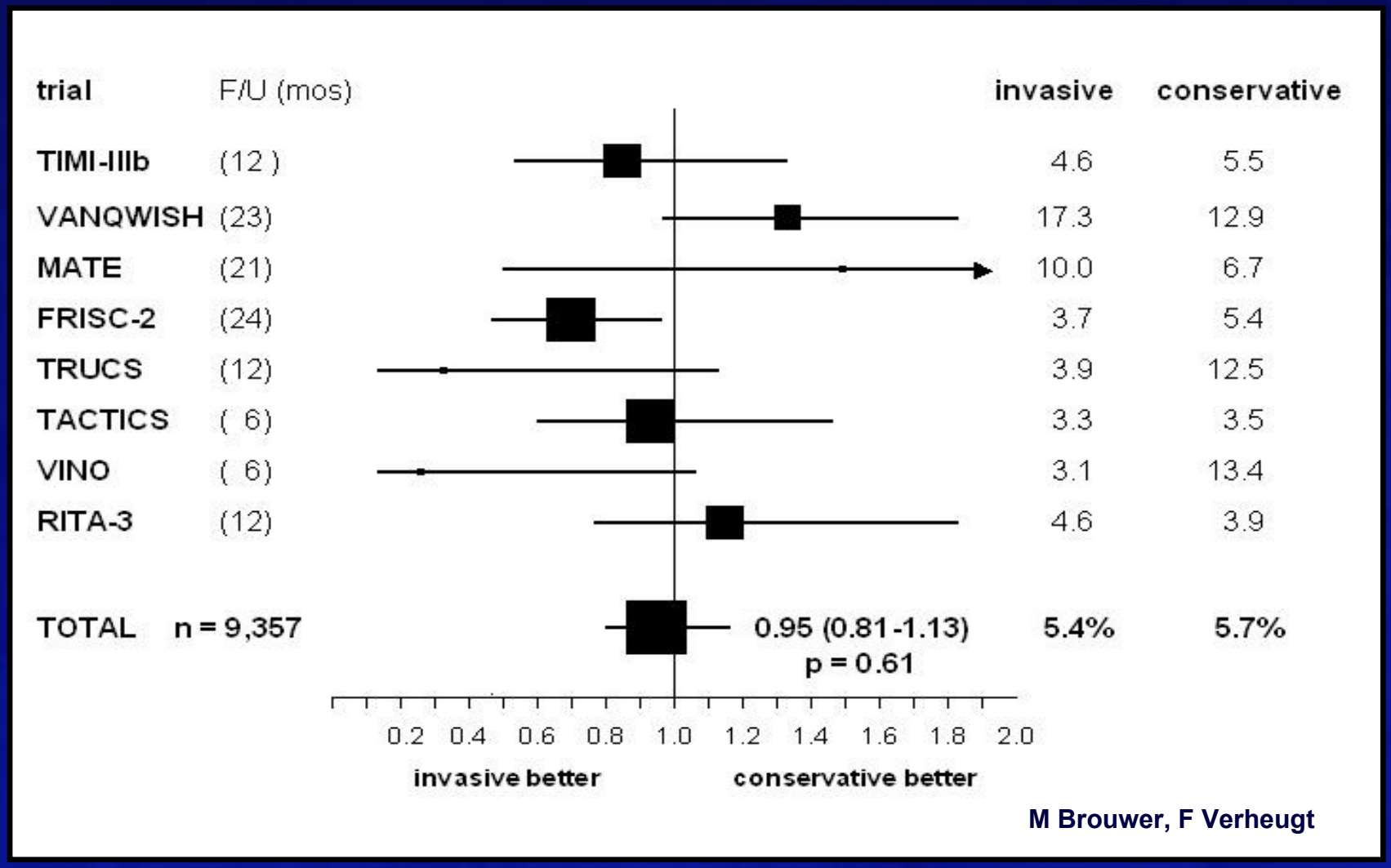


OR 1.60, P = 0.007

OR 0.76, P = 0.01

Mehta SR et al. *JAMA.* 2005;293:2908-17.

Mortality in NSTE ACS Strategy Trials



M Brouwer, F Verheugt

Where The Clinical Role of PCI Remains Uncertain…

In Patients with Chronic Angina and Stable CAD:

- While PCI improves angina and short-term exercise capacity, does it—when compared to optimal medical therapy:

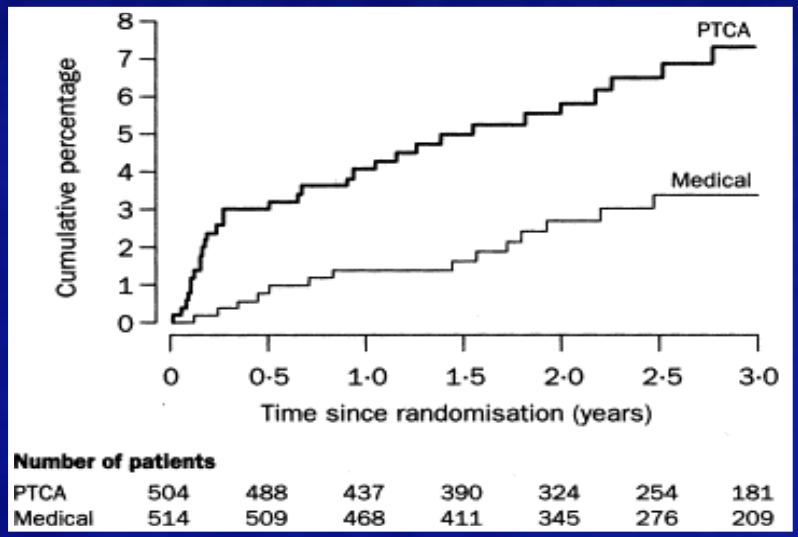
1. Prolong survival?
2. Reduce the risk of subsequent MI?
3. Reduce hospitalization for unstable angina?
4. Decrease the need for subsequent CABG surgery?
5. Improve quality of life?

Randomized Intervention Treatment of Angina (RITA-2)

1018 stable CAD patients from UK and Ireland
-504 randomized to PTCA
-514 randomized to medical treatment
47% Asymptomatic, Followup: 2.7 years

	PTCA	Medical Rx
Death	11	7
Definite MI	21	10
Total	32 (6.3%)	17 (3.3%)

*Relative Risk **1.92** **(p=0.02)***

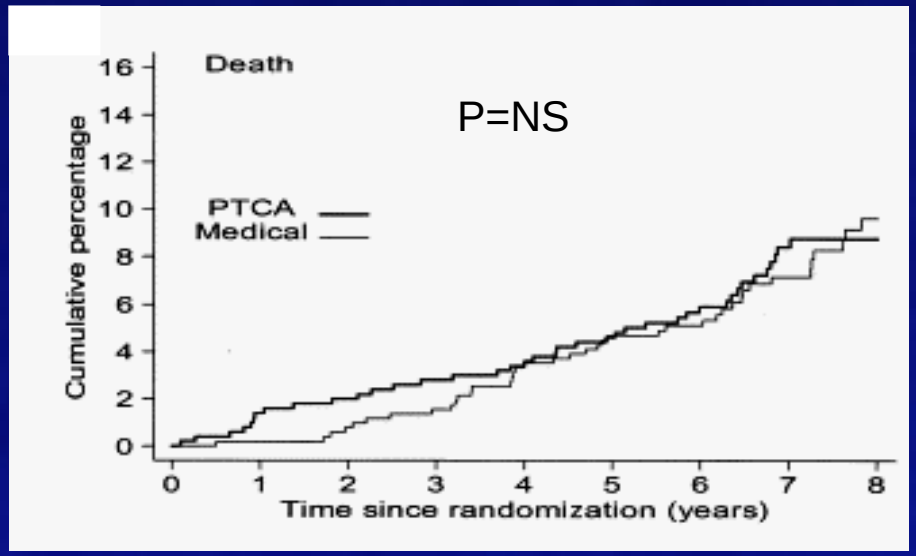


(RITA-2. Lancet 1997; 350: 461)

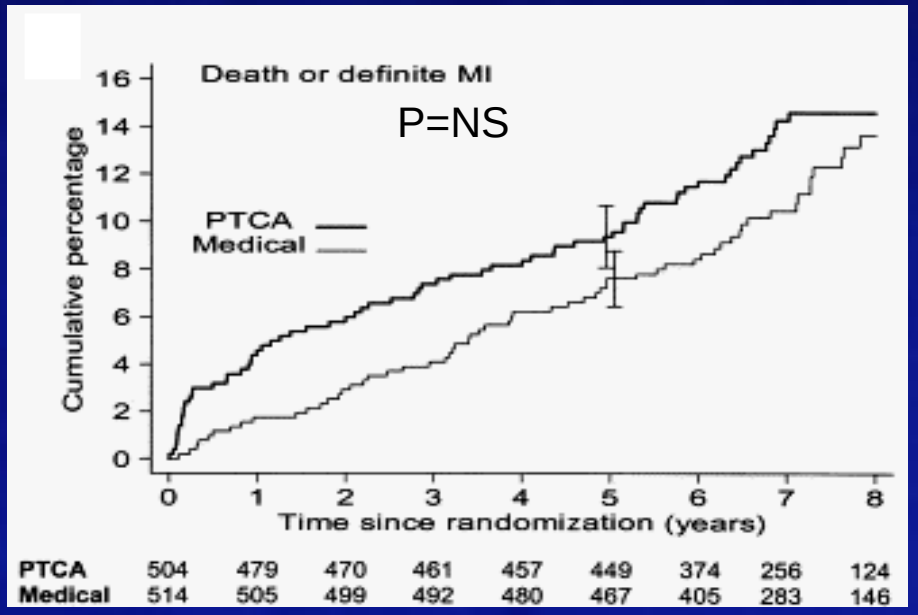
Long-Term Outcome: PCI vs Medical Management in RITA-2

RITA-2, 1018 patients (504 PTCA, 514 medical management)

Death



Death or MI

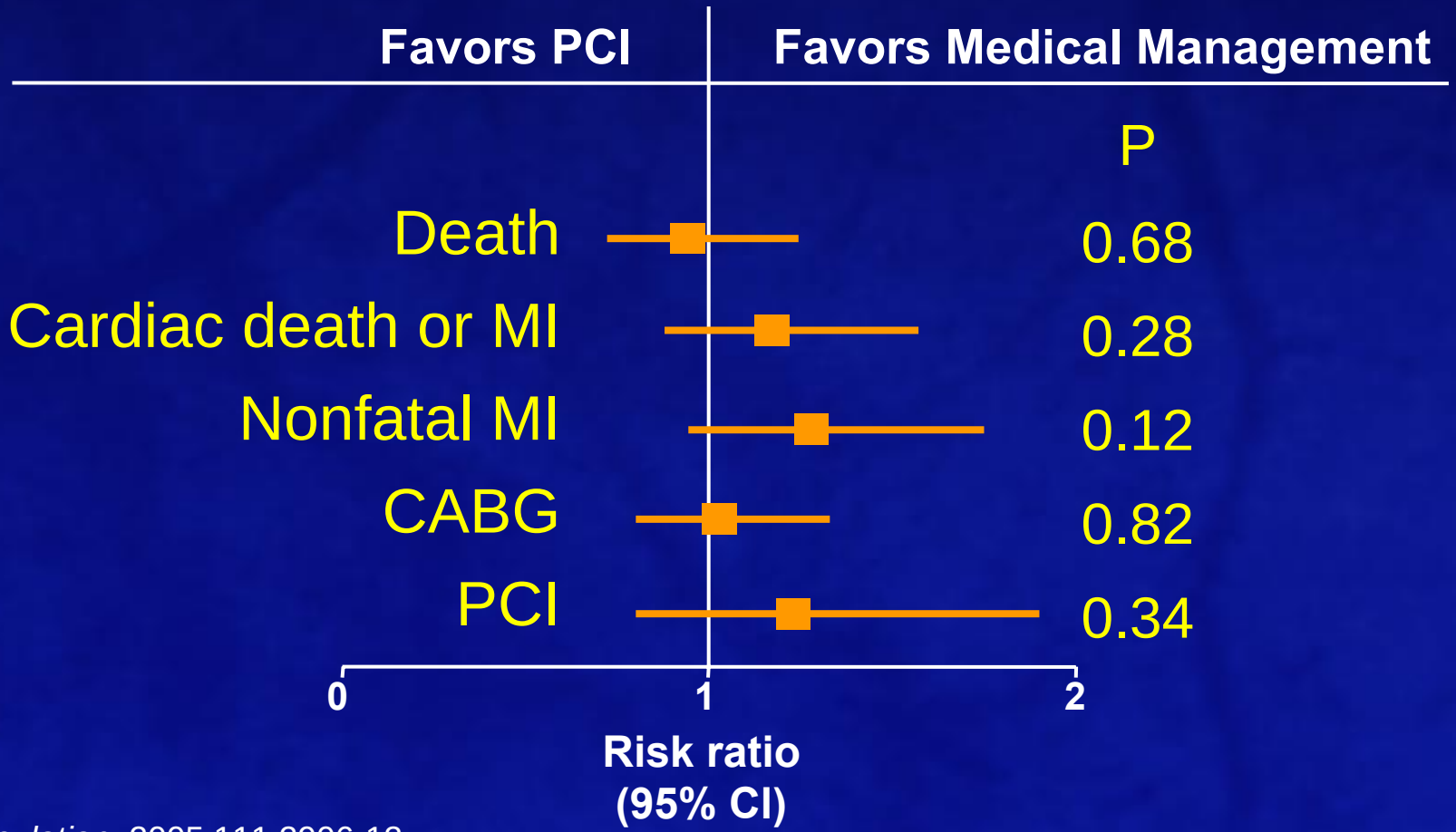


No difference in outcome over median of 7 years of follow-up

(Henderson, et al. JACC 2003;42:1161)

Stable CAD: PCI vs Conservative Medical Management

Meta-analysis of 11 randomized trials; N = 2950



Katritsis DG et al. *Circulation.* 2005;111:2906-12.

Objectives for Angina Treatment

- Prevent myocardial infarction (MI) and death
- Reduce ischemia and relieve angina symptoms
- Improve quality of life

Gibbons RJ, et al. *J Am Coll Cardiol.* 2002;33:2092-2197.

