

From PTCA to TAVR: Have We Fulfilled Gruentzig's Dream?

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Disclosure Statement of Financial Interest IHS 2013; Jerusalem, Israel

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Within the past 12 months, I or my spouse/partner have had a financial interest/arrangement or affiliation with the organization(s) listed below.

Affiliation/Financial Relationship

- Grant/Research Support
- Consulting Fees/Honoraria
- Major Stock Shareholder/Equity

Company

- Abbott, Boston Scientific, Edwards Lifesciences, Medtronic
- Meril Lifescience, Angioscore, Micell, Symetis
- Caliber, Sadra, Claret, Coherex, Medinol, Valve Medical, Backbeat, Impulse Dynamic, Angiometrix, GDS, Mitralign, Apica

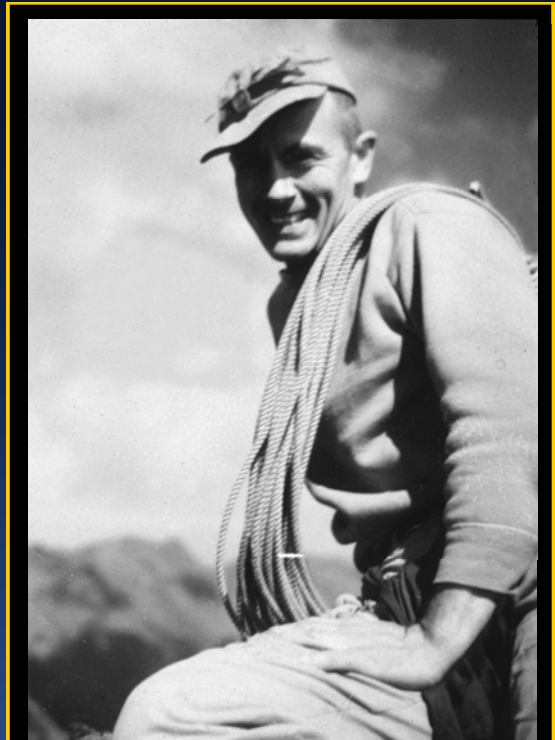
The Early Pioneers



Forsmann

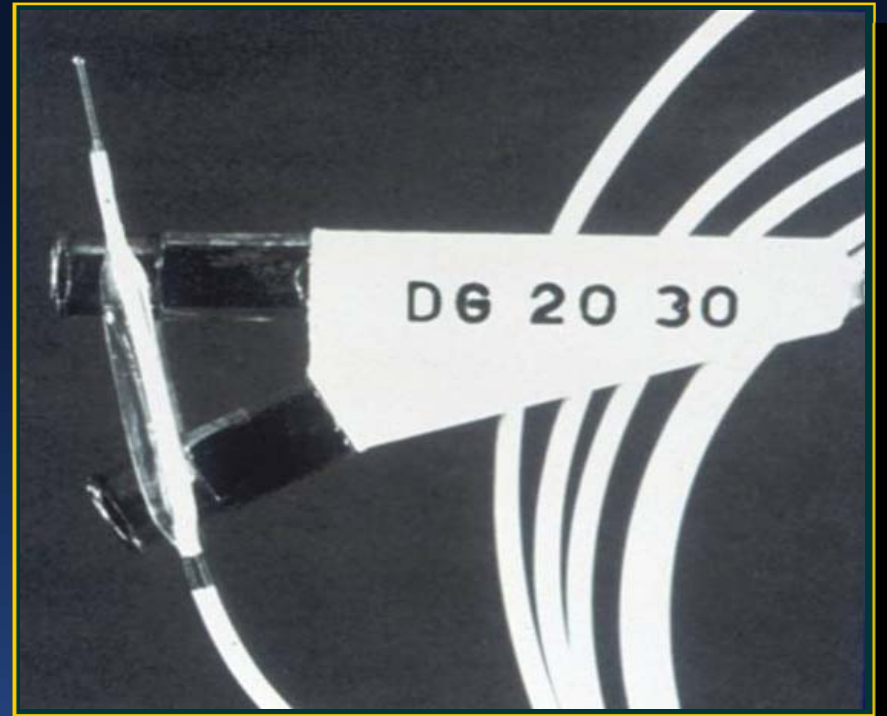


Sones

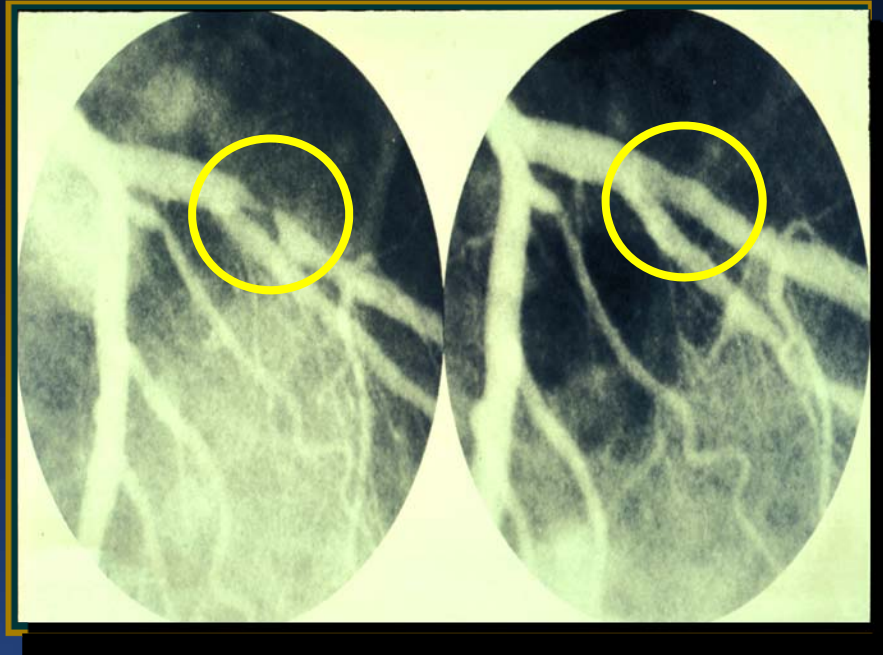


Dotter

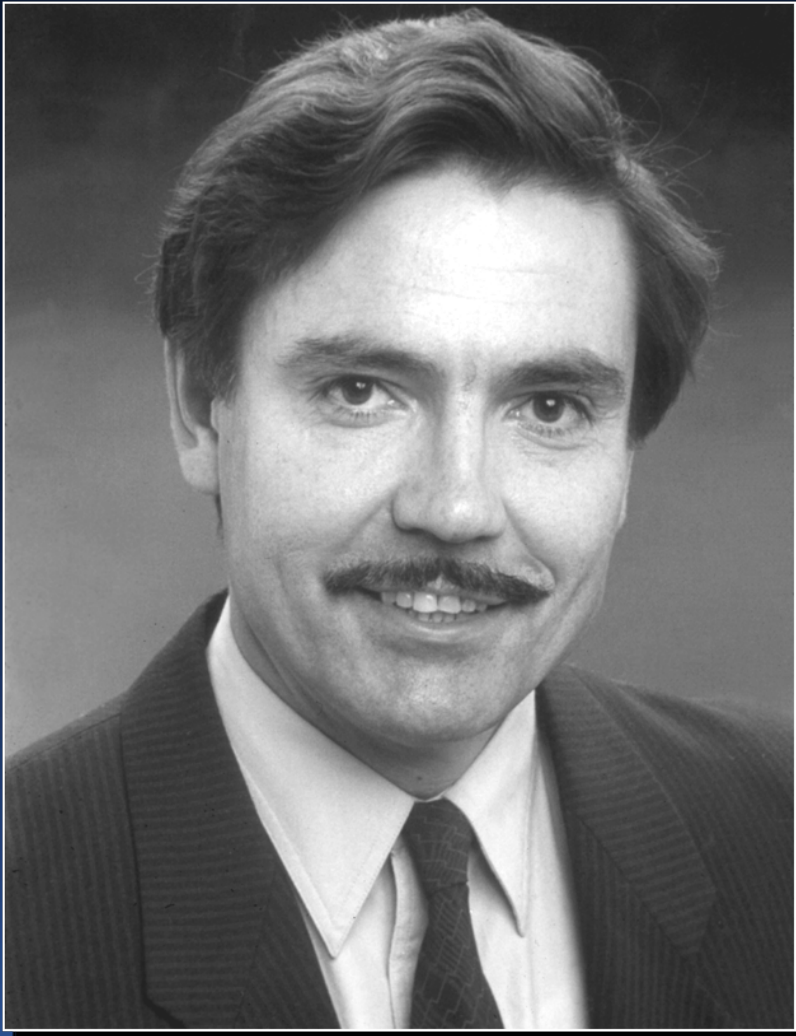
Andreas' Tools



Andreas' Results



The Founder of PTCA!



**Andreas Gruentzig
1939 - 1985**

***His dream was the
catheter-based
percutaneous
treatment of vascular
disease in alert, awake
patients!***

Gruentzig's PTCA Principles...

- **SAFE** - minimize major complications (including abrupt closure and need for surgical backup)
- **PREDICTABLE** - consistent procedural results (in all lesions and all patients)
- **APPROPRIATE APPLICATION** - (1) only treat clinically significant lesions (e.g. measure trans-lesion gradients); (2) conservative expansion from simple to more complex lesion subsets
- **DEFINITIVE OUTCOMES** - (1) optimize acute angiographic results; (2) minimize restenosis
- **EVIDENCE-BASED MEDICINE** - committed to rigorous clinical research to identify complications and justify clinical applications (e,g, NHLBI PTCA Registry)

Gruentzig's PTCA Principles...

- **TECHNOLOGY INNOVATION** - relentless effort to improve all aspects of interventional device technology, advanced angiographic imaging, and cath lab milieu
- **MULTI-DISCIPLINARY APPROACH** - apply principle of less-invasive catheter-based treatment of remote lesions across different vascular beds and by different subspecialty therapists (ie. training and commitment overrides territorial specialist considerations)

From PTCA to TAVR

PTCA and Early Stents

The Saga of Balloon Angioplasty

- ✓ Frequent dissections, recoil and poor angiographic outcomes
- ✓ Acute closure (surgical backup required)
- ✓ Ineffective in calcified (and other) lesions
- ✓ RESTENOSIS!!!

Not Good Enough!

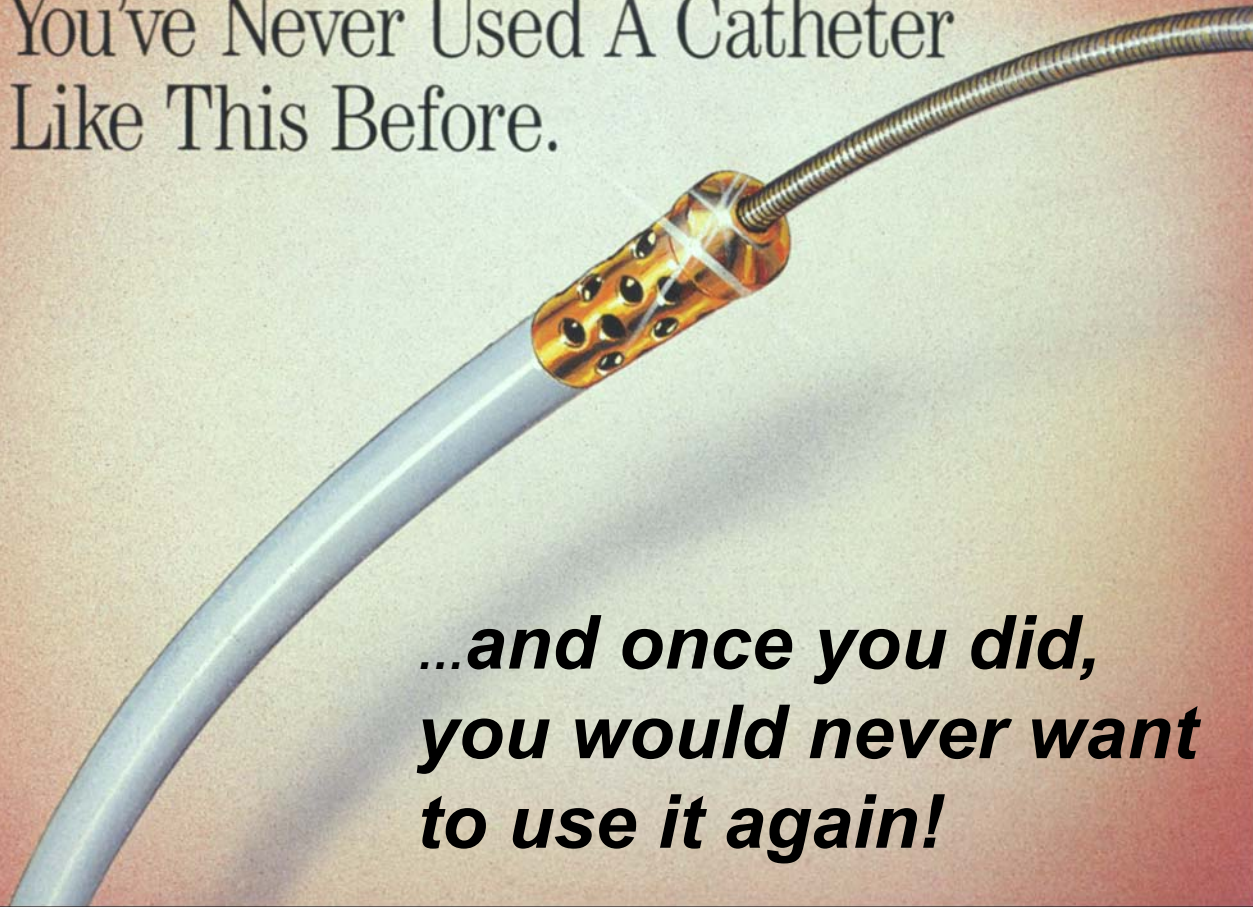


The “New Device” Era

- ***Laser Angioplasty***
- ***Atherectomy*** (directional, rotational, and extraction)
- ***Stents*** (the early days)