Pharmacotherapy for Stable Angina

- Proven therapies to prevent MI and death
  - Aspirin
  - Lipid-lowering therapy
  - ACE inhibitor

- To reduce ischemia and relieve symptoms
  - Beta-blockers
  - Calcium channel blockers
  - Nitrates
  - ? Ranolazine

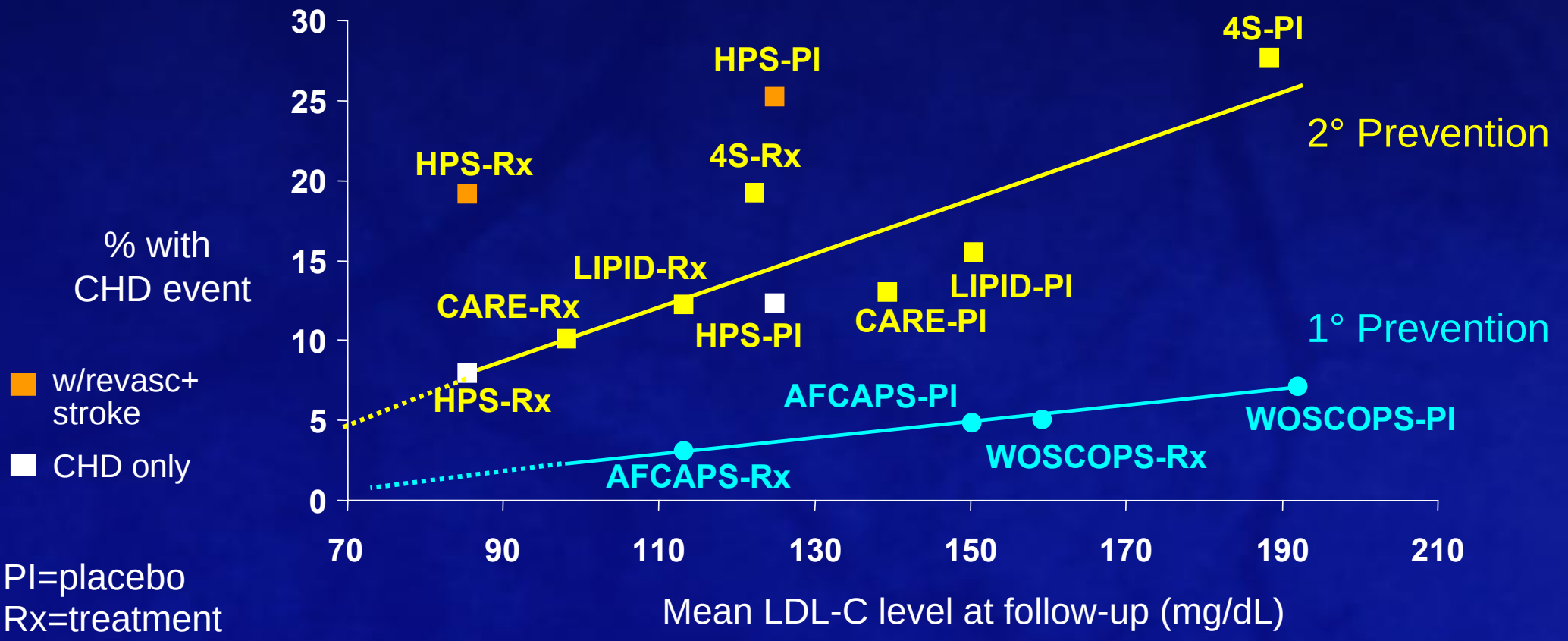
Adapted from Gibbons RJ, et al. *J Am Coll Cardiol.* 2002;33:2092-2197.

ABC's of Angina Management

- A = Aspirin and Antianginals
- B = Beta-blocker and BP control
- C = Cholesterol and Cigarettes (not!)
- D = Diet and Diabetes
- E = Exercise and Education

Gibbons RJ, et al. *J Am Coll Cardiol.* 1999;33:2092-2197.

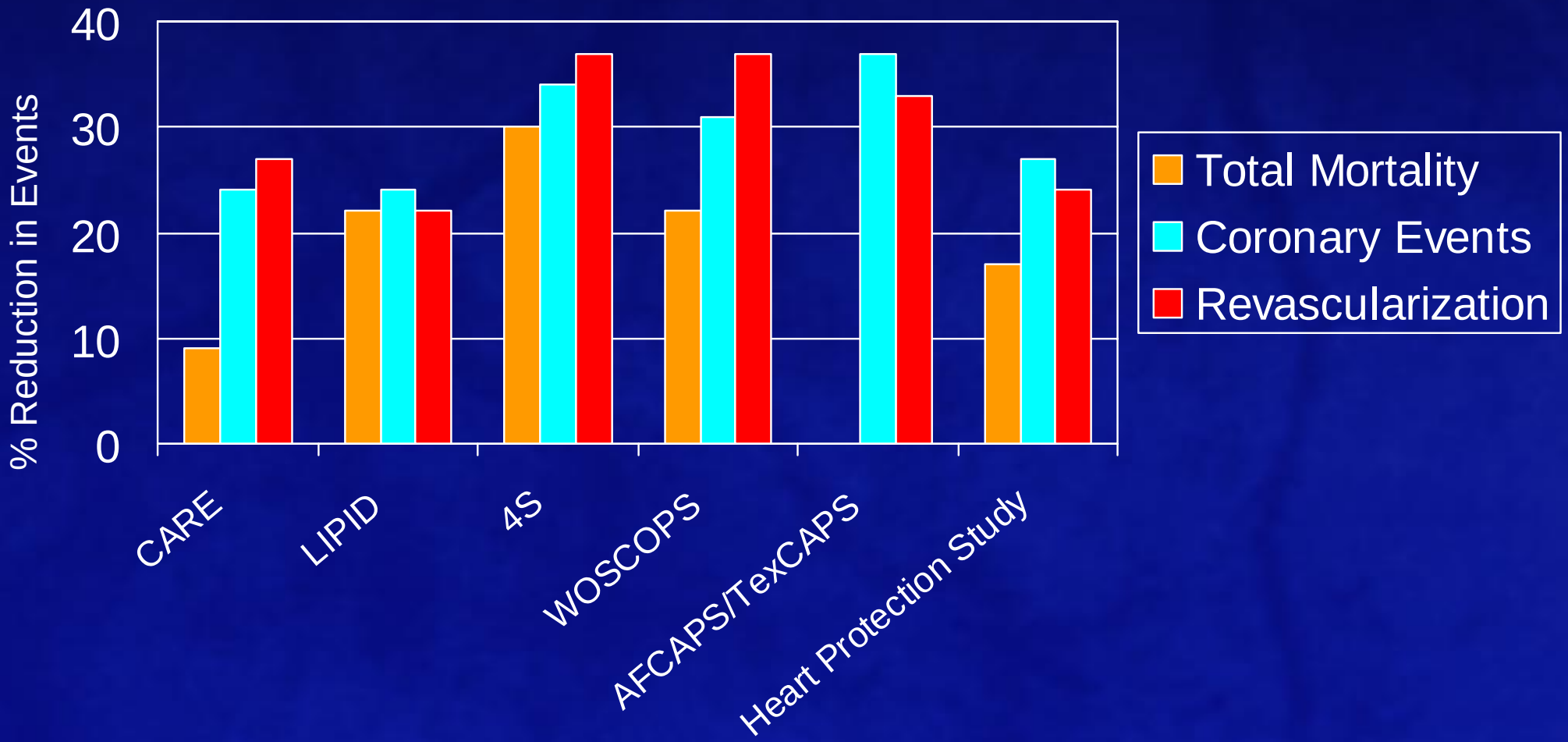
Systemic Stabilization of Plaque: Relation Between CHD Events and LDL Outcomes in Statin Trials



(HPS. *Lancet.* 2002;360:7. Downs. *JAMA*. 1998;279:1615; LIPID. *NEJM* 1998;339:1349. Sacks. *NEJM* 1996;335:1001. 4S. *Lancet.* 1995;345:1274. Shepherd. *NEJM* 1995;333:1301)

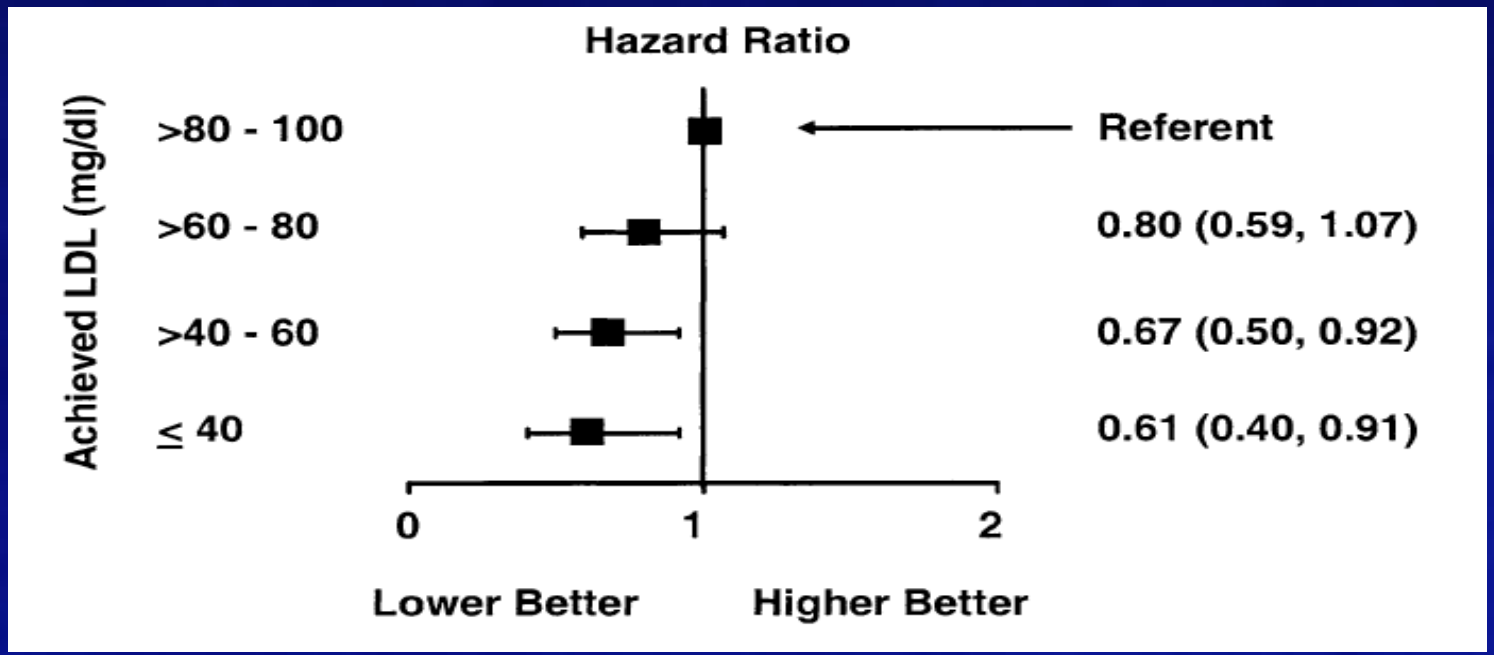
Clinical Outcome Studies Using Statins

Primary and Secondary Prevention



Systemic Stabilization of Plaque: Optimal Magnitude of LDL Lowering

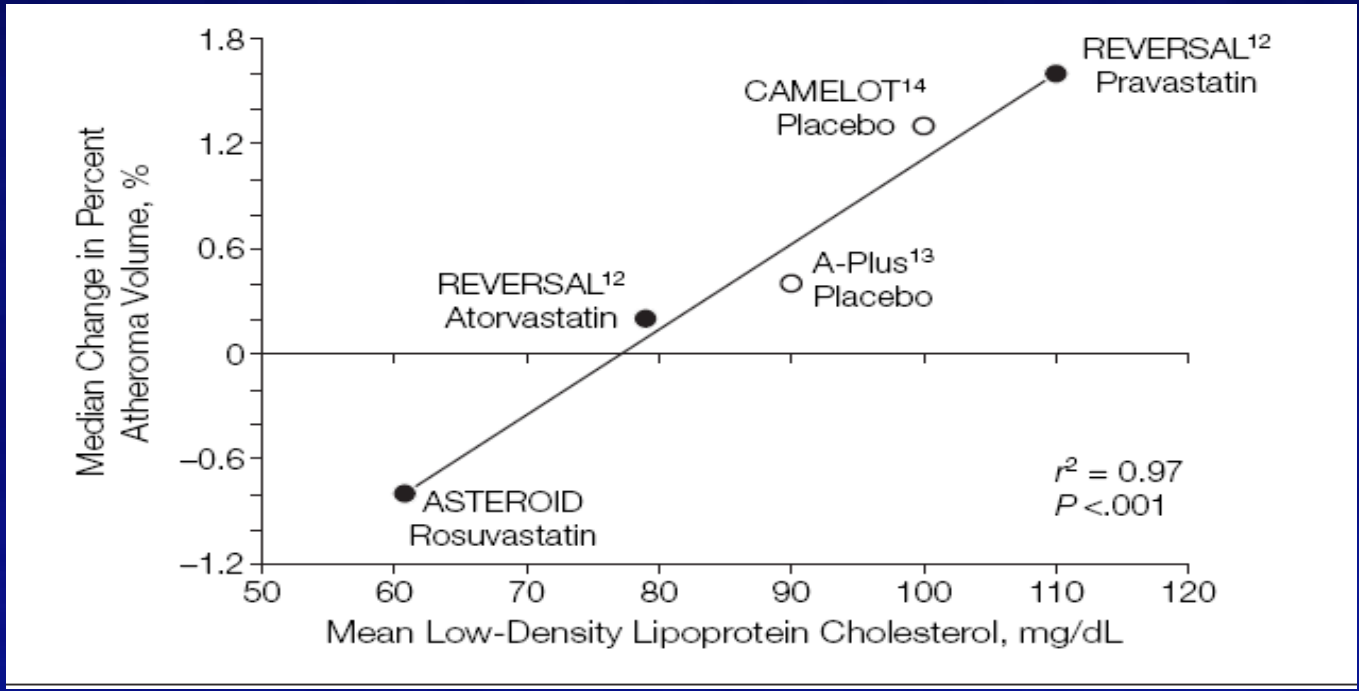
Death, MI, Stroke, Revascularization, UA requiring hospital admission



No increased incidence of side effects or complications with low LDL

(Wiviott, et al. JACC 2005;46:1411)