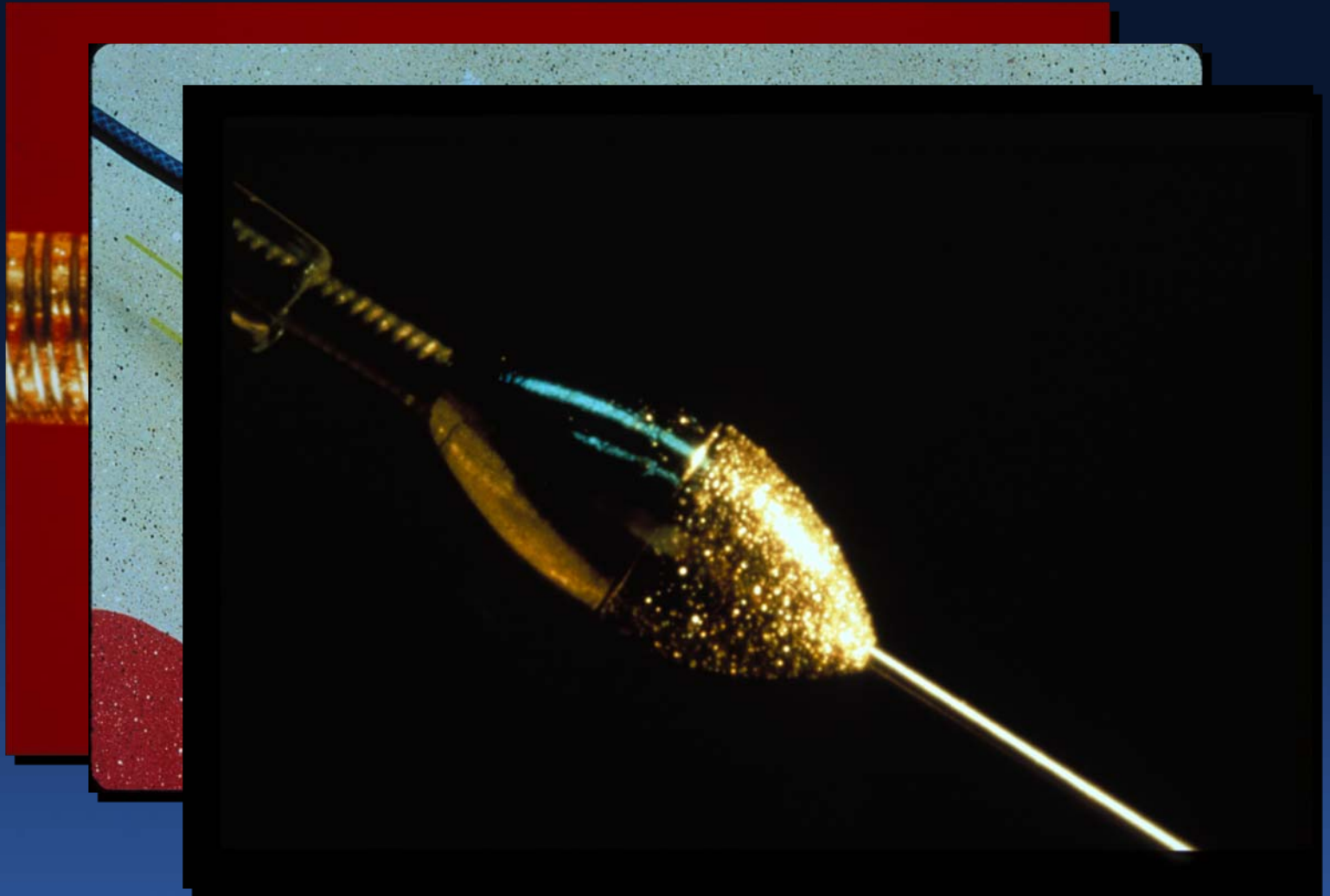
Laser “Hot Tip” Catheter

You've Never Used A Catheter
Like This Before.



*...and once you did,
you would never want
to use it again!*

Coronary Atherectomy



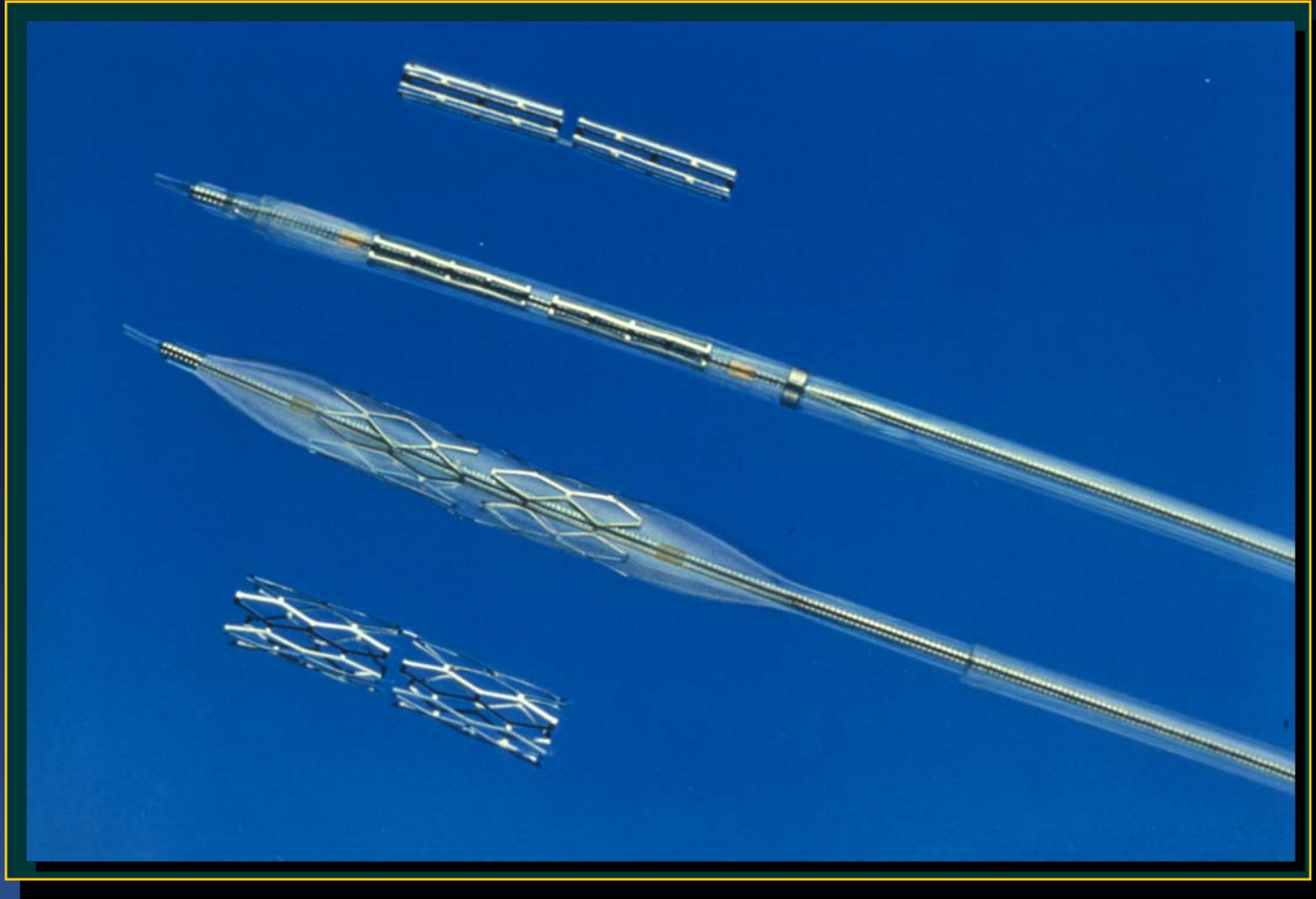
“New Device” Angioplasty Arrives

- ✓ *Frequent complications (incl. perforations)*
- ✓ *Some improvement in complex lesion subsets (e.g. calcified)*
- ✓ *Greater operator expertise required and more costly*
- ✓ **HIGHER RESTENOSIS!!!**

Still Not Good Enough!



The Palmaz-Schatz Stent



An Endovascular Scaffold



Early Days of Coronary Stents



First Palmaz-Schatz Stent in Human
December 31st, 1987

BENESTENT I

***Patients with new lesions in native
coronary arteries $\geq 3.0\text{mm}$
 $n = 516$***

Randomization

***Elective PTCA
with stent
bailout
($n = 257$)***

***Elective
P-S Stent
($n = 259$)***

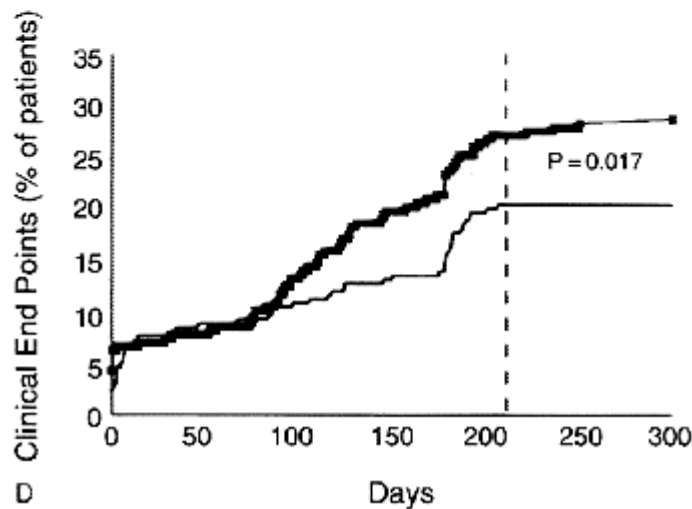
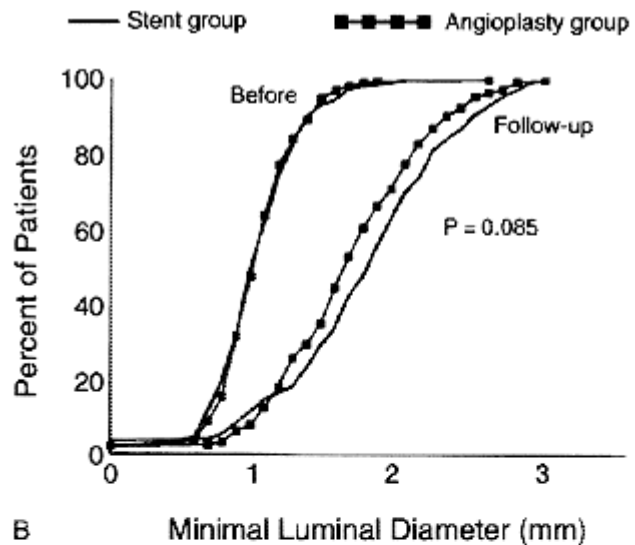
Serruys et al. NEJM;331:489, 1994

BENESTENT I

% Frequency

40
30
20
10
0

Ang



Serruys et al. NEJM;331:489, 1994

STRESS I & II Trials

*Patients with new lesions in
native coronary arteries $\geq 3.0\text{mm}$
 $n = 596$*

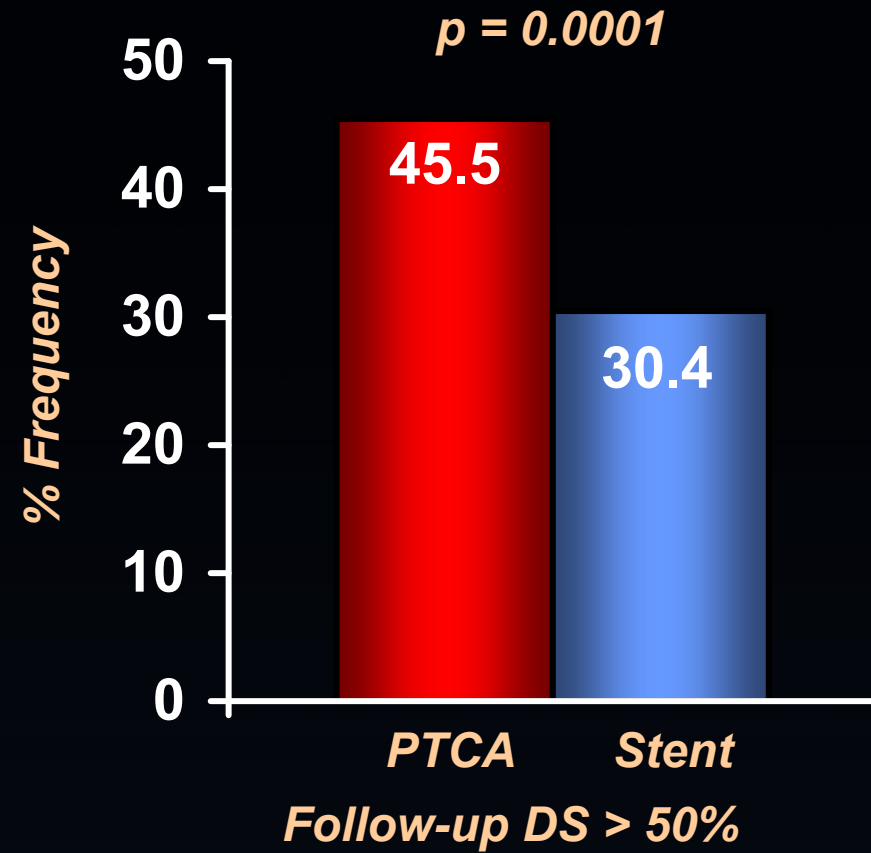
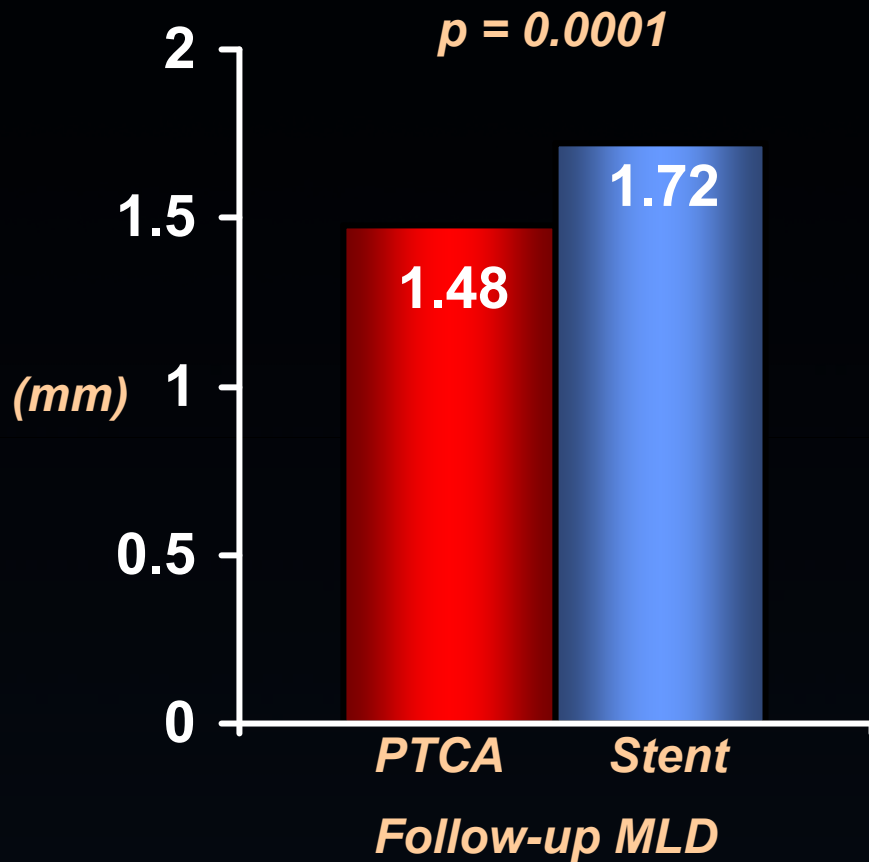
Randomization

*Elective PTCA
with stent
bailout
($n = 291$)*

*Elective
P-S Stent
($n = 305$)*

Late Clinical Outcomes: STRESS I + II

Follow-up Angiographic Findings n = 596



Finally, after 6 agonizing years of clinical studies



...and we're off and running!

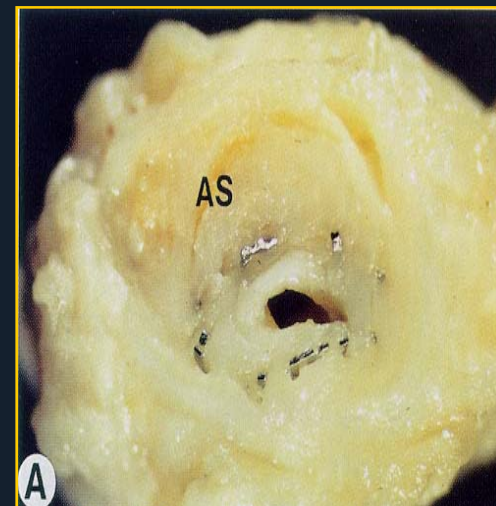
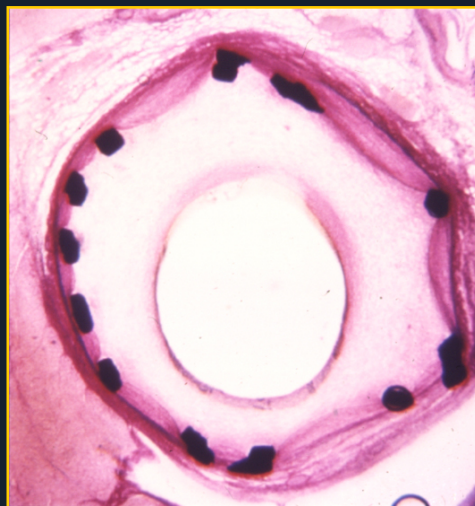
The Age of Empiricism

- In the early days of balloon PTCA (1977) thru the new device era, the determination of “clinical value” was assessed via case experiences, by “word of mouth”, and non-rigorous observational studies.
- This “pseudo-surgical” approach resulted in overly simplistic and often incorrect impressions of many interventional device therapies.
- The FDA-approval of the Palmaz-Schatz coronary stent (1994), based upon randomized controlled trials (BENESTENT and STRESS), ushered a new era of evidence-based medicine in interventional cardiology!

From PTCA to TAVR

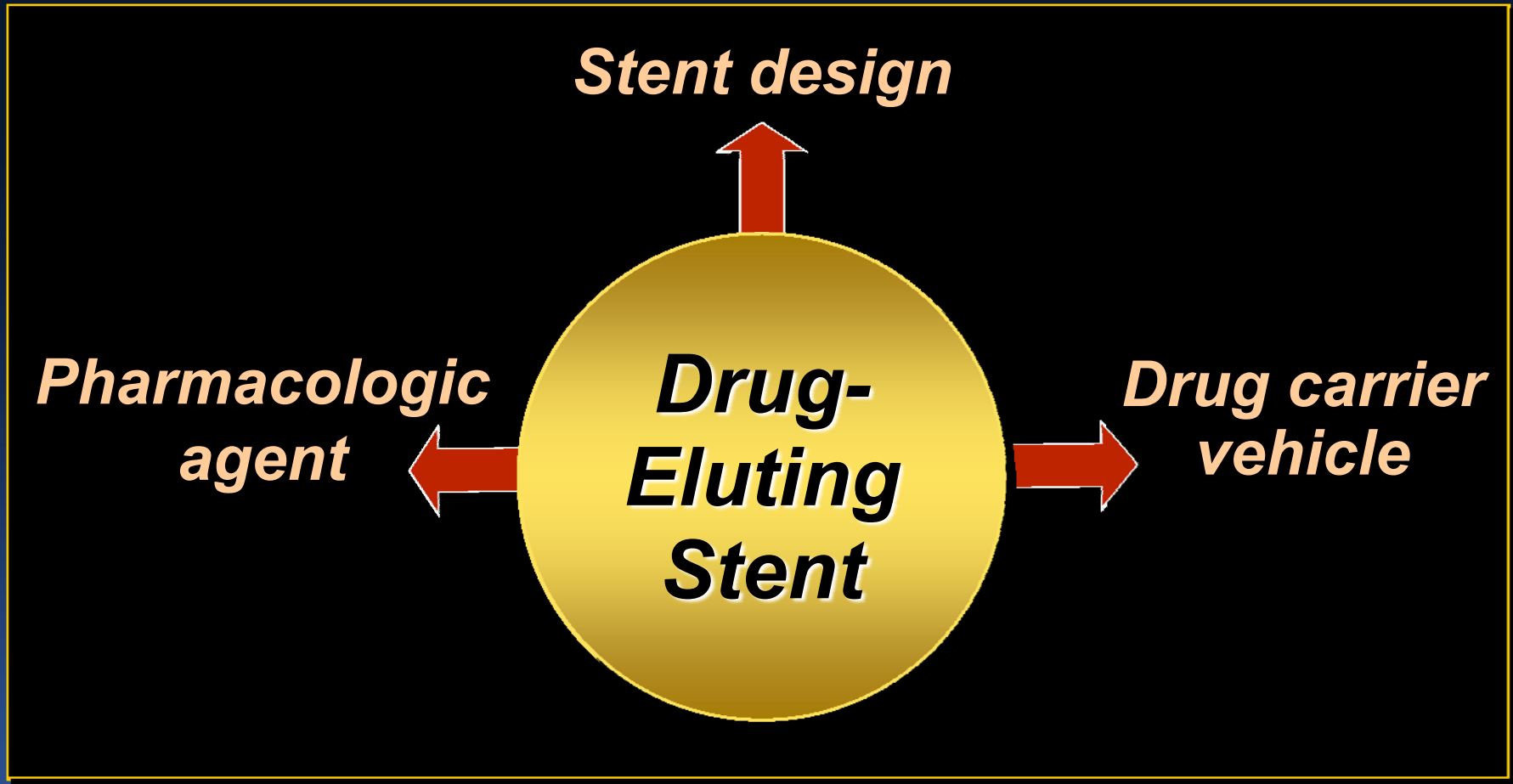
The DES Era

Bare Metal Stents.... the good, the bad, and the ugly!