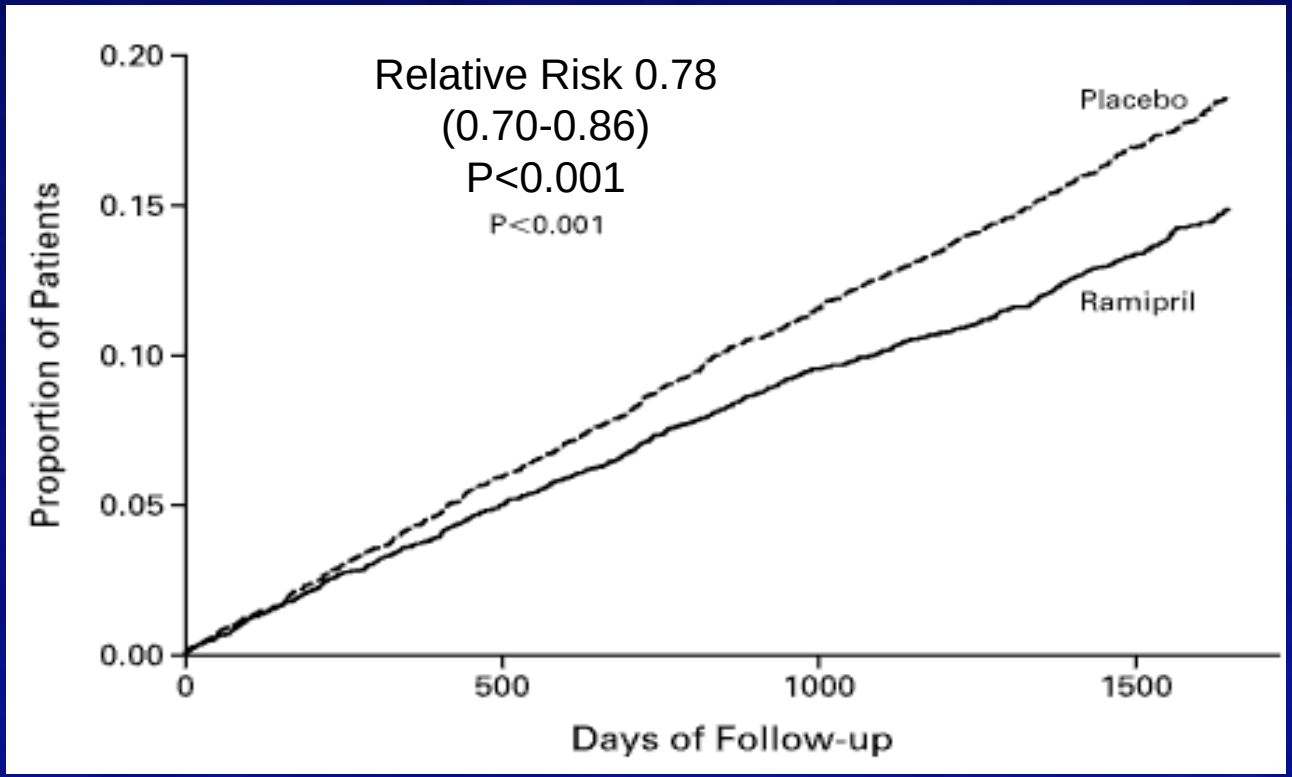
Reduction in Coronary Atherosclerotic Plaque (by IVUS) by Marked LDL Lowering



(Nissen, et al. JAMA 2006;295: E1)

Systemic Stabilization of Plaque: Effect of ACE Inhibitor to Prevent MI, Stroke, or Cardiovascular Death

The HOPE Trial



(NEJM 2000; 342:145)

Evidence-Based Outcomes in Revascularization

For PCI:

- Since the advent of PCI in 1977, tens of millions of PCI procedures have been performed worldwide, yet only 10 small studies (plus RITA-2; n =1,018) comparing PCI vs. medical therapy, comprising fewer than 3,000 patients, have been performed

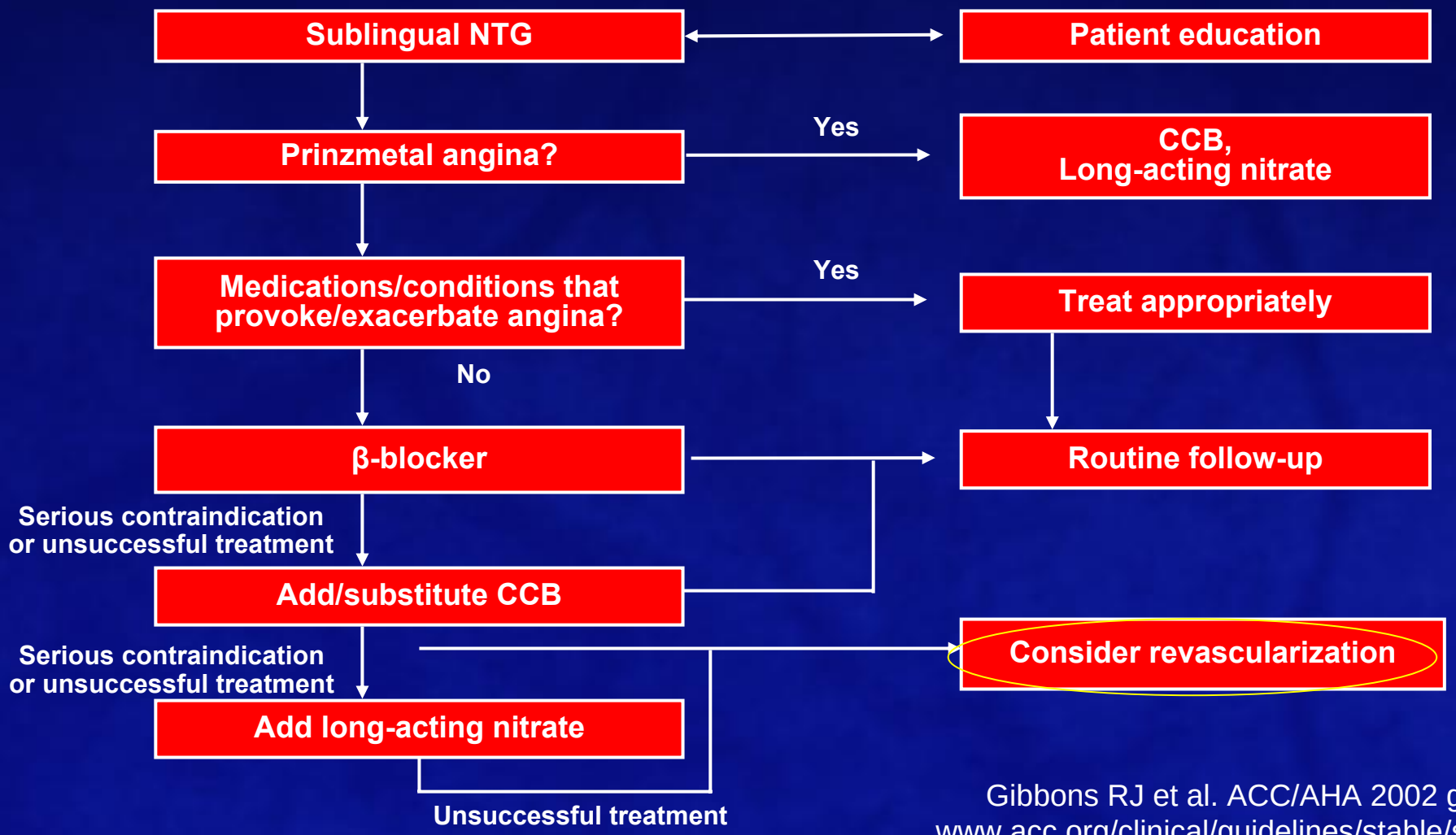
- Why has it taken 20-30 years for a properly sized, designed, and conducted RCT comparing PCI + OMT vs. OMT on “hard” outcomes to be performed?

Conventional Wisdom

Treatment Assumptions in CAD Management:

- Symptomatic CAD patients with the triad of chronic angina, objective evidence of ischemia, and significant coronary stenoses at angiography “need” revascularization; the only question is: which procedure—PCI or CABG?
- Revascularization is required to improve prognosis
- PCI is less invasive than CABG surgery (i.e., it is safer) and, hence, should be the preferred approach

ACC/AHA Guidelines: Chronic Stable Angina Treatment



Gibbons RJ et al. ACC/AHA 2002 guidelines. www.acc.org/clinical/guidelines/stable/stable.pdf.

Perspectives to Ponder…

1. Since we justify performing PCI in ACS patients to reduce death/MI, it seems fundamentally illogical that we attempt to justify performing PCI in stable CAD patients **only** to reduce angina.

2. Since PCI performed in stable CAD patients is procedurally identical to that performed in ACS patients, it is intuitive to most physicians and patients that the durable clinical benefit associated with successful PCI in ACS patients would likewise accrue in patients with stable CAD, whose flow-limiting stenoses are successfully treated with PCI.

Patient Expectations About Elective PCI for Stable CAD

- 52 consecutive patients scheduled for first elective PCI completed semi-structured questionnaire prospectively

Do you think the angioplasty will prevent a heart attack?	
Yes	75%
Do you think the angioplasty will help you live longer?	
Yes	71%

Holmboe et al. J Gen Intern Med 2000;15:632.

Cardiac Procedures in the U.S. Between 1987 and 2006

Procedure	*Rate of Rise*
• Coronary Angiography	163%
• CABG Surgery	102%
• PCI	***5,946%**

* **In 2005, over 1 million procedures…**

- Gillum et al: National Center for Health Statistics; Trends in hospital utilization: U.S. 1987-2006. Government Printing Office, 2006.

"Do you want that with or without angioplasty ?"

In Search of Truth…

"The great enemy of the truth is very often not the lie—deliberate, contrived, and dishonest—but the myth—persistent, persuasive and unrealistic"

-John F. Kennedy, 1962

The Role of PCI in Stable CAD

The Past, the Present and the Future:

- How did we get to where we are today
- COURAGE—a Pivot Point for Change…
- Can/Should We Change the Future?

COURAGE

COURAGE

Clinical **O**utcomes **U**tilizing

Percutaneous **R**evascularization and

Aggressive **G**uideline-Driven

Drug **E**valuation

The NEW ENGLAND JOURNAL of MEDICINE

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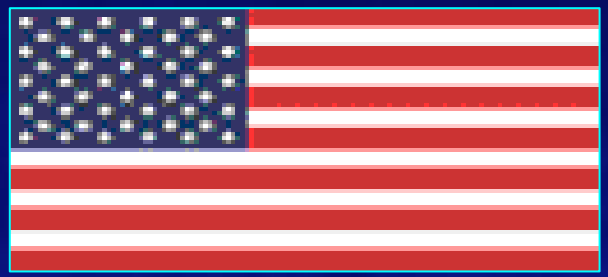
Optimal Medical Therapy with or without PCI for Stable Coronary Disease

William E. Boden, M.D., Robert A. O'Rourke, M.D., Koon K. Teo, M.B., B.Ch., Ph.D., Pamela M. Hartigan, Ph.D., David J. Maron, M.D., William J. Kostuk, M.D., Merril Knudtson, M.D., Marcin Dada, M.D., Paul Casperson, Ph.D., Crystal L. Harris, Pharm.D., Bernard R. Chaitman, M.D., Leslee Shaw, Ph.D., Gilbert Gosselin, M.D., Shah Nawaz, M.D., Lawrence M. Title, M.D., Gerald Gau, M.D., Alvin S. Blaustein, M.D., David C. Booth, M.D., Eric R. Bates, M.D., John A. Spertus, M.D., M.P.H., Daniel S. Berman, M.D., G.B. John Mancini, M.D., and William S. Weintraub, M.D., for the COURAGE Trial Research Group*

A North American Trial

16 Canadian Hospitals

15 VA Hospitals



19 US Non-VA Hospitals

50 Hospitals

2,287 CHD patients enrolled between 6/99-1/04; follow-up concluded on 6/30/06

Aim of the COURAGE Trial

To determine whether PCI plus optimal medical therapy, ***when used as an initial management strategy***, reduces the risk of death or nonfatal MI in ***moderate to high-risk patients with stable CAD***, as compared with optimal medical therapy alone.

Design

- Randomization to PCI + Optimal Medical Therapy vs Optimal Medical Therapy alone
- Intensive, guideline-driven medical therapy and lifestyle intervention in *both* groups
- 2.5 to 7 year (median 4.6 year) follow-up

Hypothesis

PCI + Optimal Medical Therapy

will be Superior to

Optimal Medical Therapy Alone

Optimal Medical Therapy

Pharmacologic

- Anti-platelet: aspirin; clopidogrel in accordance with established practice standards
- Statin: simvastatin ± ezetimibe or ER niacin
- ACE Inhibitor or ARB: lisinopril or losartan
- Beta-blocker: long-acting metoprolol
- Calcium channel blocker: amlodipine
- Nitrate: isosorbide mononitrate

Applied to Both Arms by Protocol and Case-Managed

Optimal Medical Therapy

Lifestyle Counseling:

- Smoking cessation
- Exercise
- Nutrition
- Weight control

Applied to Both Arms by Protocol and Case-Managed

Risk Factor Goals

Variable	Goal
Smoking	Cessation
Total Dietary Fat / Saturated Fat	<30% calories / <7% calories
Dietary Cholesterol	<200 mg/day
LDL cholesterol (primary goal)	1.55-2.20 mmol/L
HDL cholesterol (secondary goal)	>1.00 mmol/L
Triglyceride (secondary goal)	<1.70 mmol/L
Physical Activity	30-45 min. moderate intensity 5X/week
Body Weight by Body Mass index	<u>Initial BMI</u> — <u>Weight Loss Goal</u> 25-27.5 — BMI <25 >27.5 — 10% relative weight loss
Blood Pressure	<130/85 mmHg
Diabetes	HbAlc <7.0%

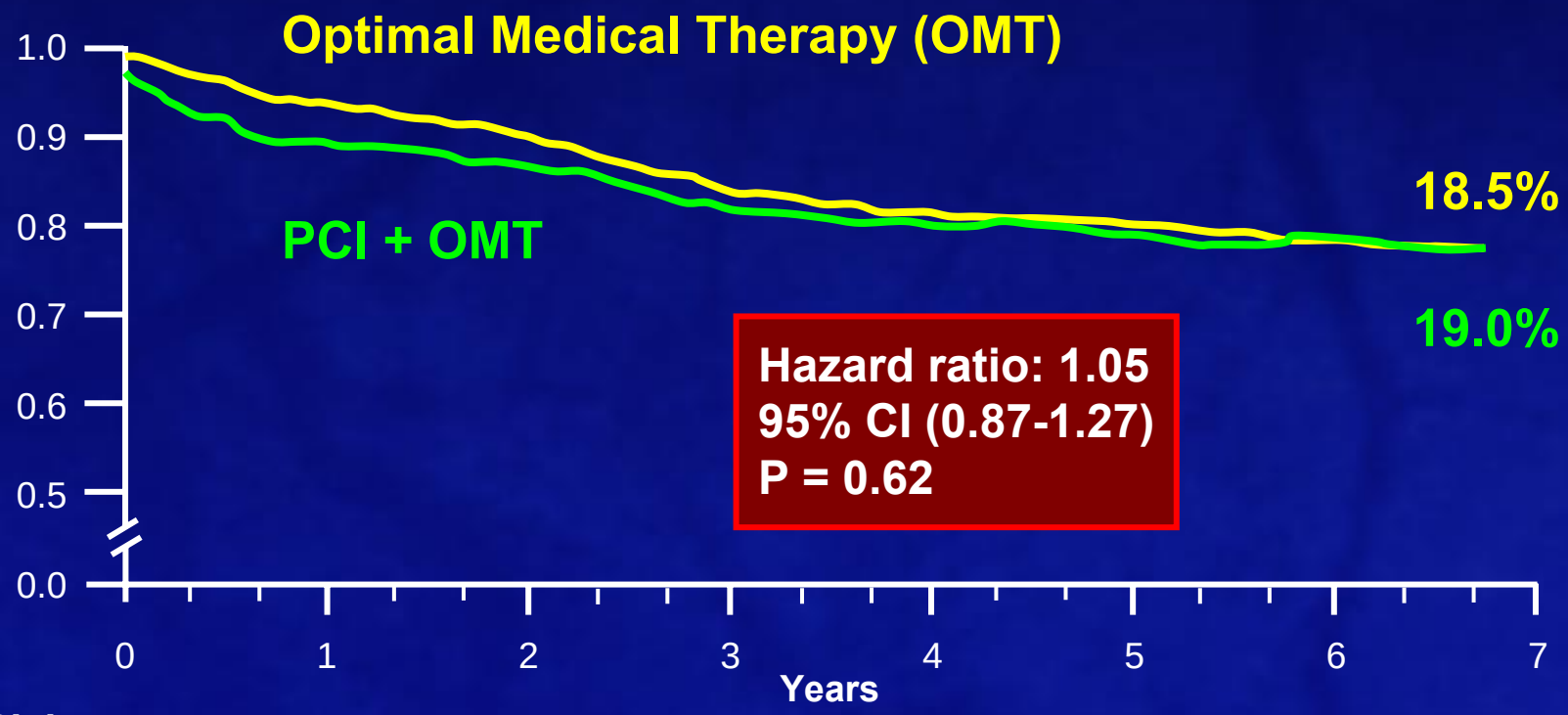
Are COURAGE Patients Generalizable to Contemporary Clinical Practice?

- Significant clinical co-morbidity: 67% HTN; 34% DM; 71% dyslipidemic; 29% smokers; 39% prior MI
- Significant angina at baseline in 88% (12% had “silent ischemia”); 58% were CCS Class II or III
- Significant ischemia at baseline in 95% of pts: 5% had UA and no ischemia testing (but with 80% cor. angio. stenosis); 10% had ischemic rest ECG changes; 85% had inducible ischemia (57% ETT and 43% stress MPI, of whom 67% had multiple reversible ischemic defects)
- 69% of patients had multivessel CAD with at least a 70% proximal visual stenosis (68% with proximal LAD disease) in one or more epicardial coronary arteries

Long-Term Improvement in Treatment Targets (Group Median ± SE Data)

Treatment Targets	Baseline		60 Months	
	PCI +OMT	OMT	PCI +OMT	OMT
SBP	131	130	124	122
DBP	74	74	70	70
Total Cholesterol mmol/L	4.30	4.43	3.58	3.50
LDL mmol/L	2.50	2.55	1.78	1.80
HDL mmol/L	0.98	0.98	1.03	1.00
TG mmol/L	1.59	1.66	1.37	1.46
BMI Kg/M^2	28.7	28.9	29.2	29.5
Smoking	23%	23%	17%	20%
Moderate Activity (5x/week)	25%	25%	42%	36%

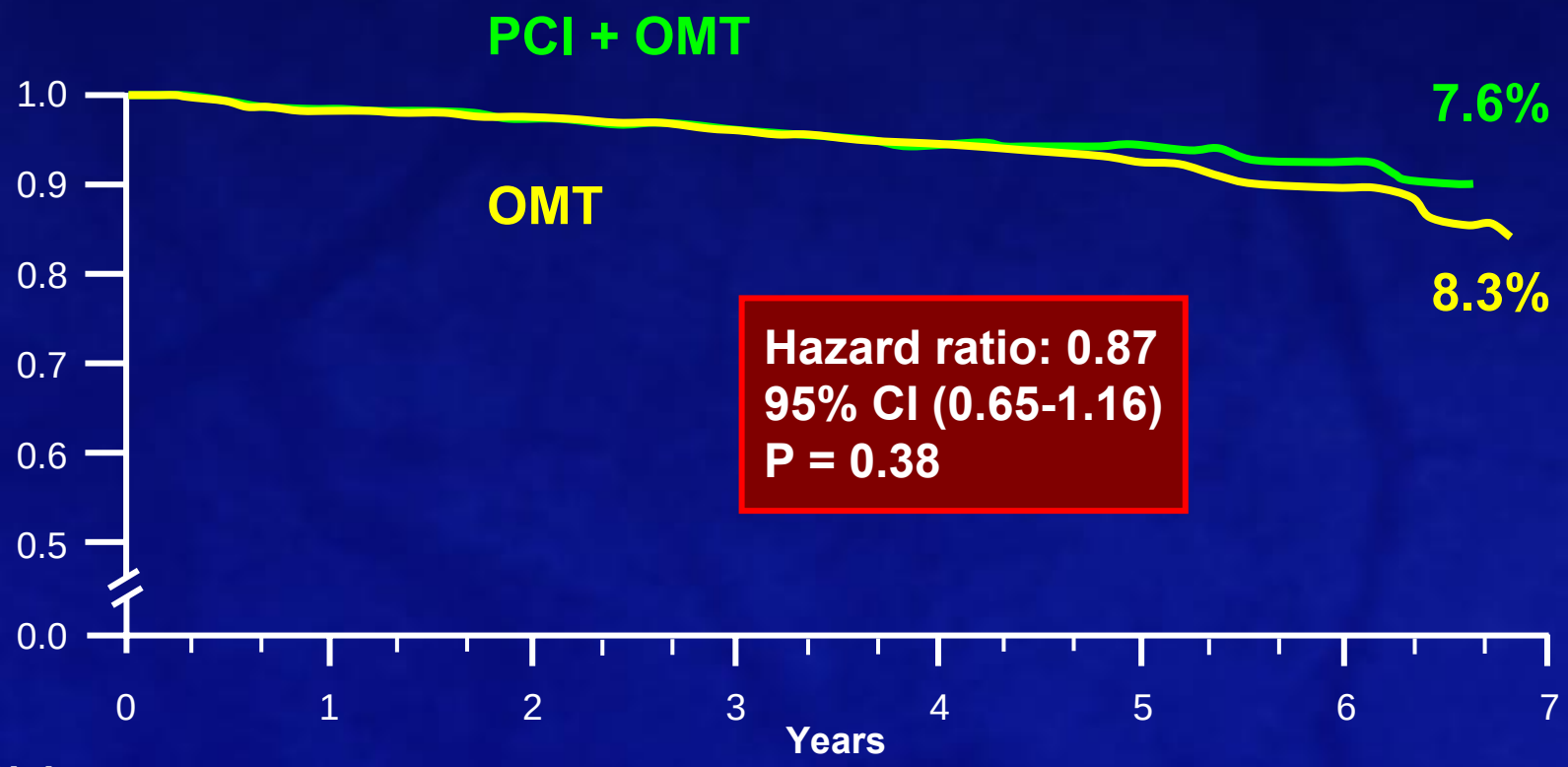
Survival Free of Death from Any Cause and Myocardial Infarction



Number at Risk

Medical Therapy	1138	1017	959	834	638	408	192	30
PCI	1149	1013	952	833	637	417	200	35

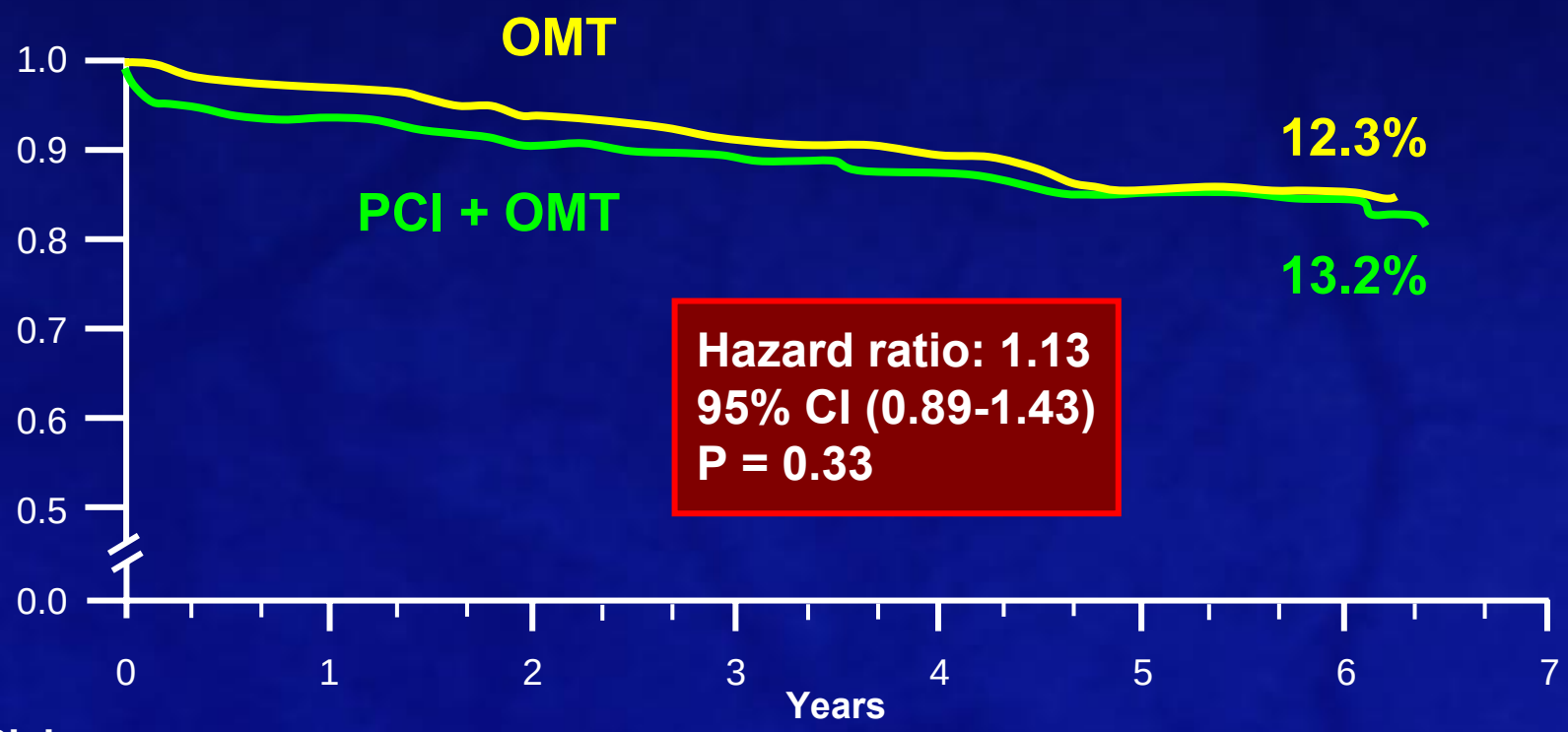
Event-Free Survival



Number at Risk

Medical Therapy	1138	1073	1029	917	717	468	302	38
PCI	1149	1094	1051	929	733	488	312	44

Survival Free of Myocardial Infarction



Number at Risk

Medical Therapy	1138	1019	962	834	638	409	192	120
PCI	1149	1015	954	833	637	418	200	134

Need for Subsequent Revascularization*

	PCI + OMT	OMT
Revascularization	21%	33%
CABG	77	81
Time to Revasc.†	10 months	10.8 months

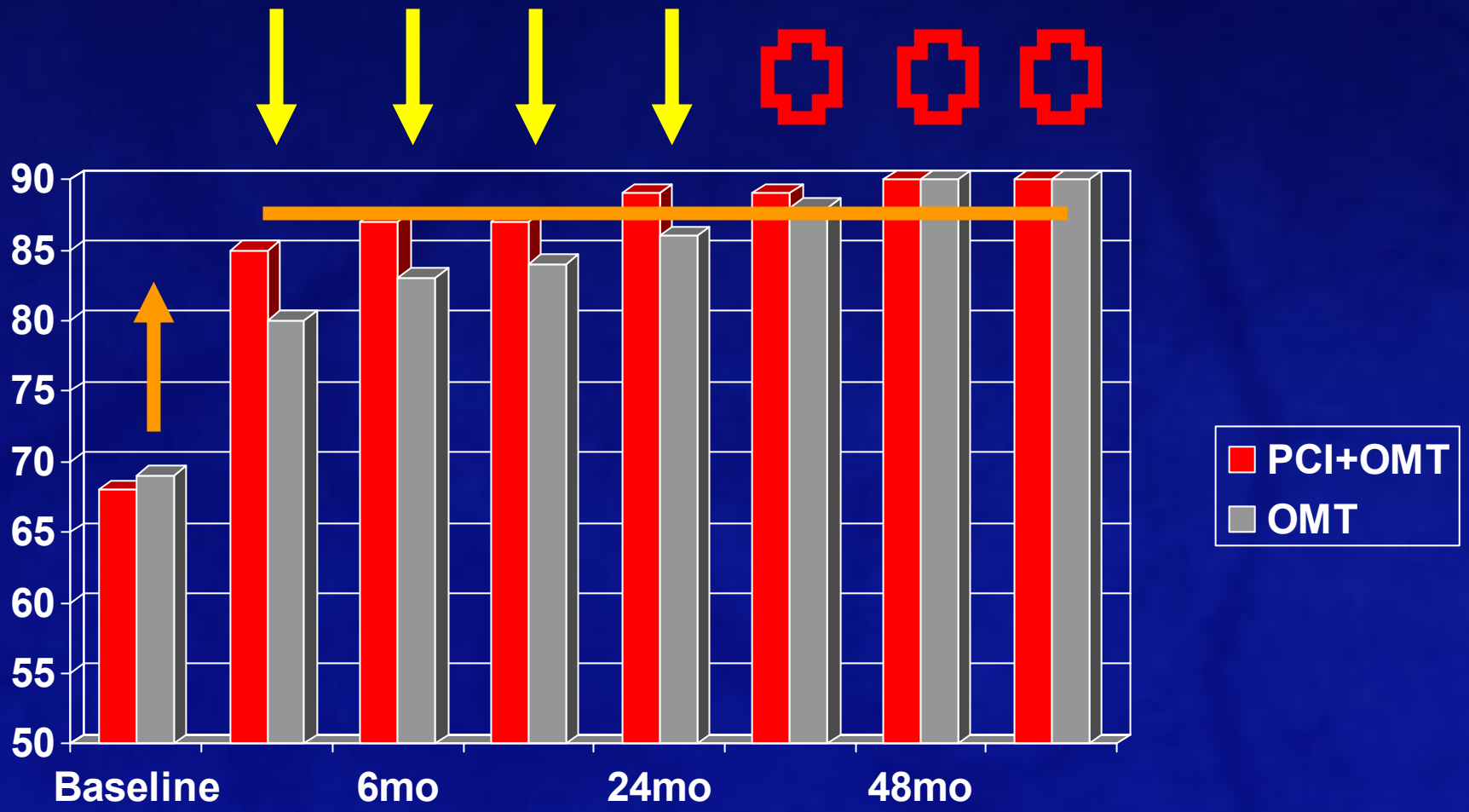
*During median 4.6 years of follow-up
†Median