Drug-Eluting Stents

Advanced Biotechnology Platform



First Generation DES

TAXUS

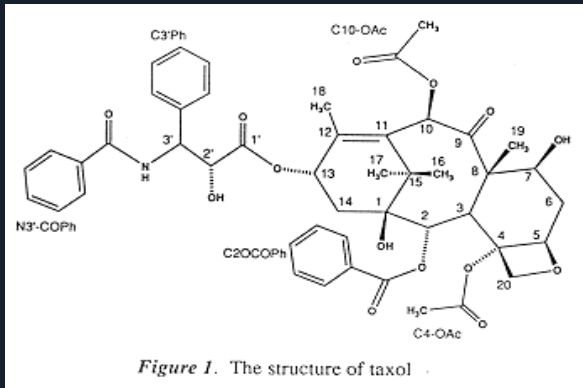
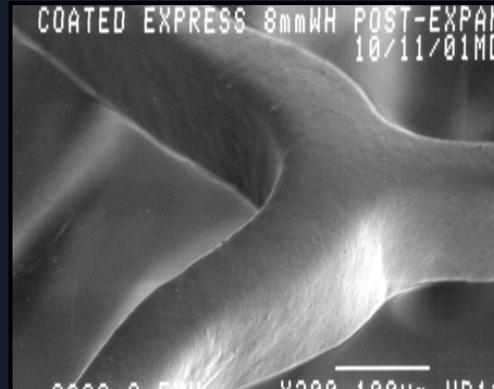
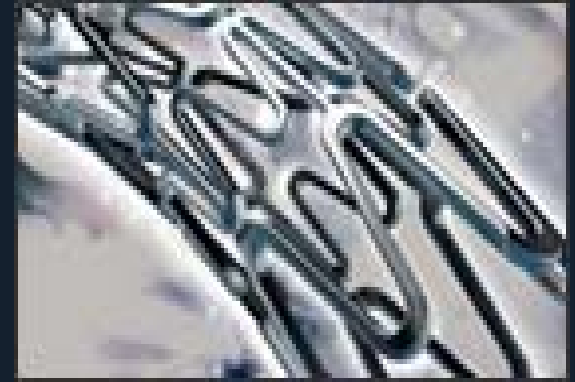


Figure 1. The structure of taxol

Paclitaxel
Drug

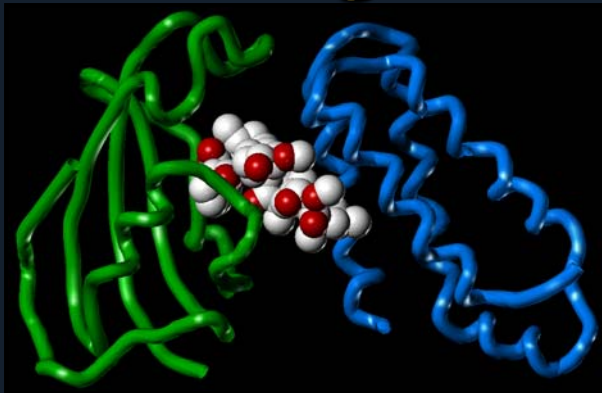


Polyolefin derivative
Polymer

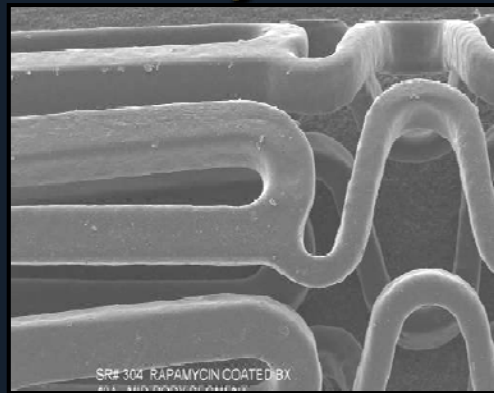


Express²
Stent

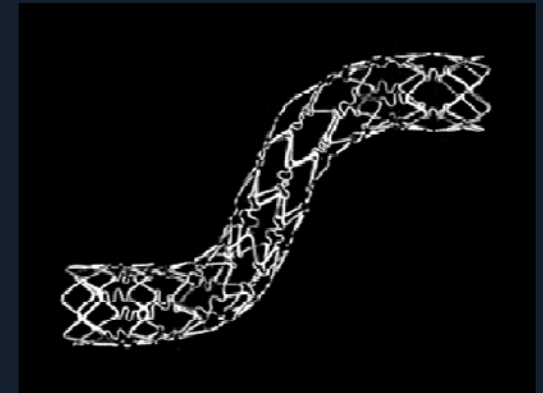
Cypher



Sirolimus

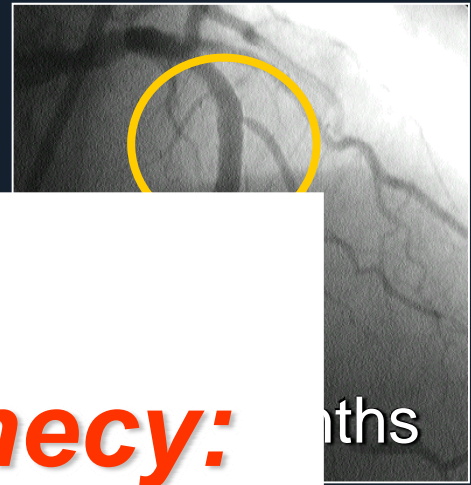
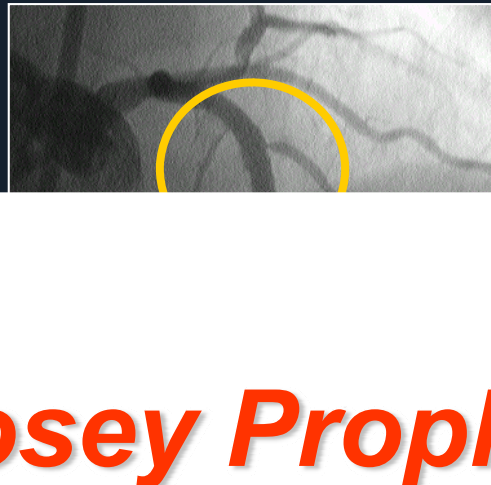
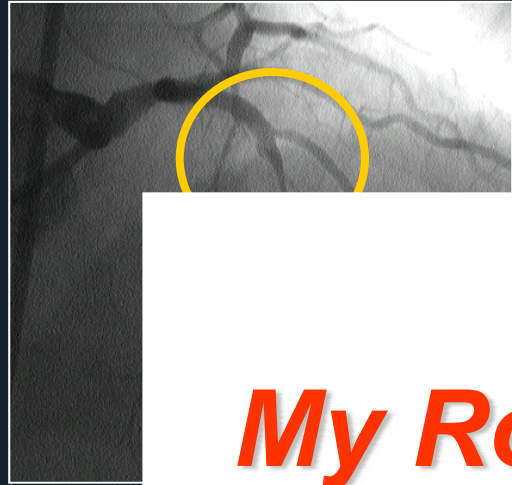


PEVA + PBMA blend



BX Velocity

DES - A Transforming Technology



***My Rosey Prophecy:
Restenosis is CURED!***

12 months

24 months

48 months

First-In-Man study with CYPHER

Sao Paulo, FU completed

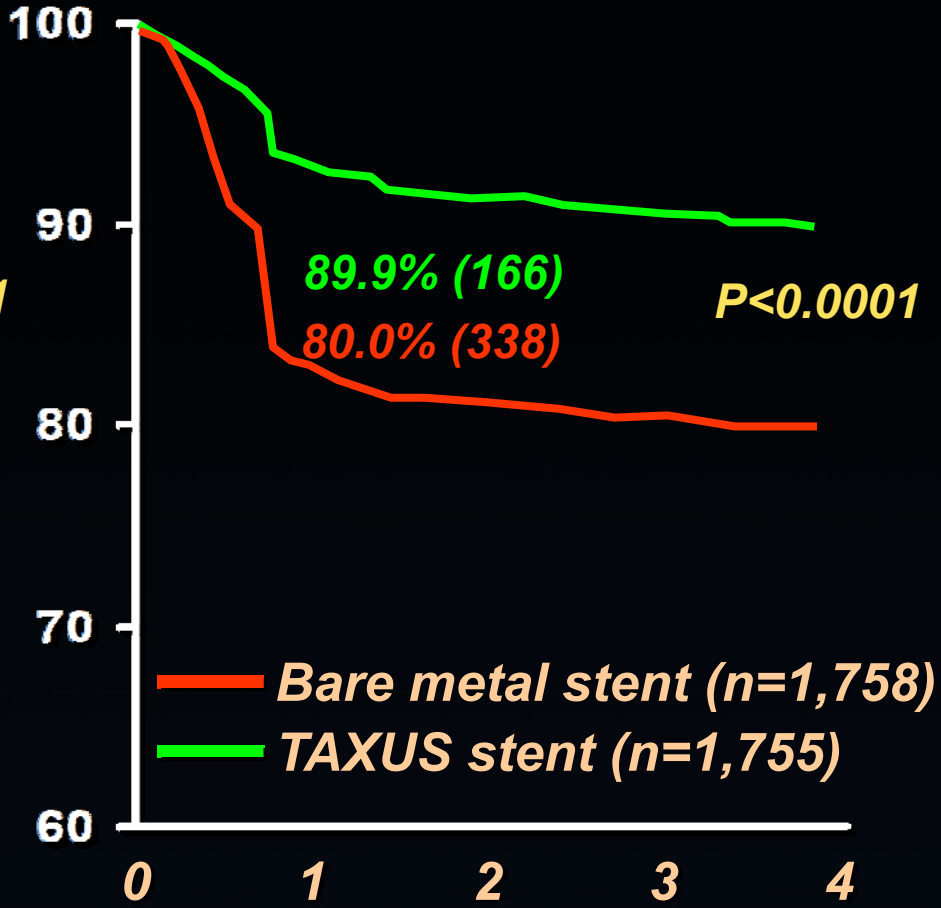
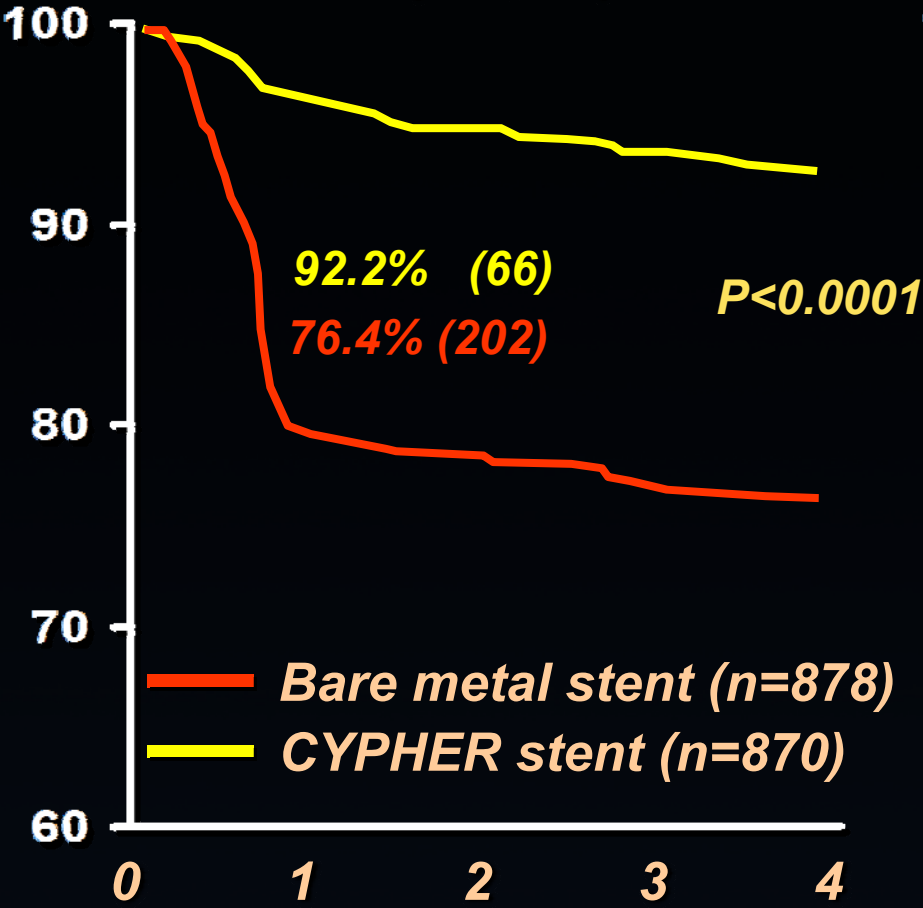


9 Prospective, Double-Blind, Randomized Trials

Freedom From Ischemic TLR

RAVEL, SIRIUS, E-SIRIUS, C-SIRIUS
(n=1,748)

TAXUS I, II, IV, V, VI
(n=3,513)