Freedom from Angina During Long-Term Follow-up

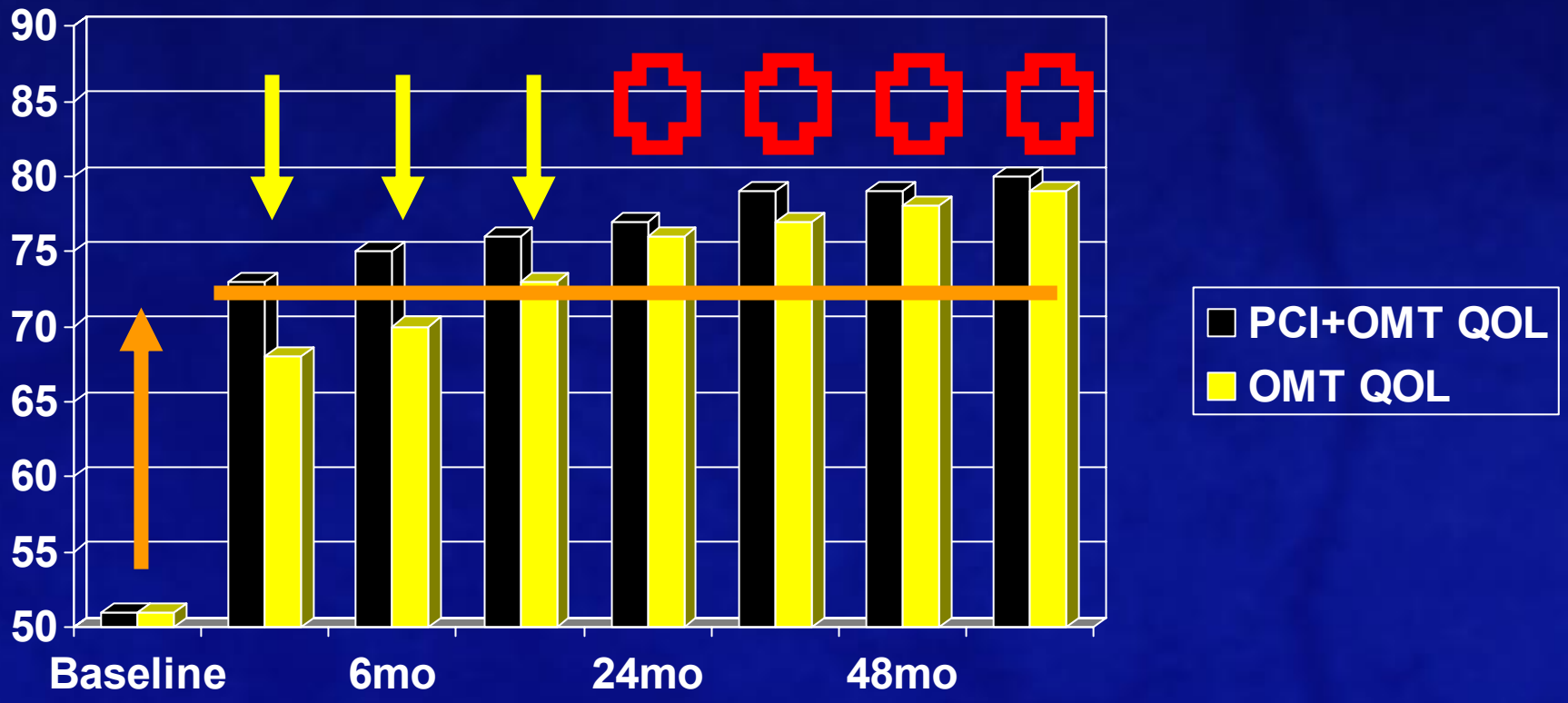
Characteristic	PCI + OMT	OMT
CLINICAL		
Angina free – no.		
Baseline	12%	13%
1 Yr	*66%	58%
3 Yr	*72%	67%
5 Yr	74%	72%

* The comparison between the PCI group and the medical-therapy group was significant at 1 year (P<0.001) and 3 years (P=0.02) but not at baseline or 5 years.

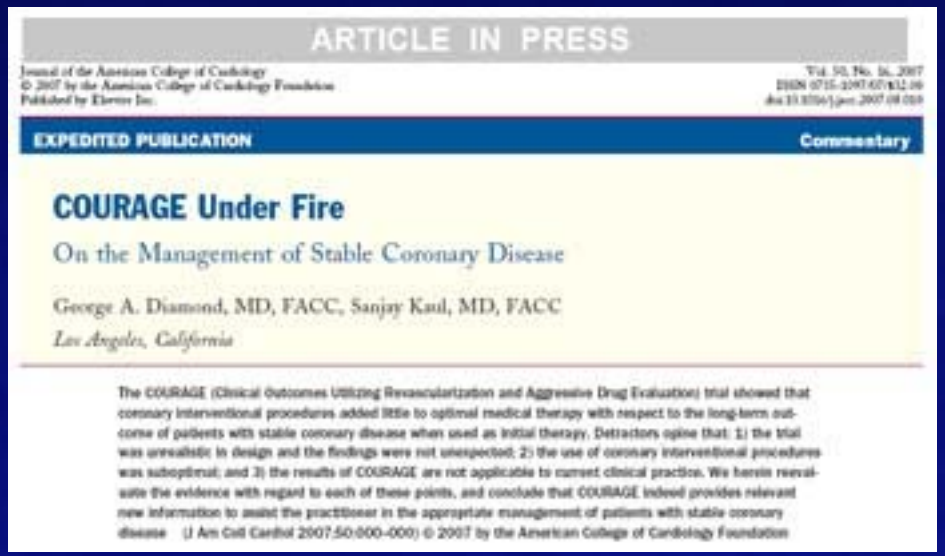
SAQ Angina Frequency Scores



SAQ Quality of Life Scores



COURAGE: Continuing Controversy & Discourse After 6 Months…



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EXPEDITED PUBLICATION — Commentary

COURAGE Under Fire

On the Management of Stable Coronary Disease

George A. Diamond, MD, FACC, Sanjay Kaul, MD, FACC
Los Angeles, California

The COURAGE (Clinical Outcomes Utilizing Revascularization and Aggressive Drug Evaluation) trial showed that coronary interventional procedures added little to optimal medical therapy with respect to the long-term outcome of patients with stable coronary disease when used as initial therapy. Detractors opine that: 1) the trial was unrealistic in design and the findings were not unexpected; 2) the use of coronary interventional procedures was suboptimal; and 3) the results of COURAGE are not applicable to current clinical practice. We herein reevaluate the evidence with regard to each of these points, and conclude that COURAGE indeed provides relevant new information to assist the practitioner in the appropriate management of patients with stable coronary disease. (J Am Coll Cardiol 2007;50:000–000) © 2007 by the American College of Cardiology Foundation

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EXPEDITED PUBLICATION — Viewpoint

The Truth and Consequences of the COURAGE Trial

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Cincinnati, Ohio; La Jolla, California; Rochester, Minnesota; Durham, North Carolina; Miami, Florida; Washington, DC; Providence, Rhode Island; Boston, Massachusetts; New York, New York; and Clayton, Australia

Percutaneous coronary intervention (PCI) has played an integral role in the therapeutic management strategies for patients who present with either acute coronary syndromes or stable angina pectoris. The COURAGE (Clinical Outcomes Utilizing Revascularization and Aggressive Drug Evaluation) trial enrolled patients with chronic stable angina and at least 1 significant (≥70%) angiographic coronary stenosis who were randomly assigned to an initial treatment of either PCI in conjunction with optimal medical therapy or optimal medical therapy alone. Although the initial management strategy of PCI did not reduce the risk of death, myocardial infarction, or other major cardiovascular events, improvement in angina-free status and a reduction in the requirement for subsequent revascularization was observed. An in-depth analysis of the COURAGE trial design and execution is provided. (J Am Coll Cardiol 2007;50:000–000) © 2007 by the American College of Cardiology Foundation

The Three Stages of Truth…

-Schopenhauer: 1788-1860; Diamond & Kaul JACC 2007; 50; 1-5

As Applied to the Results of COURAGE:

- First, it is ridiculed
- Second, it is violently opposed
- Third, it is accepted as being self-evident

Observations from Clinical Trials & Observational Studies

- The value and benefits of OMT in reducing clinical events are absolutely unquestioned
- The clinical benefits of DES vs. BMS (and the clinical consequences of re-stenosis) are largely overstated, while the clinical consequences of late stent thrombosis are largely understated

No Clear Benefit of DES vs. BMS on Death or MI - ESC/WCC, Sept. 2006

Long-Term Follow-Up of "On-Label" Use of DES (RCTs)

			Incidence (%)			NNH	Probability	
Trial	End Point	Follow-Up	DES	BMS	p Value	(NNT)*	Benefit	Harm
Camenzind et al. meta-analysis								
SES vs. BMS (n=1,748) (4 trials)	**Death; Q-wave MI**	Last F/U (>3 yrs)	**6.3**	**3.9**	**0.03**	**42**	**1%**	**99%**
PES vs. BMS (n=3,364) (5 trials)	Death or Q-wave MI	Last F/U (>3 yrs)	3.3	2.8	0.46	227	23%	77%
Nordmann et al. meta-analysis (4 trials)								
SES vs. BMS (n=1,748)	**Death**	**3 yrs**	**4.7**	**3.1**	**0.09**	**66**	**4%**	**96%**
SES vs. BMS (n=1,748)	**Non-Cardiac Death**	3 yrs	**3.2**	**1.6**	**0.04**	**66**	**2%**	**98%**
SIRIUS (SES vs. BMS)	Death	4 yrs	6.0	4.6	0.30	71	15%	85%
	Death or MI	4 yrs	8.4	6.7	0.27	58	13%	87%
RAVEL (SES vs. BMS)	Death	5 yrs	12.1	7.1	0.26	20	13%	87%
	Death or MI	5 yrs	**18.9**	**10.5**	**0.09**	12	4%	96%
BASKET (SES or PES vs. BMS)	Death or MI	18 mo	8.4	7.5	0.63	111	31%	69%

*Numbers needed to treat for benefit are shown in parentheses (NNT or NNH values ranging from 30 to 80 are deemed clinically important).

Kaul, Shah, Diamond. As Time Goes By – Current Status and Future Directions in the Controversy Over Stenting. JACC 2007; 50; 1-10.

Extraordinarily High Rates of Death/MI 2º to Stent Thrombosis

Low Incidence But Severe Consequences

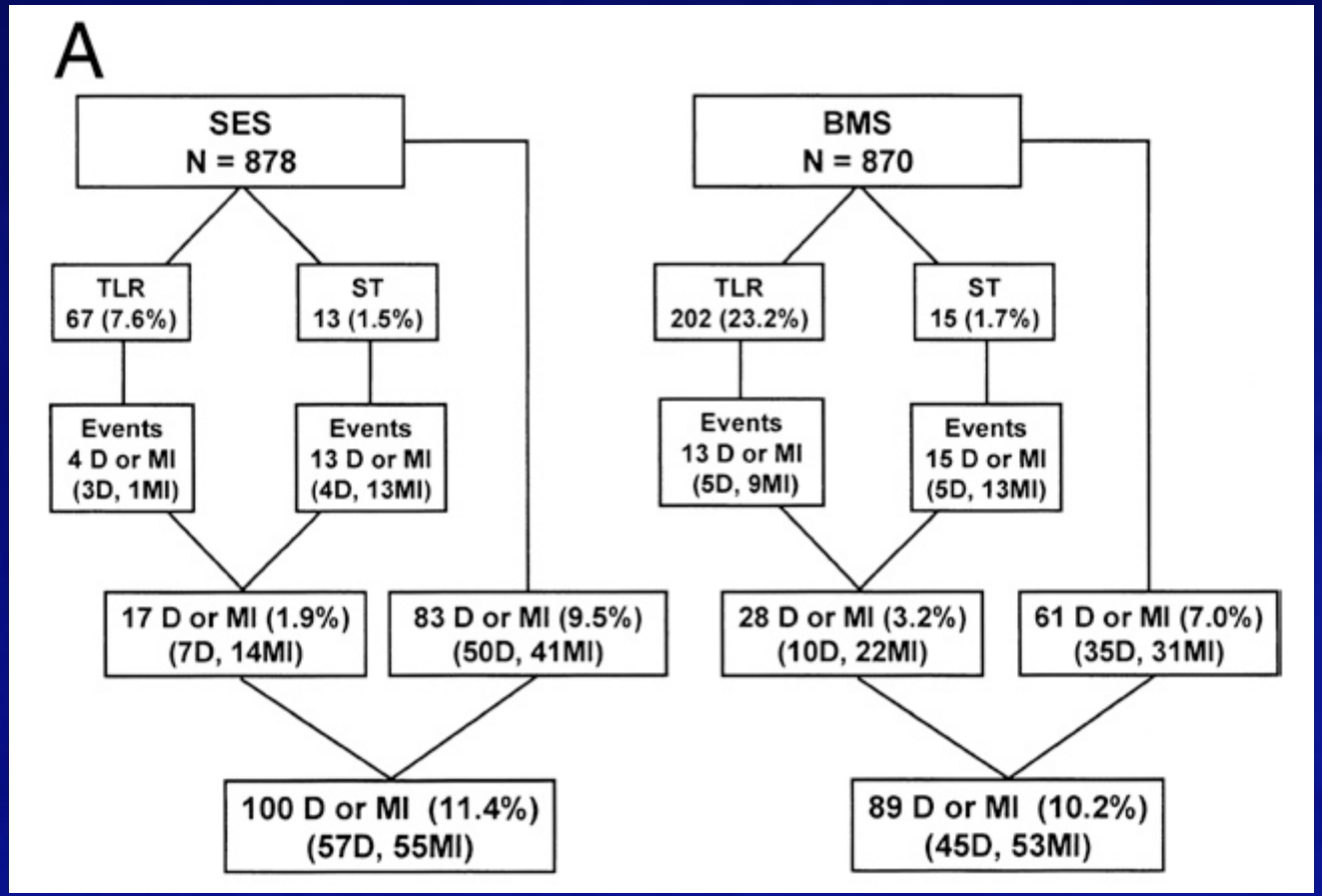
Study	Stent Type	Confirmation of Stent Thrombosis	Duration	Death	Death or MI
Cutlip et al., 2001 (14) (n = 6,186)	BMS	Angiogram or clinical	6 months	21%	**70%**
Heller et al., 2001 (15) (n = 1,855)	BMS	Angiogram plus acute MI	9 months	17%	**100%**
Iakovou et al., 2005 (7) (n = 2,229)	DES	Angiogram or clinical	9 months	45%	**93%**
Ong et al., 2005 (16) (n = 2,016)	DES	Angiogram plus clinical	1 month	25%	**100%**
Kuchulakanti et al., 2006 (8) (n = 2,974)	DES	Angiogram	6 months	31%	**72%***
BASKET-LATE, 2006 (10) (n = 746)	DES	Angiogram plus clinical	18 Months	19%**	**88% ****
Mauri et al., 2007 (17) (n= 4,545)	DES	Angiogram plus clinical	4 years	31%	**84%***

*Only MI rates reported; ** cardiac death.

Kaul, Shah, Diamond. As Time Goes By – Current Status and Future Directions in the Controversy Over Stenting. JACC 2007; 50; 1-10.

Only ~ 6% of TLR Resulted in Death or MI for SES or BMS

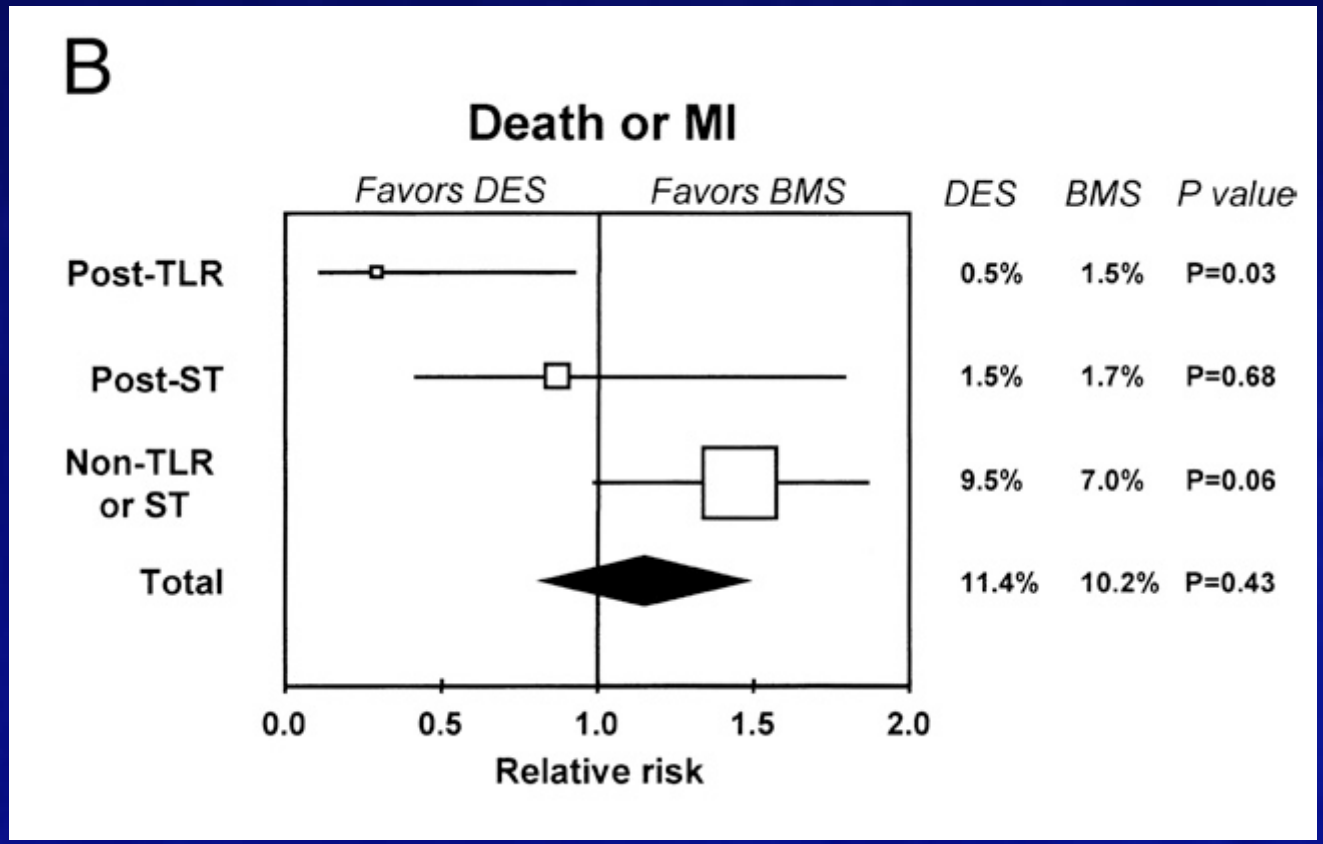
Pooled Analysis of RAVEL, SIRIUS, E-SIRIUS, and C-SIRIUS Trials



Kaul, Shah, Diamond. As Time Goes By – Current Status and Future Directions in the Controversy Over Stenting. JACC 2007; 50: 1-10.

Most D/MI Events post-SES Unrelated to TLR or ST

Pooled Analysis of RAVEL, SIRIUS, E-SIRIUS, and C-SIRIUS Trials



Kaul, Shah, Diamond. As Time Goes By – Current Status and Future Directions in the Controversy Over Stenting. JACC 2007; 50: 1-10.

There is a 100% Effective "Cure" for Re-stenosis, TLR & TVR…

- Whenever possible, avoid or defer the initial PCI…
- Initiate and maintain evidence-based, multifaceted optimal medical therapy and treat patients aggressively to their risk factor targets

5 Traits That Characterize MD Behavior

From Freidson E: Profession of Medicine: a study of the sociology of applied knowledge. New York, NY; Harper & Row, 1970; 168-69

1. **We believe in what we are doing.** When things go right, we take the credit.
2. **We prefer action to inaction.** Even action with little chance of success is preferred over no action at all.
3. **We are pragmatic.** We see apparent cause-effect relationships even in the absence of any theoretic foundation.
4. **We are highly subjective.** We depend more on “gut feelings” than on “book knowledge”.
5. **We emphasize uncertainty in our defense.** When things go wrong, it is not our fault. Because we deal with individuals and not groups, we cannot rely on epidemiologic concepts or probabilities derived from population statistics.

Why We Often Practice "Selective" Evidence-Based Medicine…

- When scientific evidence conflicts with our clinical judgment (or collides with our pre-existing belief systems), we tend to resist it

- But, when evidence is consistent with our judgment (or reinforces our pre-existing treatment biases), we tend to embrace it

How Some Interventionalists Are Choosing to Interpret COURAGE…

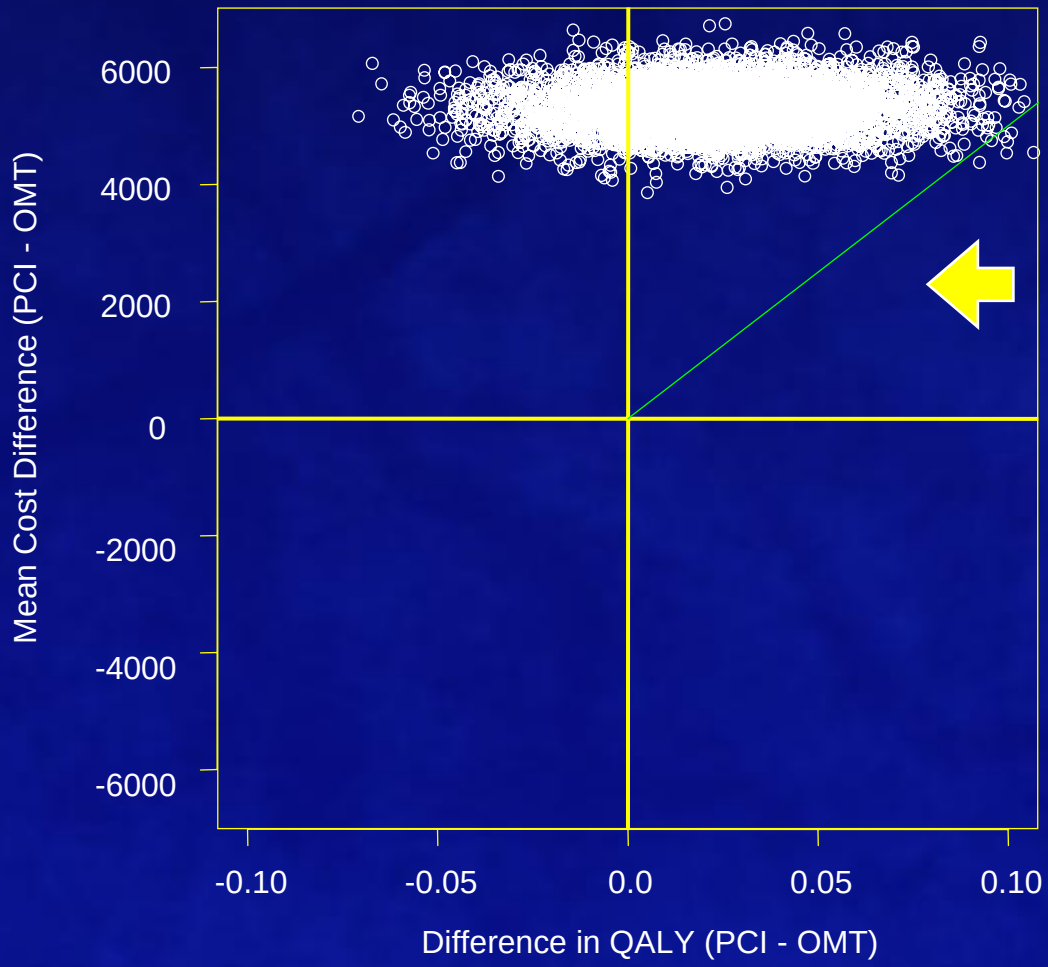
- Since PCI is better than OMT for angina relief and improving QOL…and
- Since PCI is no worse/better than OMT for reducing death/MI during long-term f/u…
- Then, we should perform PCI as the initial approach to management in most stable CAD patients…
- Except, what about cost and value?

Importance and Rationale for Cost-Effectiveness Analysis

- Health Care currently costs $1.5 trillion, 14% of GDP.
- Cost-effectiveness analysis can help allocate resources rationally.
- Cost-effectiveness is used when one form of therapy is both more effective and more expensive than a previous standard.
- Cost-effectiveness is generally measured in cost per life years gained or cost per quality adjusted life years gained

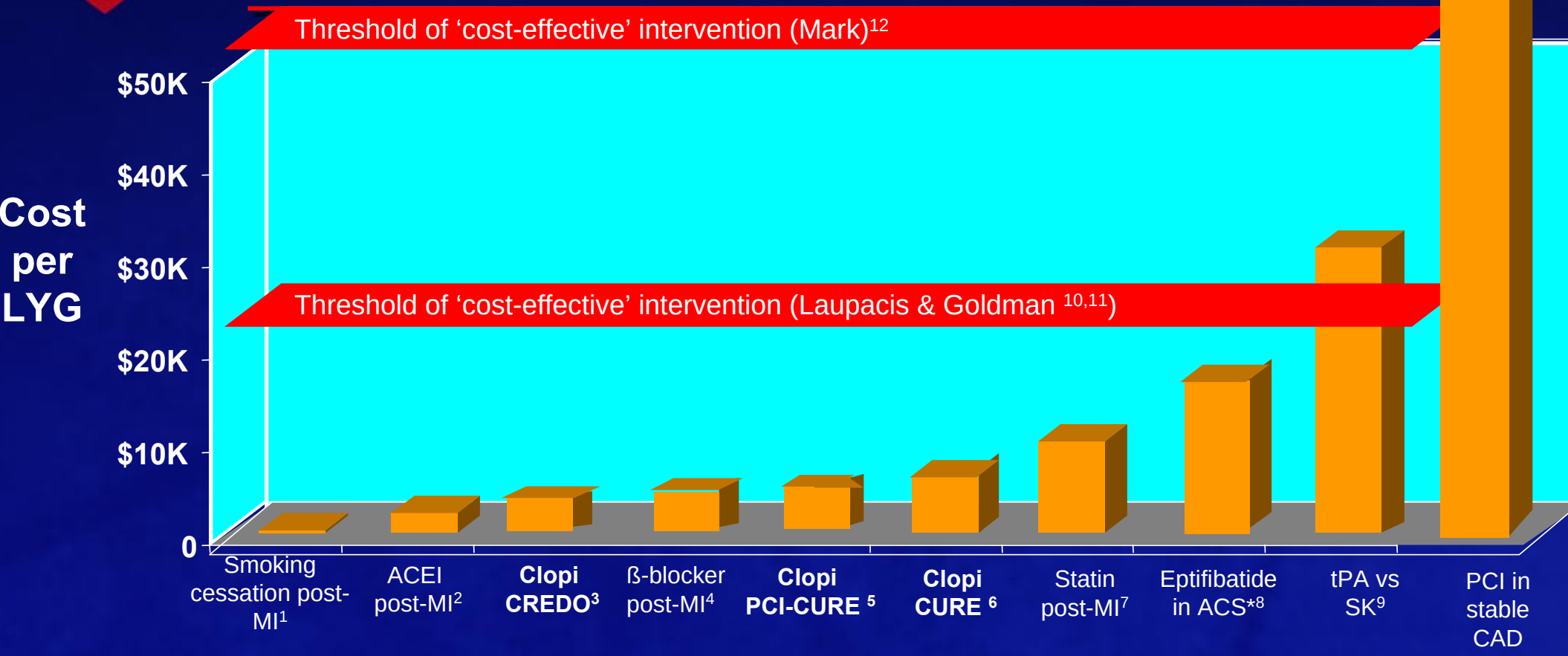
Joint Distribution of Cost and Effectiveness

ICER point estimate: $216,993/QALY gain



< $50,000/QALY gain

ICERS for CV Interventions



* Unstable angina / non–Q-wave MI

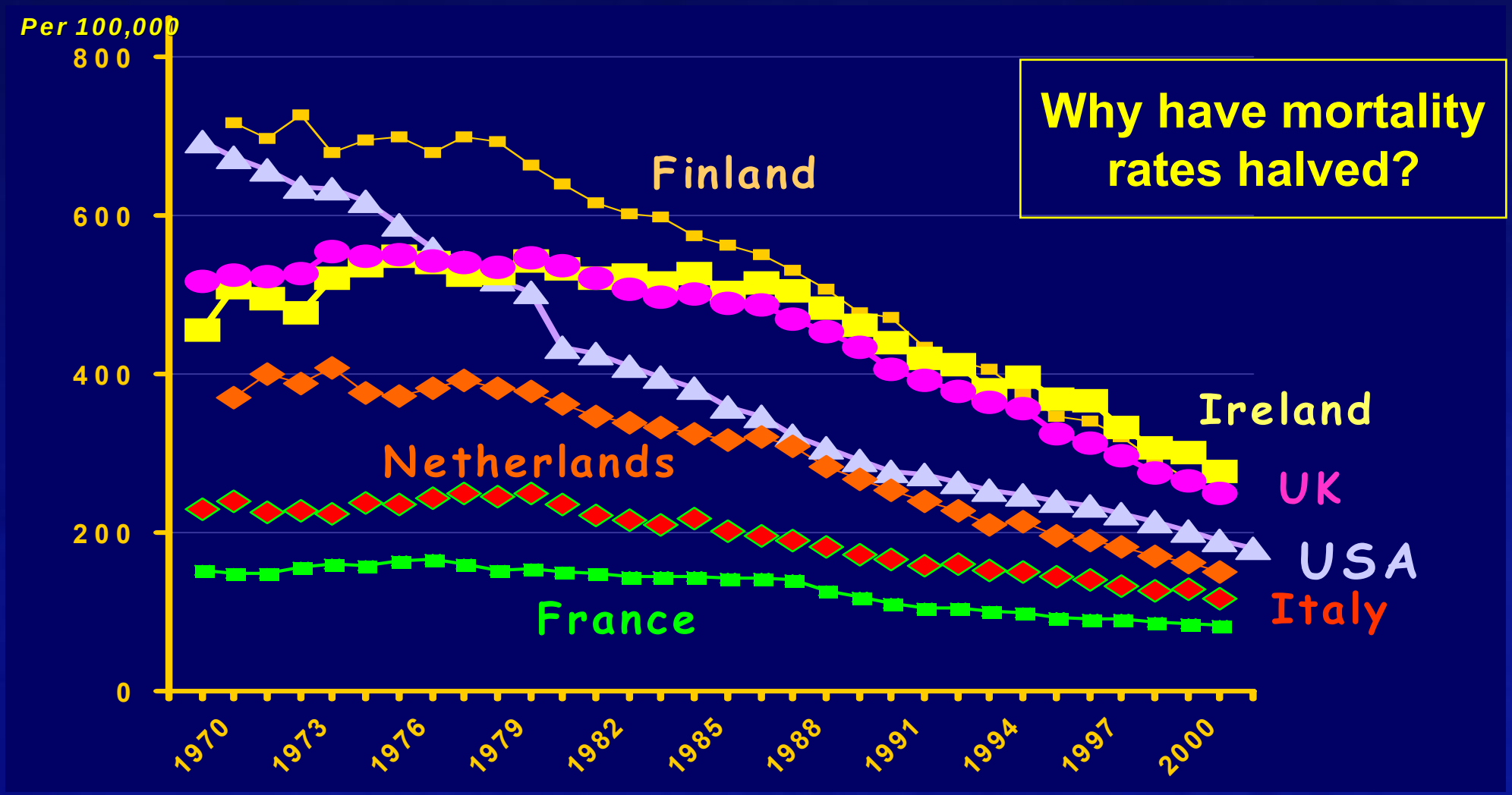
LYG = life-year gained

1. Krumholz et al. *J Am Coll Cardiol*. 1993;22:1697-1702.
2. Franzosi et al. *Pharmacoeconomics*. 1995;13:337-346.
3. Beinart, CREDO, AHA Congress Nov. 2003.
4. Goldman et al. *N Engl J Med* 1988;319:152-57.
5. Mahoney, PCI-CURE, AHA Congress Nov. 2003.
6. Weintraub, et al. JACC 2005;45(6):838-845.
7. Johannesson et al. *N Engl J Med* 1996;336(5):335;332-336.
8. Mark et al. *Circulation*. 2000; 101: 366–371.
9. Mark et al. *N Engl J Med*. 1995;332:1418-1424.
10. Laupacis et al. *Can Med Assoc J*. 1993;148:927-929.
11. Goldman et al. *Circulation*. 1992;85:1960-1968.
12. Mark. In: Topol (ed.). *Textbook of Cardiovascular Medicine*. Philadelphia, PA: Lippincott-Raven; 1998

What Drives Event Reduction in Stable CAD: Anatomy or Biology?