Time after Initial Procedure (years)

Time after Initial Procedure (years)

The Early Days of DES

Belief, hope, and hyperbole > the evidence

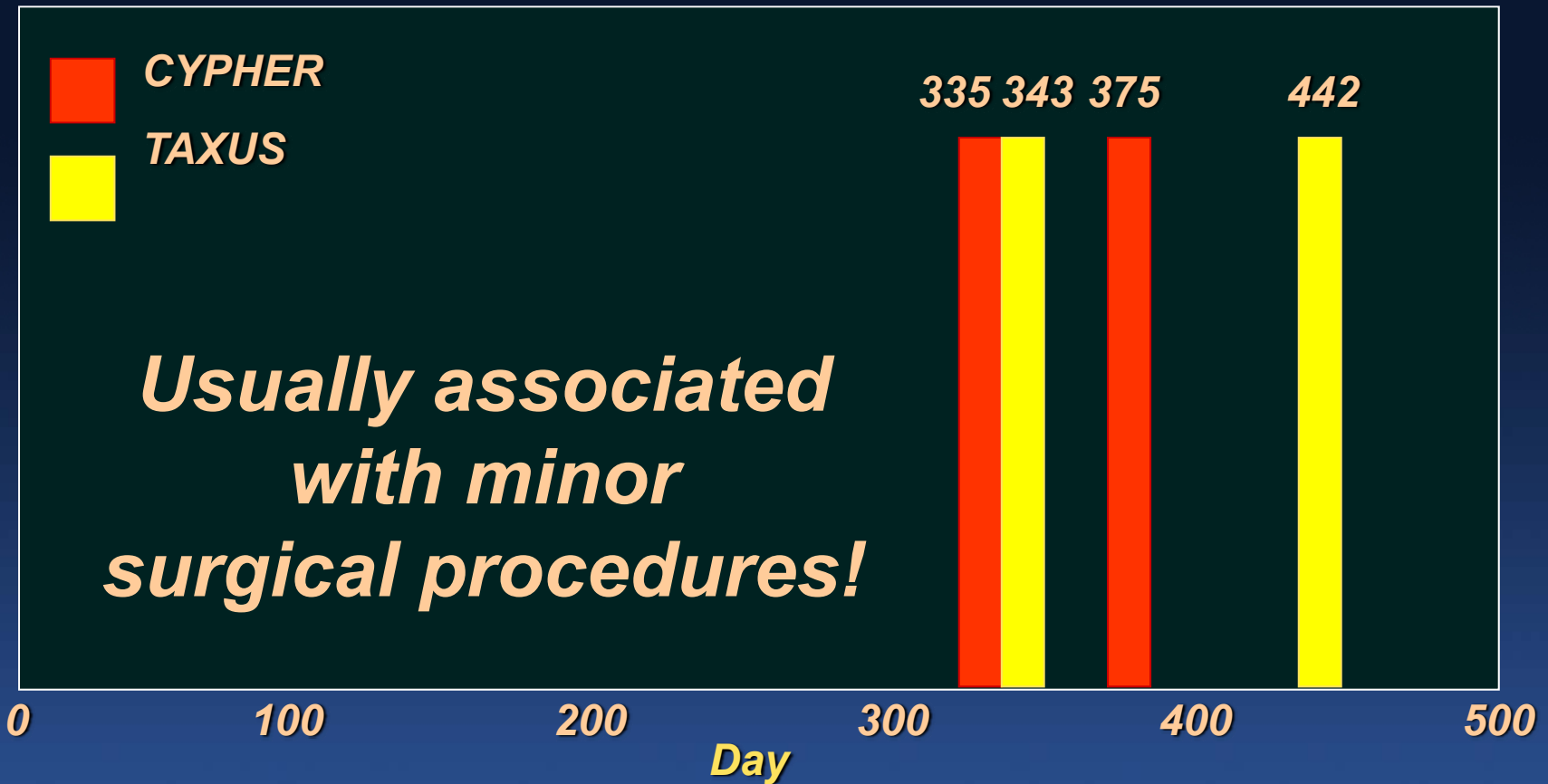
Potential DES over-exuberant use

2002-06 →

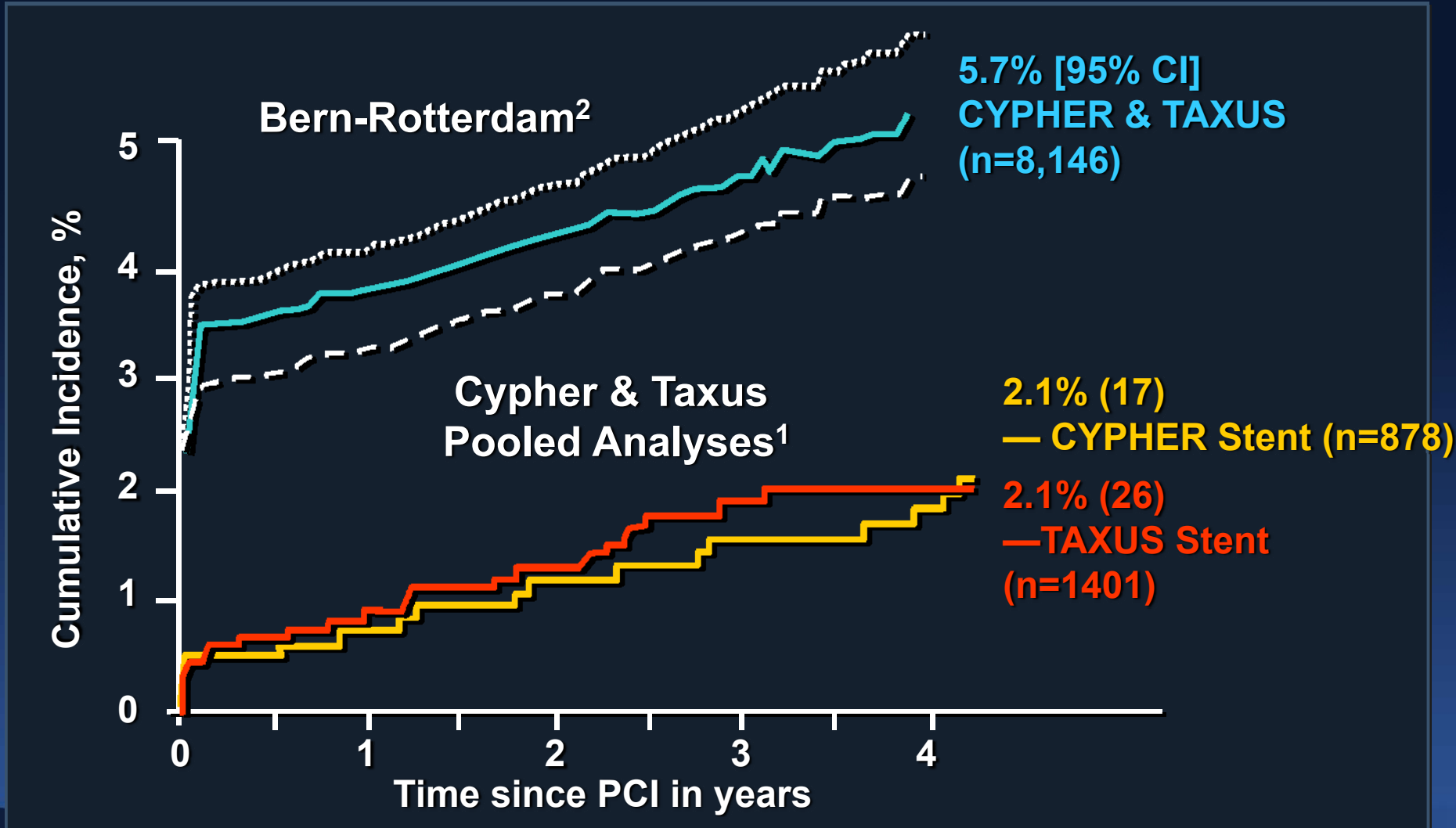
- DES solves restenosis
- Pivotal data look good (safety and efficacy)
- *Maybe they are good for all lesions types and in all patients*

~90%
penetration
(in U.S.)

Late DES thrombosis after discontinuation of antiplatelet therapy



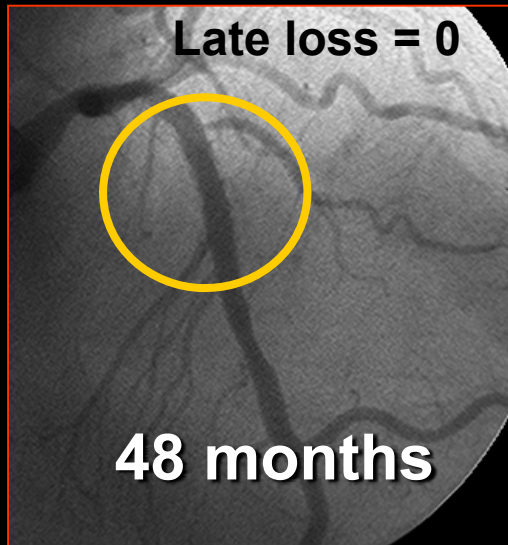
Cumulative Incidence of ARC Def/Prob ST over 4 yrs after DES (CYPHER & TAXUS)



¹ Mauri et al; N Engl J Med 2007;356:1020-9

² Wenaweser et al; J Am Coll Cardiol 2008;52:1134-40

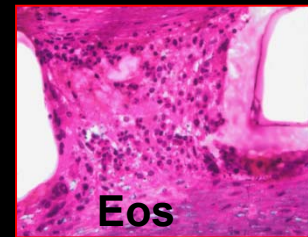
DES....the good, the bad, and the ugly!



Delayed Healing!



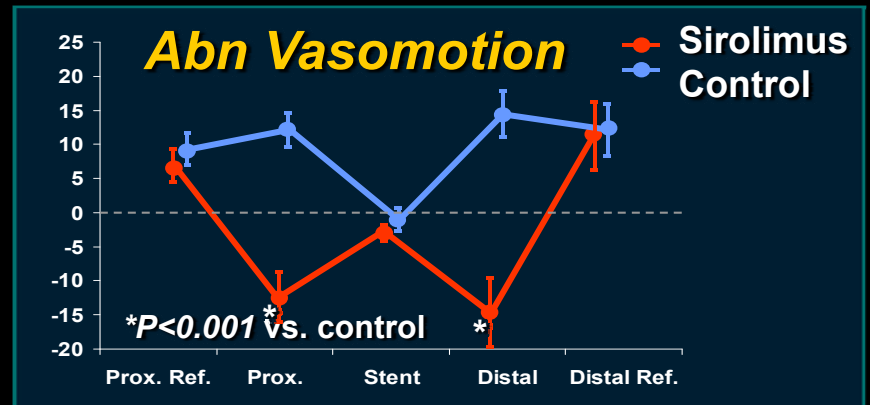
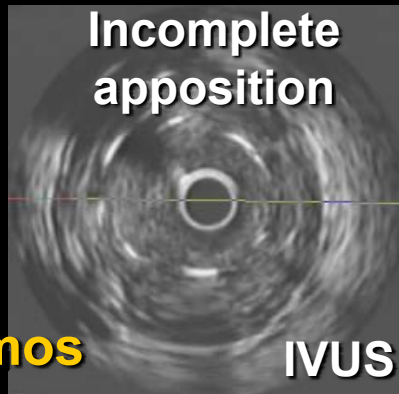
Angioscopy



Inflammation



40 mos



The ESC Firestorm (August '06)

TUESDAY

ESC Congress News



 **WORLD HEART FEDERATION*** **World Congress of Cardiology 2006**
The unique meeting of the European Society of Cardiology Congress 2006
and the World Heart Federation's XVth World Congress of Cardiology 

Do drug-eluting stents increase deaths?

TWO SEPARATE, independent meta-analyses, presented in Hot Line session I, suggest drug-eluting stents (DES) may increase death, Q-wave myocardial infarction (clinical surrogates of in-stent thrombosis) and cancer deaths, bringing the long-term safety of DES firmly into the spotlight. Discussant Salim Yusuf (McMaster University, Canada) hailed the data as one of the most important presentations to come out of this year's meeting.

"Six million people in the world have been implanted with DES, yet their long-term safety and efficacy is unknown," said Yusuf. "I've a feeling the data we're seeing today is only the tip of the iceberg. We need to encourage more public access to the data."