PCI fixes the lesion, but *not* the artery or the patient; OMT reduces clinical events

International CHD Mortality Trends in Men, 1968-2003



Source:BHF Heartstats (WHO statistics Men aged 35 - 74, Standardized)

Explaining the Decrease in U.S. Deaths from CHD, 1980-2000

Ford et al NEJM 2007; 356: 2388-98; CDC

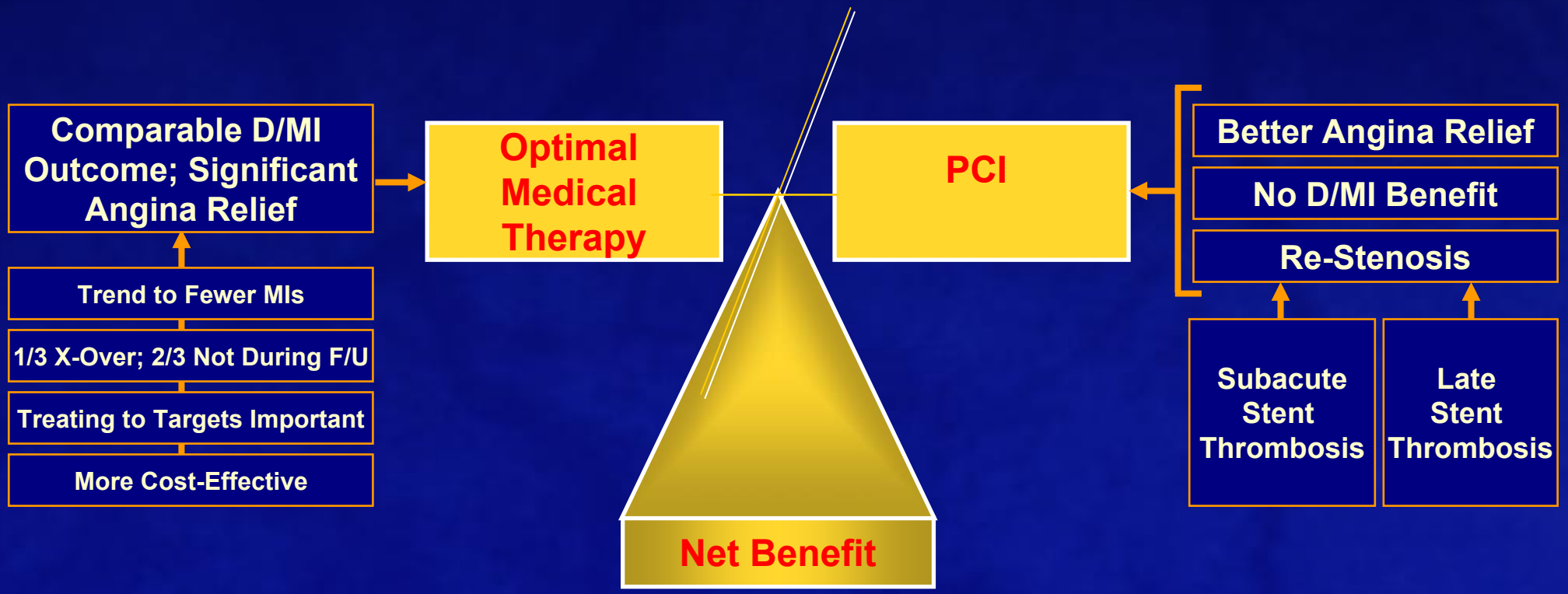
- Age-adjusted death rate for CHD fell from 543 to 267 deaths/100,000 men and from 263 to 134 deaths/100,000 women, resulting in 341,745 fewer deaths in 2000 vs. 1980.
- 47% of this decrease was attributed to evidence-based medical therapies and secondary prevention for MI and CHD (statins, ACEI, BB, etc.) and treatment for CHF
- 44% of this decrease was attributed to changes in risk factors (decreased cholesterol, BP, smoking, physical inactivity, etc.).
- Only 5% of this decrease was attributable to revascularization (CABG or PCI) for chronic stable angina, and **only 1.3% was attributable to PCI**
- Of the 22,059,760 PCIs performed for stable CHD between 1980-2000, the **RRR for death was 13% and ARR was 0.2%**

The Case for Medical Therapy as the Initial Choice in Chronic Stable Angina

1. Aggressive medical therapy without initial PCI can be implemented safely in the majority of patients with stable CAD—1/3 of whom may require a symptom-driven procedure, but 2/3's of whom may not require even a first revascularization during long-term follow-up. This initial management approach incurs no disadvantage with respect to death, MI, ACS, or CABG.

2. Although routine PCI + OMT provides some advantages in angina/physical limitation/QOL, these differences are numerically small, not durable, and achieved only at an unattractive cost for chronic stable disease management.

Net Clinical Benefits and Risks of PCI for Chronic Angina in Stable CAD

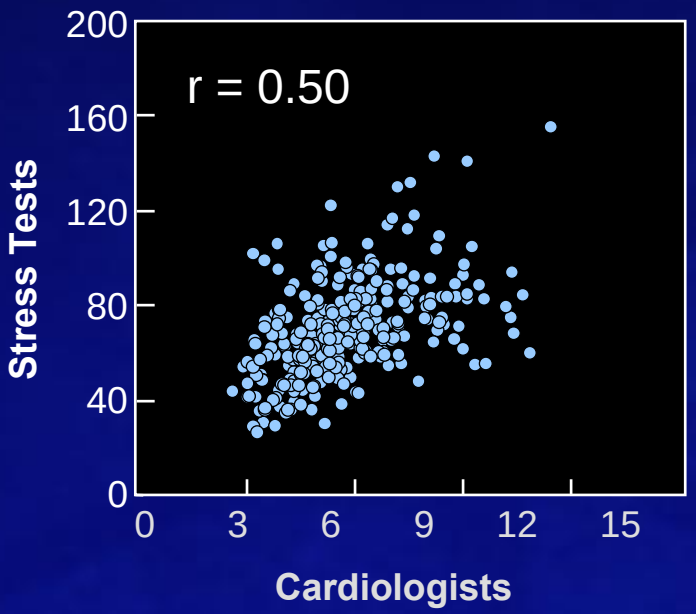


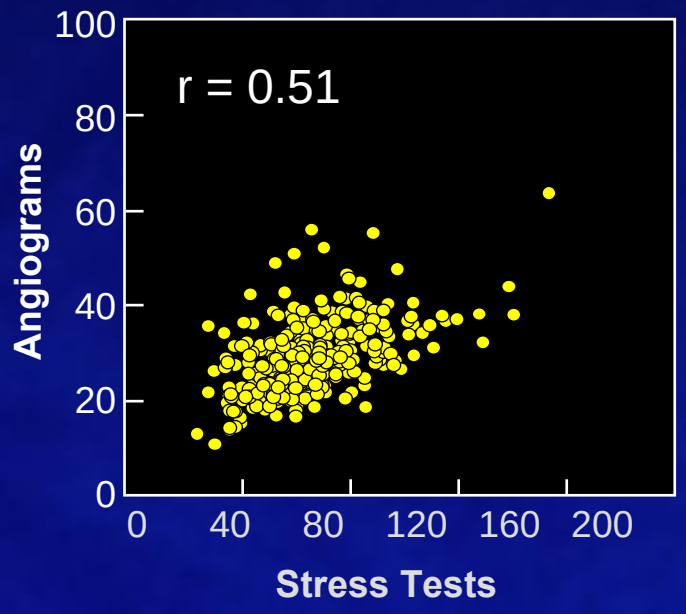
The Role of PCI in Stable CAD

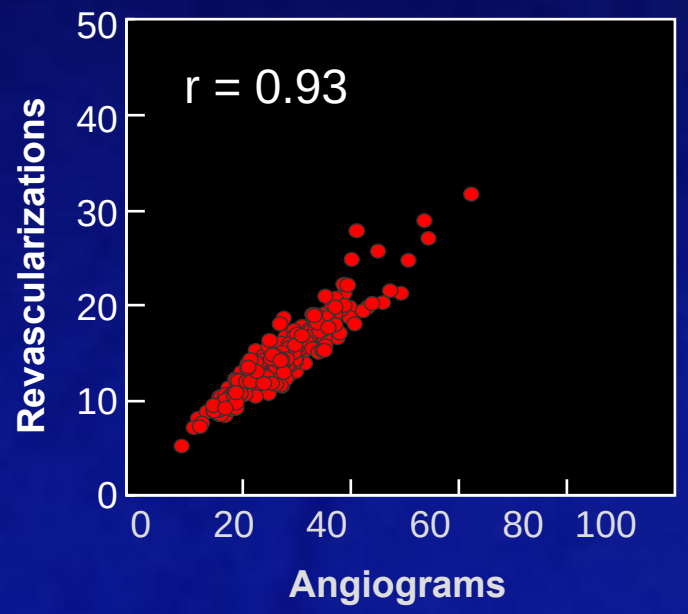
The Past, the Present and the Future:

- How did we get to where we are today?
- COURAGE—a Pivot Point for Change…
- Can/Should We Change the Future?

How Fee-for-Service Drives Utilization

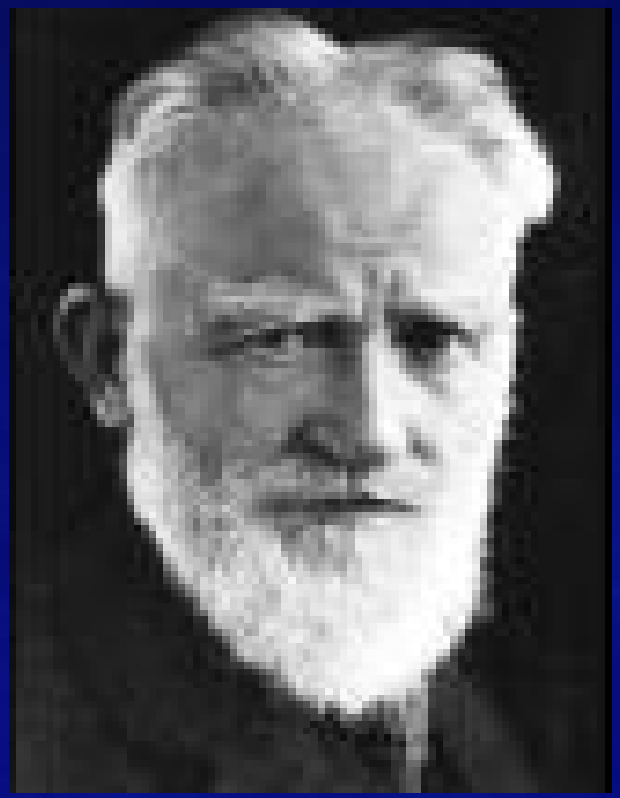






Dartmouth Atlas (1996)

Misalignment of Incentives Drives Over-Utilization

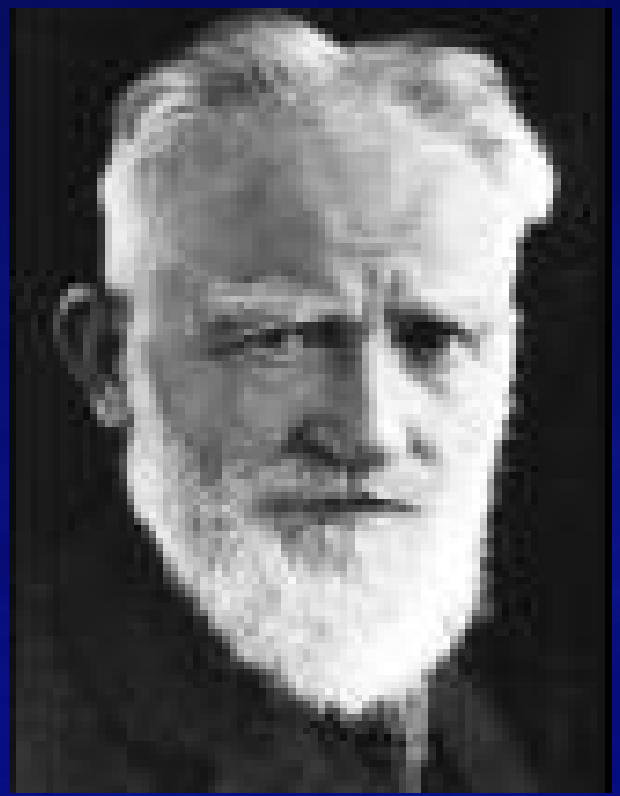


G. B. SHAW

Having observed that you could provide for the supply of bread by giving bakers a pecuniary interest in baking, we go on to give a surgeon a pecuniary interest in cutting off your leg.

The Doctor's Dilemma, 1911

Misalignment of Incentives



G. B. SHAW

Shaw's Laws

1. Payment drives up utilization
2. Utilization drives down quality

Realignment of Incentives

JEAN-BAPTISTE COLBERT

Pluck the goose so as to obtain the most feathers with the least hissing.