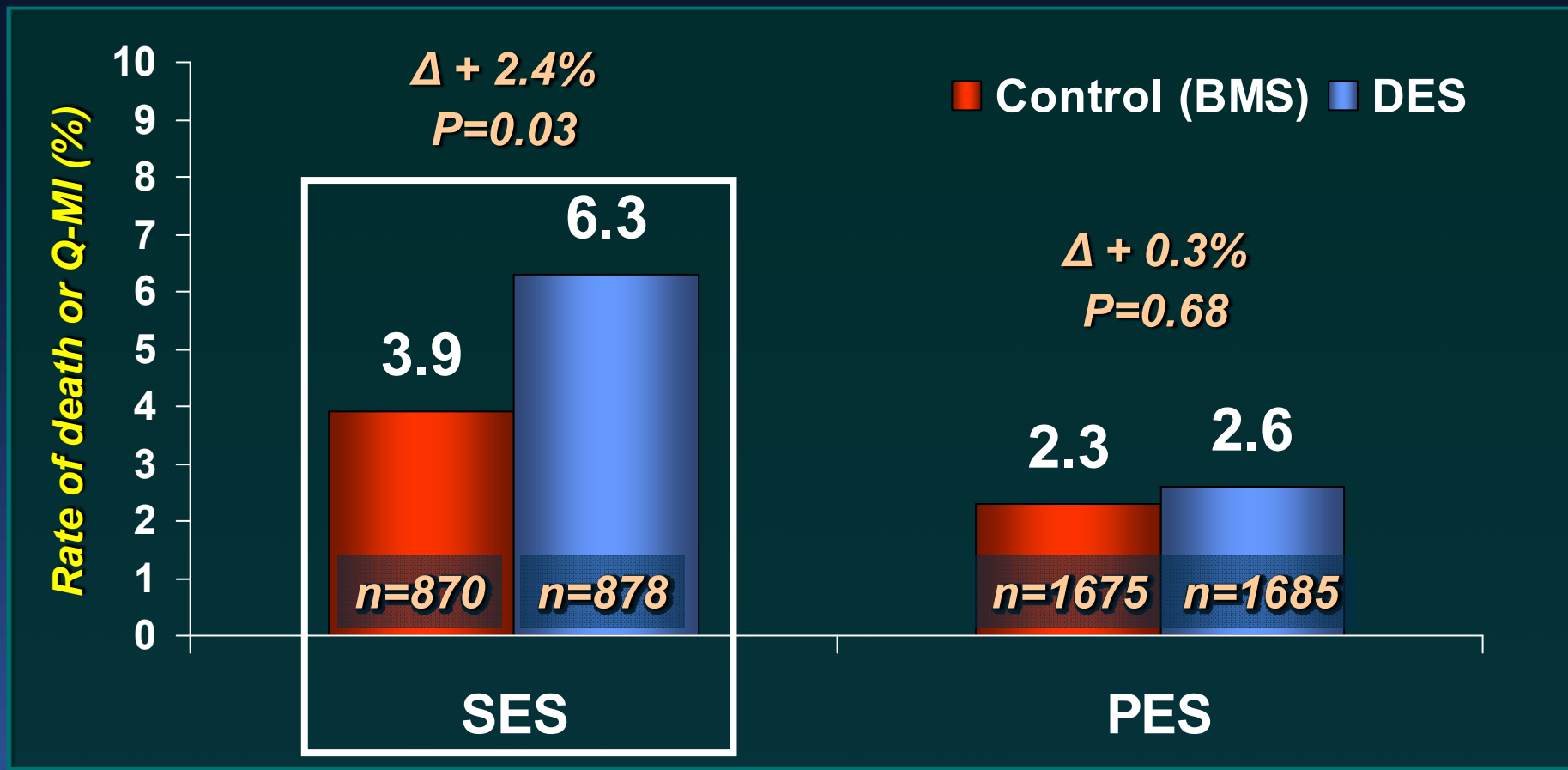
obtain this data from the manufacturer," said Nordmann. He speculated that the increase in cancer might be due to a rapid impairment of the immune system.

Yusuf widened the debate to include percutaneous coronary intervention (PCI). "The overuse of PCI is an insidious change in the culture of cardiology that needs to be reversed," he said. The use of PCI was established in MI, high-risk unstable angina and cardiogenic shock. However, its use in stable disease was a totally different question.

"There's no beneficial influence on mortality – PCI does nothing to prevent heart attack. All we are doing is providing short-term relief of chest pain. It's not re-stenosis that kills but the

Incidence of Serious or Adverse Events Death or Q-Wave MI

All randomized studies up to latest available follow-up



GOOGLE VS. MICROSOFT
THE RACE TO REV UP THE SEARCH ENGINE

America's Largest Private Companies
Howard Stern—Is Anyone Listening?
SCORE! Hockey Is Hot Again

NOVEMBER 27, 2006 | WWW.FORBES.COM

Forbes

STENTS
DEFIBRILLATORS
SPINAL DISCS
ARTIFICIAL KNEES

**Are These
As Safe As
You Think?**

\$4.99 | CANADA \$6.99



**DES =
“a million
ticking time
bombs”**

The Dark Days of DES

*Fear-based avoidance and distortions
> the (true) evidence*

Definite DES under-use

← 2006-07

- DES = ↑ thrombosis and ↑ mortality
- COURAGE drives more medical Rx
- *Maybe DES use should be dramatically reduced*

~60%
(<50% EU)
penetration

DES Clinical Trials

Evidence-Based Medicine

Over 2,500 peer review manuscripts on DES clinical use have been published between 2002 and 2012!

Columbia / CRF DES vs. BMS Meta-Analysis

Interventional Cardiology

Safety and Efficacy of Drug-Eluting and Bare Metal Stents Comprehensive Meta-Analysis of Randomized Trials and Observational Studies

Ajay J. Kirtane, MD, SM; Anuj Gupta, MD; Srinivas Iyengar, MD; Jeffrey W. Moses, MD;
Martin B. Leon, MD; Robert Applegate, MD; Bruce Brodie, MD; Edward Hannan, PhD;
Kishore Harjai, MD; Lisette Okkels Jensen, MD; Seung-Jung Park, MD, PhD; Raphael Perry, MD;
Michael Racz, PhD; Francesco Saia, MD, PhD; Jack V. Tu, MD, PhD; Ron Waksman, MD;
Alexandra J. Lansky, MD; Roxana Mehran, MD; Gregg W. Stone, MD

The “definitive” DES efficacy/safety meta-analysis?

Study Flow Diagram

Pubmed search thru 2/08: stent AND bare AND (eluting OR sirolimus OR paclitaxel)

834 articles

115 no/unclear clinical outcomes described

81 no BMS/DES comparison

84 with <1 year f/u or <100 pts

221 review articles or editorials

104 sub-studies/more recent papers

100 basic science or non-approved device

92 case reports, meta-analyses, non-coronary studies, or other

37 articles

AHA (3/246),

TCT (9/206),

ESC (4/243),

ACC (0/468)

abstracts and reference searches

16 abstracts
met criteria

56 studies

3 articles
met criteria

EuroIntervention search (146 articles)

RCT studies: 22 (9,470 patients)

Registry studies: 34 (182,901 patients)

Summary: DES vs. BMS

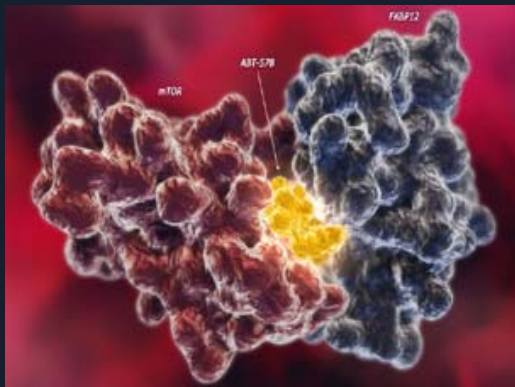
DES Treatment Effect Estimates

***P<0.05**

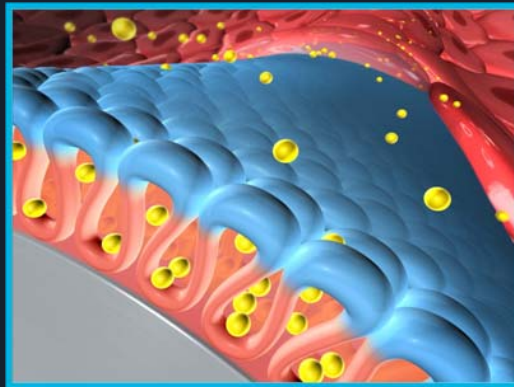
	Mortality	MI	TVR
RCTs	8,867 pts, 21 trials	8,850 pts, 20 trials	7,291 pts, 16 trials
- Fixed effects	3%↓	5%↓	-
- Random effects	-	-	55%↓*
Registries	161,595 pts, 31 studies	130,191 pts, 25 studies	74,154 pts, 18 studies
- Fixed effects	-	-	-
- Random effects	22%↓*	13%↓*	46%↓*

Second Generation DES

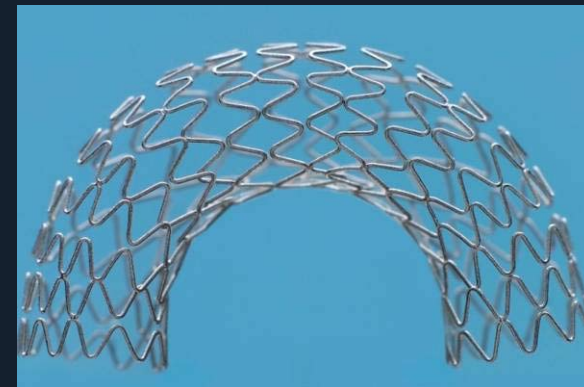
Resolute



Zotarolimus
Drug

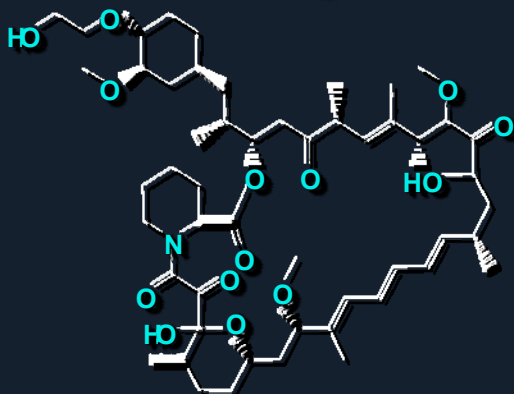


BioLinx copolymer
Polymer



Driver
Stent

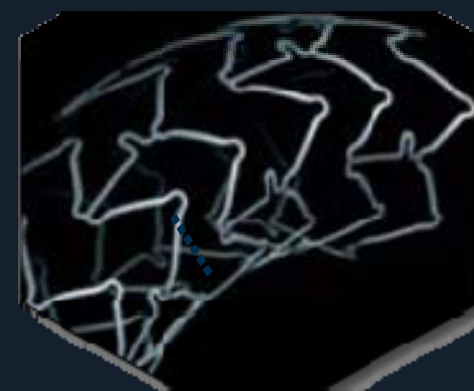
Xience V*



Everolimus



VDF + HFP copolymer



Vision

***AKA Promus**

A Slow Return to DES “Normalcy”

Reliance on overwhelming evidence

Can we regrow the DES forest?

2007 (late) → now

- PCI better for Sx relief and reducing ischemia
- DES doesn't ↑ mortality or MI (on or off-label use) and reduces TVR ~50% (real world)
- *More confident DES use, but with careful DAPT*

~75%
penetration

The Evolution to EBM

- **The transition to evidence-based medicine has distinguished IC as a modern subspecialty, committed to scientific principles and the highest ethical standards of conduct.**
- **Undoubtedly, now and in the future, all new important therapies will require EBM validation, in the form of well conducted clinical trials.**
- **However, EBM is not perfect, and if the data are not interpreted in a balanced fashion, EBM can result in more confusion than clarification!**
- **Other factors beyond EBM must also be heavily weighed to optimize clinical decision-making.**

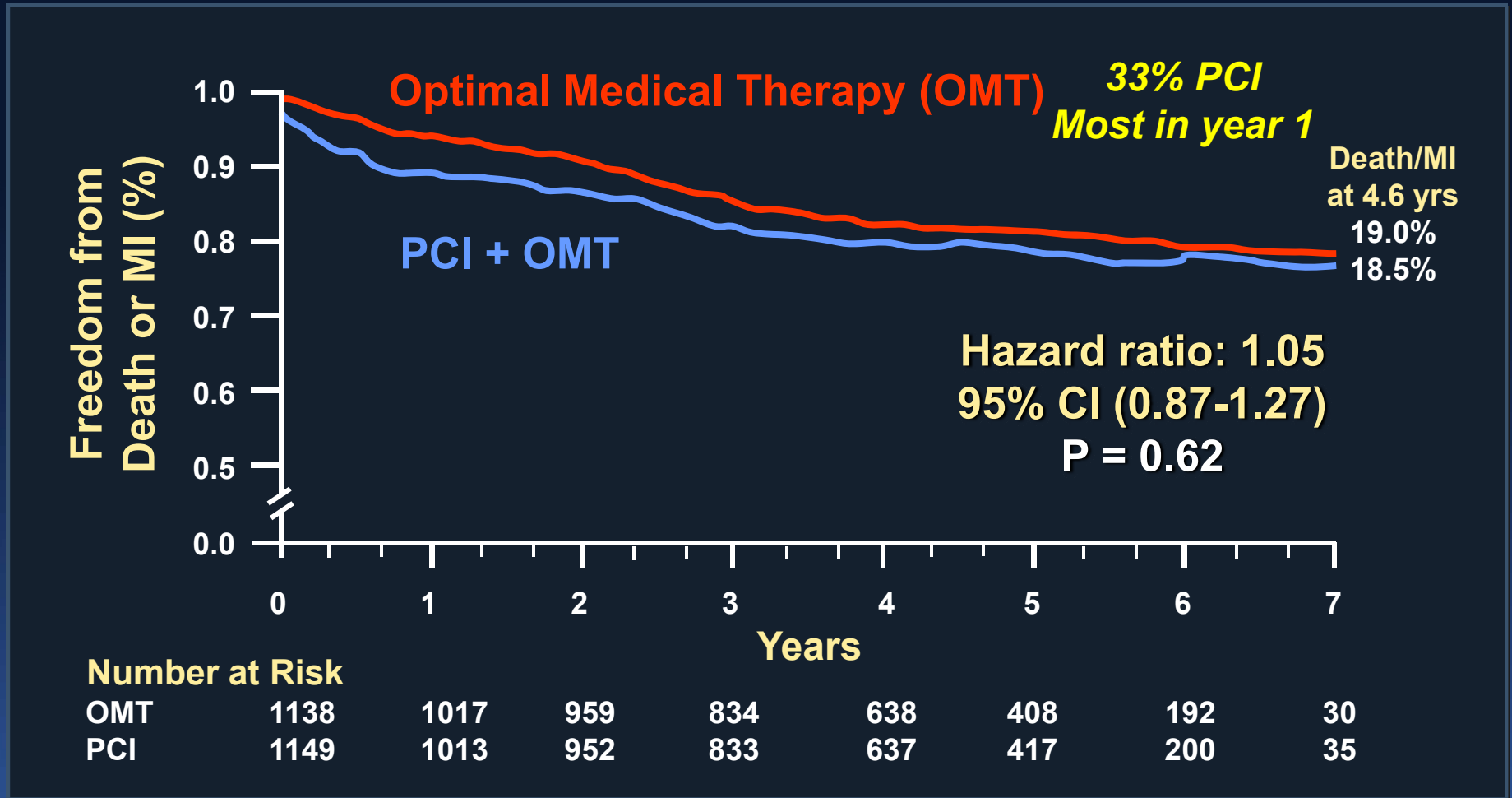
From PTCA to TAVR

Transition to TAVR



PCI in Stable CAD: **COURAGE**

Median FU 4.6 years (n=2,287)

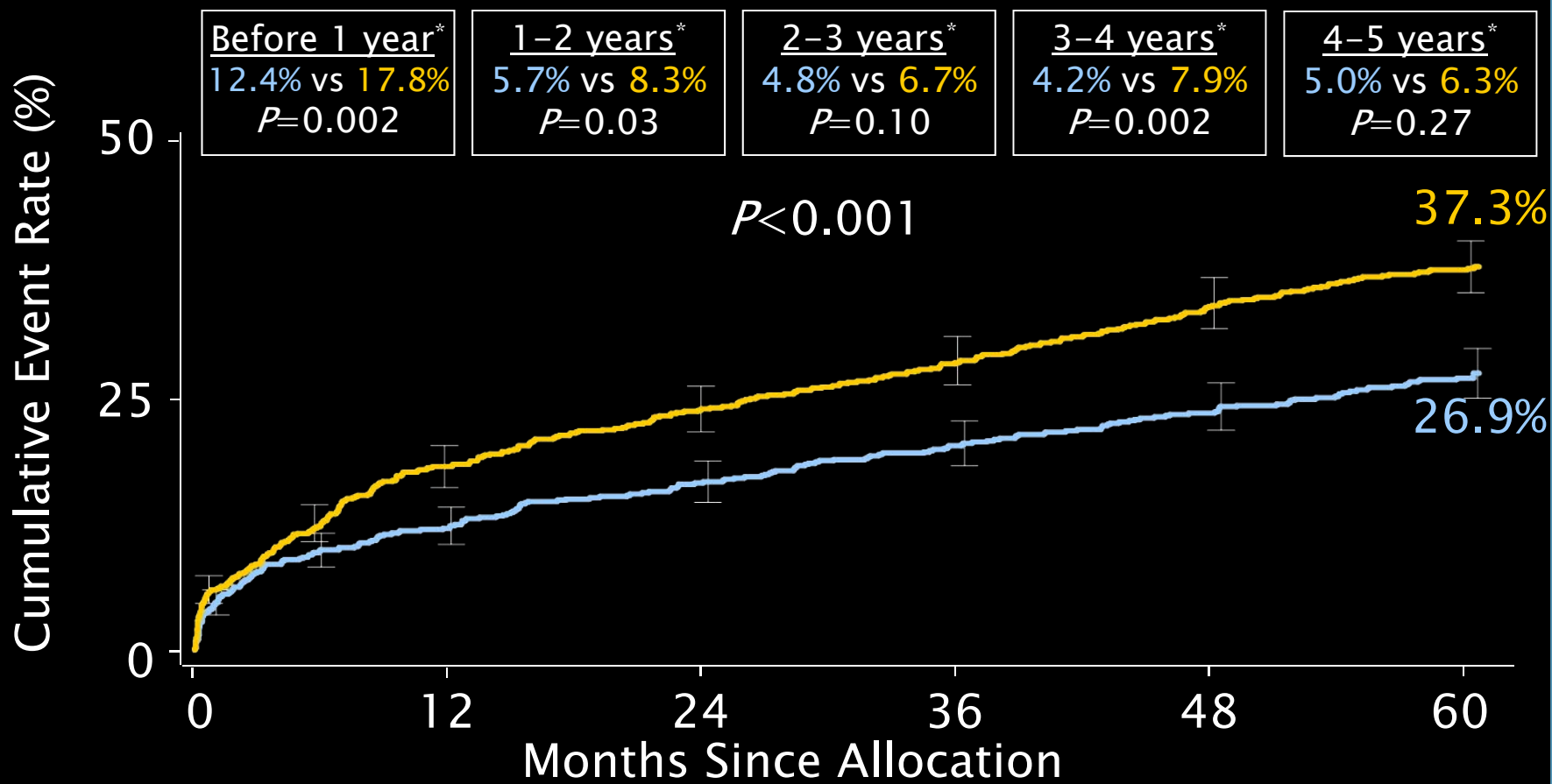


Primary Endpoint MACCE to 5 Years



■ CABG (N=897)

■ TAXUS (N=903)