Realignment of Incentives

JEAN-BAPTISTE COLBERT

Colbert's Laws

1. Evidence drives payment
2. Payment drives quality

Fee-for-Benefit

Fee-for-Benefit: A Strategy to Improve the Quality of Health Care and Control Costs Through Reimbursement Incentives

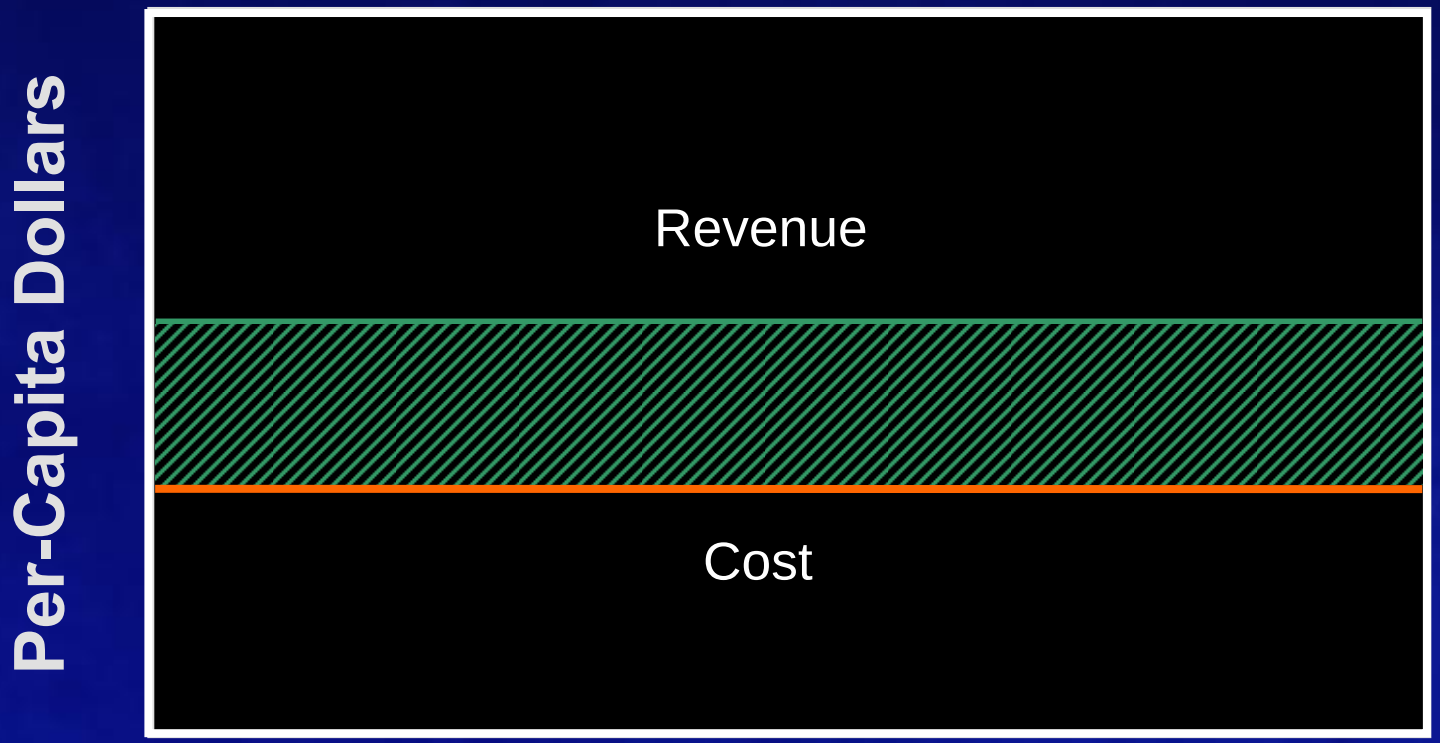
GEORGE A. DIAMOND, MD, FACC, TIMOTHY A. DENTON, MD,
JACK M. MATLOFF, MD, PhD, FACC

Los Angeles, California

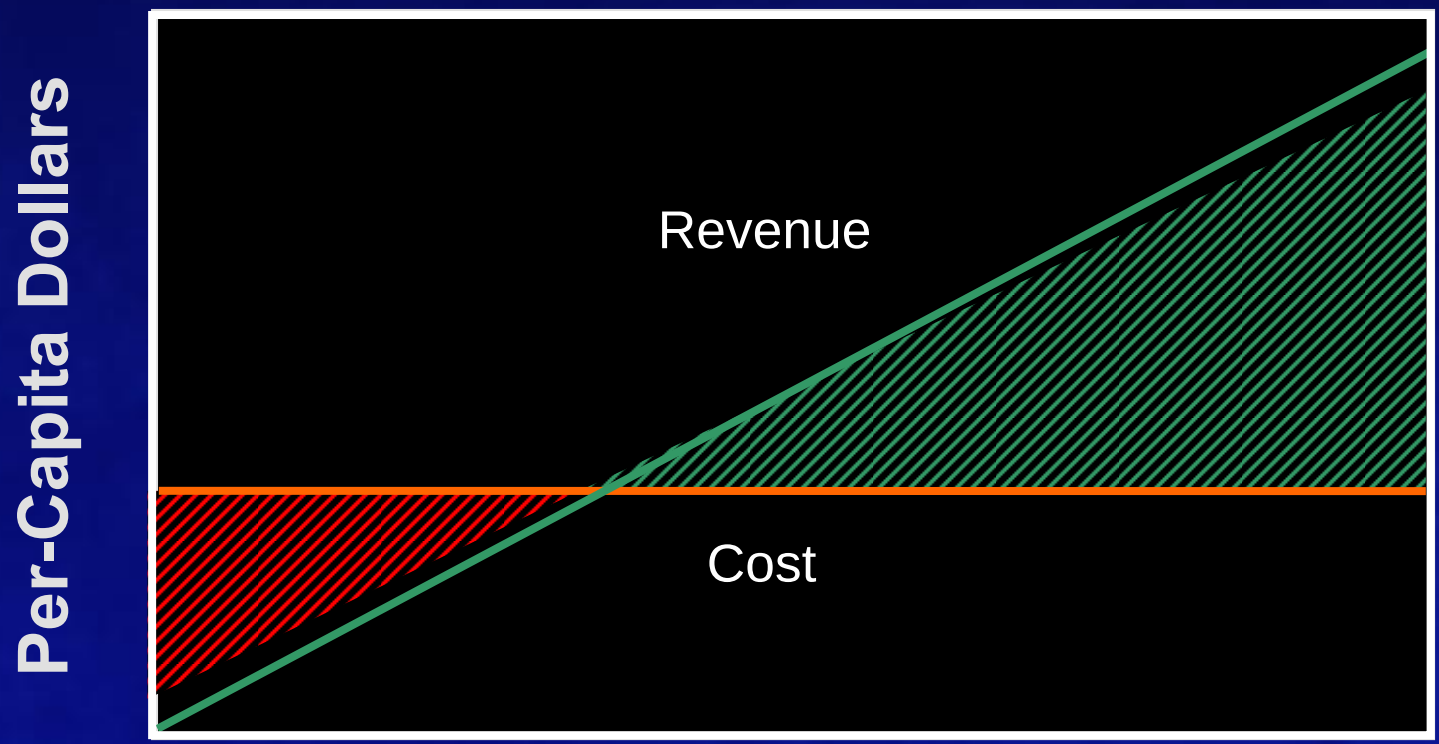
Persistent efforts at cost control will eventually induce health care providers to adopt performance improvement practices that allow them to compete on the basis of quality rather than price.

J Am Coll Cardiol 1993;22:343

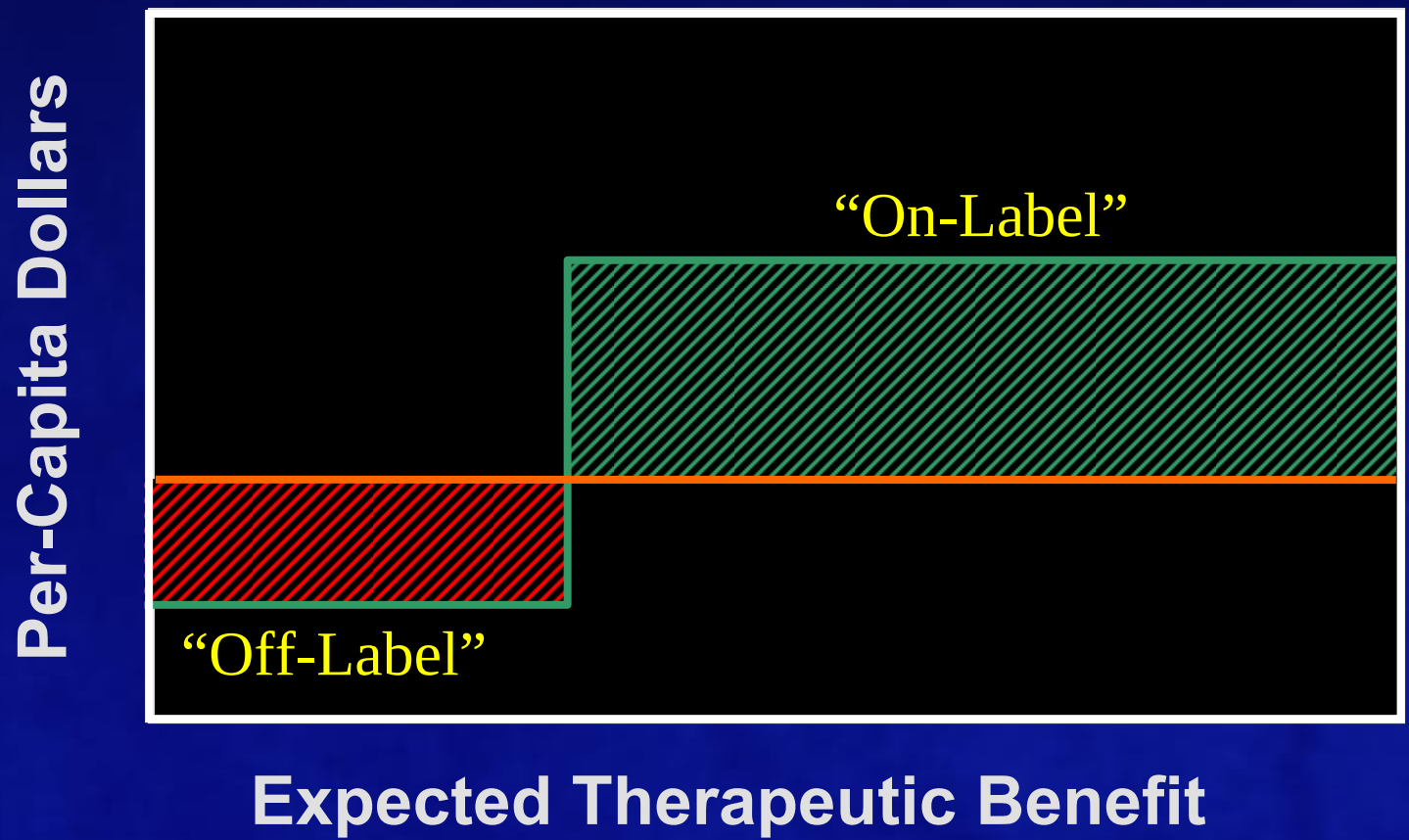
Fee-for-Service



Fee-for-Benefit



Fee-for-Benefit



Prospective Evaluation of Pay-for-Performance

Early Experience With Pay-for-Performance

From Concept to Practice

Meredith B. Rosenthal, PhD
Richard G. Frank, PhD
Zhonghe Li, MA
Arnold M. Epstein, MD, MA

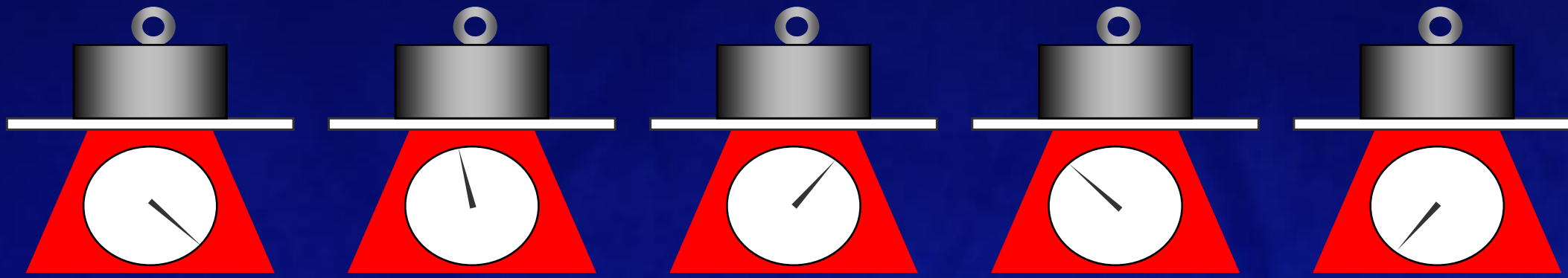
Paying clinicians to reach a common fixed performance target may produce little gain in quality for the money spent and largely rewards those with higher performance or volumes at baseline.

JAMA 2005,294:1788

Comparison of Incentives

	Pay-for-Performance	Fee-for-Benefit
Foundation	Expert Opinion	Empirical Data
Incentive Structure	Imposed	Negotiated
Application	Groups	Individuals
Feedback	Remote	Point of Service
Magnitude of Incentive	Relatively Small	Relatively Large
Reward Horizon	Delayed	Immediate

Inconsistent Referent Standards of Quality



Guidelines	FDA	CMS	Payer	Courts
"Useful and Effective"	"Safety and Efficacy"	"Reasonable and Necessary"	"Usual and Customary"	"Prudent and Cautious"

Population > > > Individual

Inconsistent Meanings of "Benefit" Among Stakeholders

Industry	Surrogate Improvement
Clinician	Objective Improvement
Patient	Symptomatic Improvement

Inconsistency is OK in Politics and Art, but not in Science and Law

Politics

Art

Future Directions in Optimizing Quality, Outcomes, & Cost …

Where We Go From Here:

- Government/foundation funding to support long-term clinical trials with hard clinical endpoints devoid of industry influence and bias
- Renewed emphasis on practicing evidence-based medical management
- Evidence-based reimbursement as the principal driver of quality

Evidence-Based Financial Incentives

- Evidence-based reimbursement
- Evidence-based discounting
- Evidence-based patient rewards

Evidence-Based Financial Incentives

- Evidence-based reimbursement
  - Diagnosis-related payment
  - On-label vs Off-label
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Evidence-Based Financial Incentives

- Evidence-based reimbursement
  - Diagnosis-related payment
  - On-label vs Off-label
- Evidence-based discounting
  - YESCOR vs NOCOR
  - YESTRIL vs YESCOR
- Evidence-based patient rewards
  - Good patient discounts
  - Health insurance rebates

Future Agenda: A Partnership Among Physicians, Payers, Government and Industry to Advance Quality

1. Quantitative measures of evidence
2. Consistent standards of quality
3. Appropriate definitions of benefit
4. Effective economic incentives
5. Continuous feedback and improvement