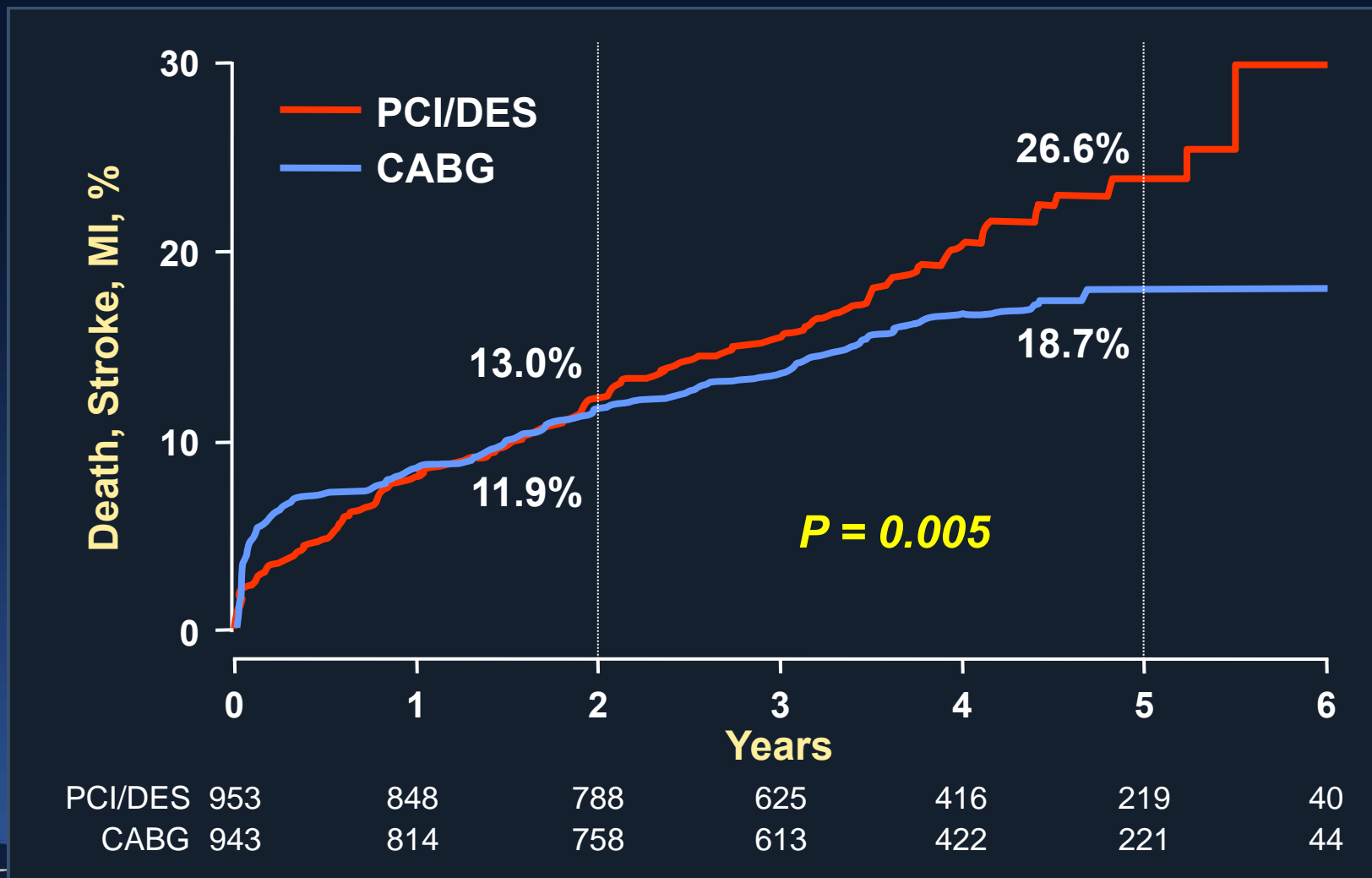


Cumulative KM Event Rate \pm 1.5 SE; log-rank Pvalue; *Binary rates

ITT population



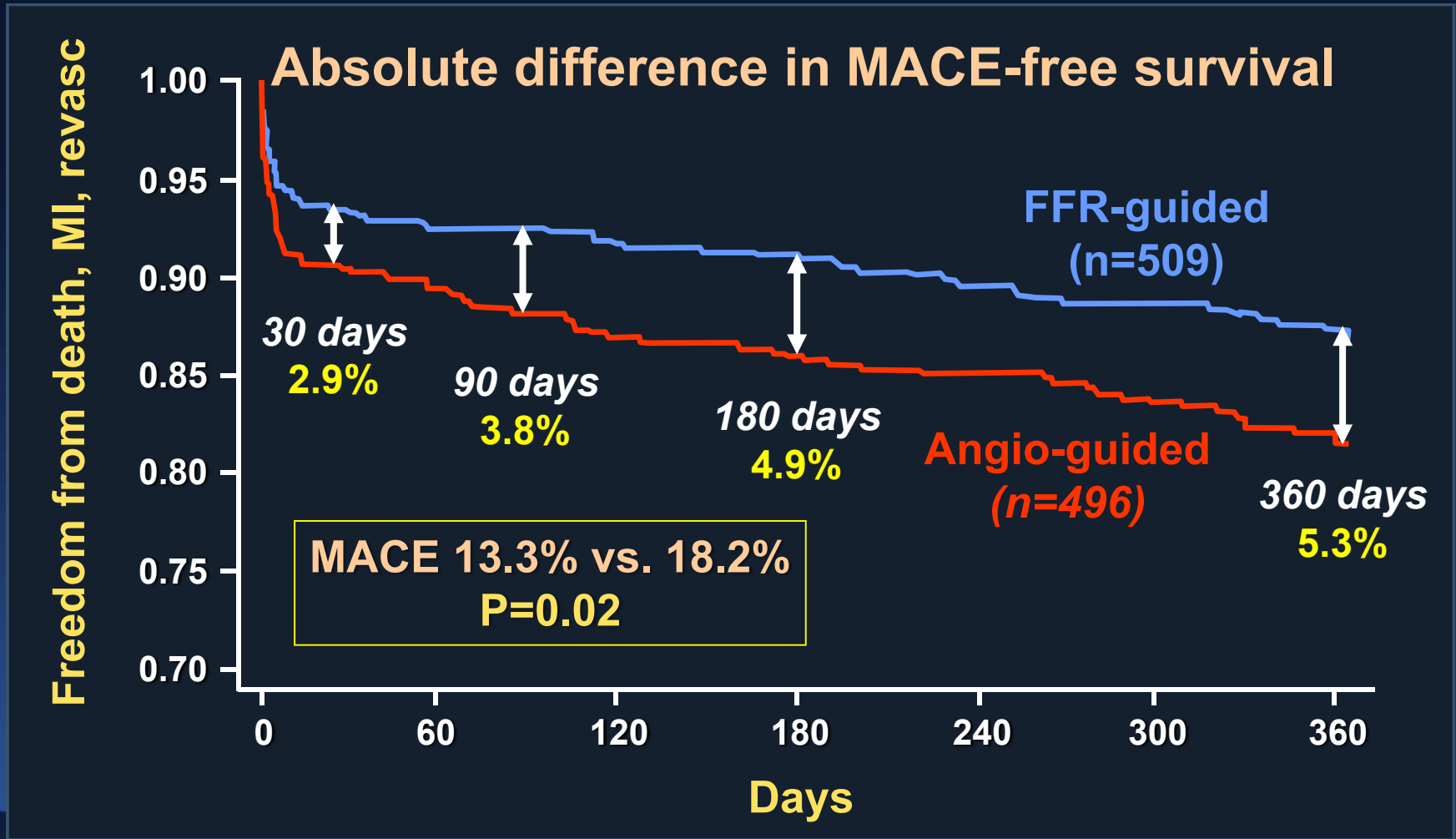
FREEDOM: 1900 pts with diabetes +MVD randomized to SES/PES vs. CABG **1° Endpoint:** Death, Stroke, or MI



FAME: Primary Endpoint

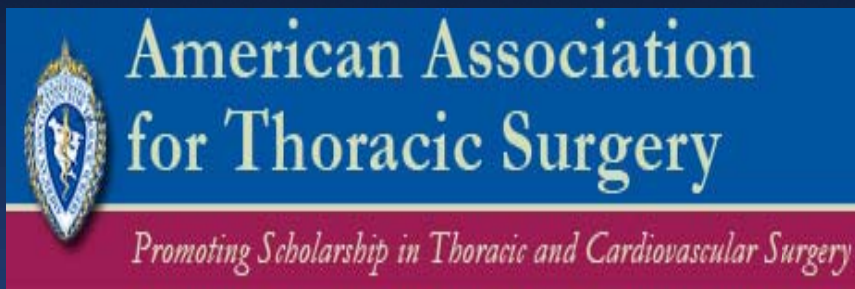
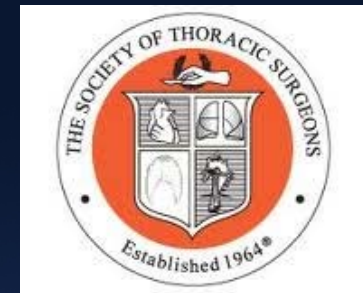


1005 pts with MVD undergoing PCI with DES were randomized to FFR-guided vs. angio-guided intervention

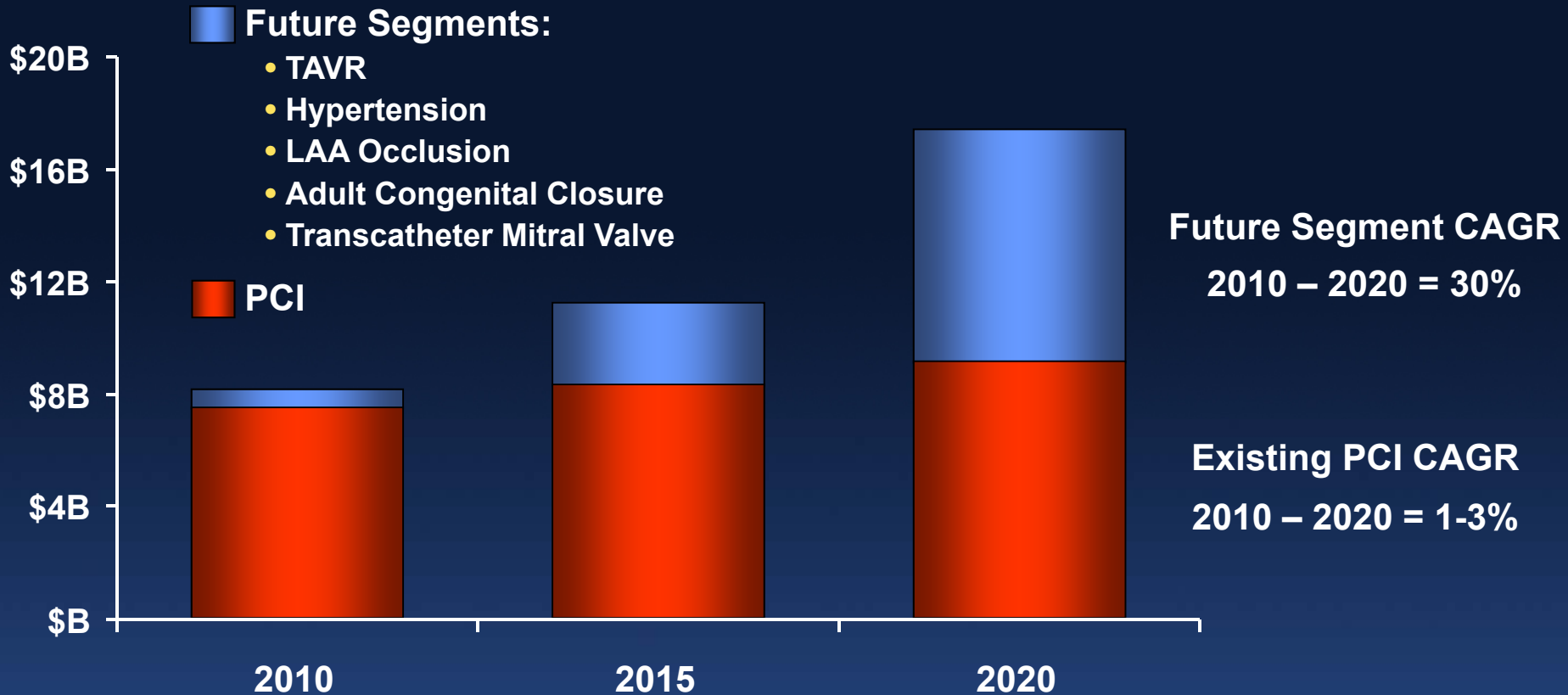


Tonino PAL et al. NEJM 2009;360:213-24

Appropriate Use Criteria for Coronary Revascularization Focused Update 2012



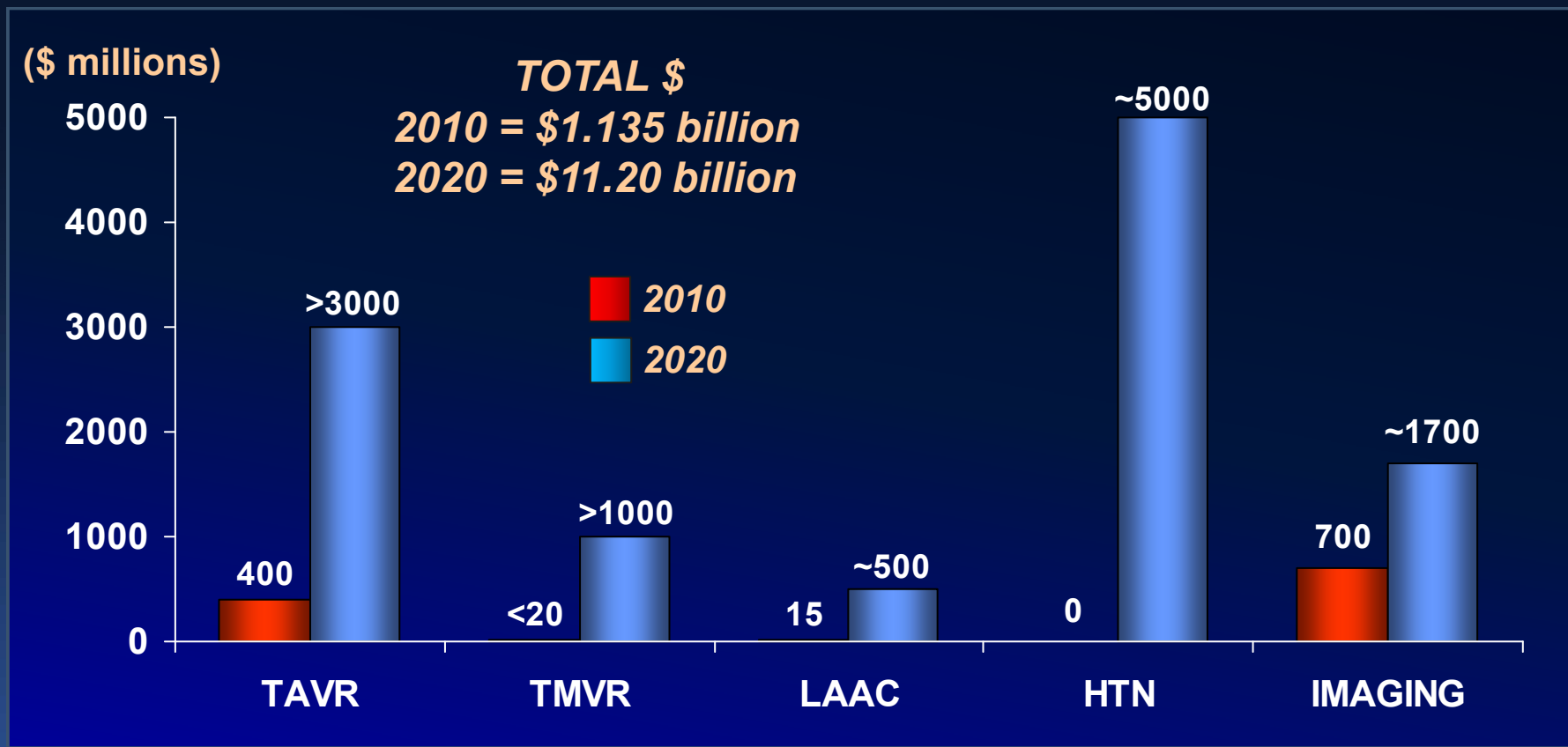
WW Cardiology Market Trends



- New market segments may exceed PCI market size by 2020
- Emergence of future segments relies on technology and clinical data
- OUS markets will lead and exceed the size of US markets

Selected Interventional Growth Markets

Projected Revenue Opportunities (2010-2020)



STRUCTURAL Heart Disease

What is it?

STRUCTURAL heart disease... “wastebasket” term referring to...

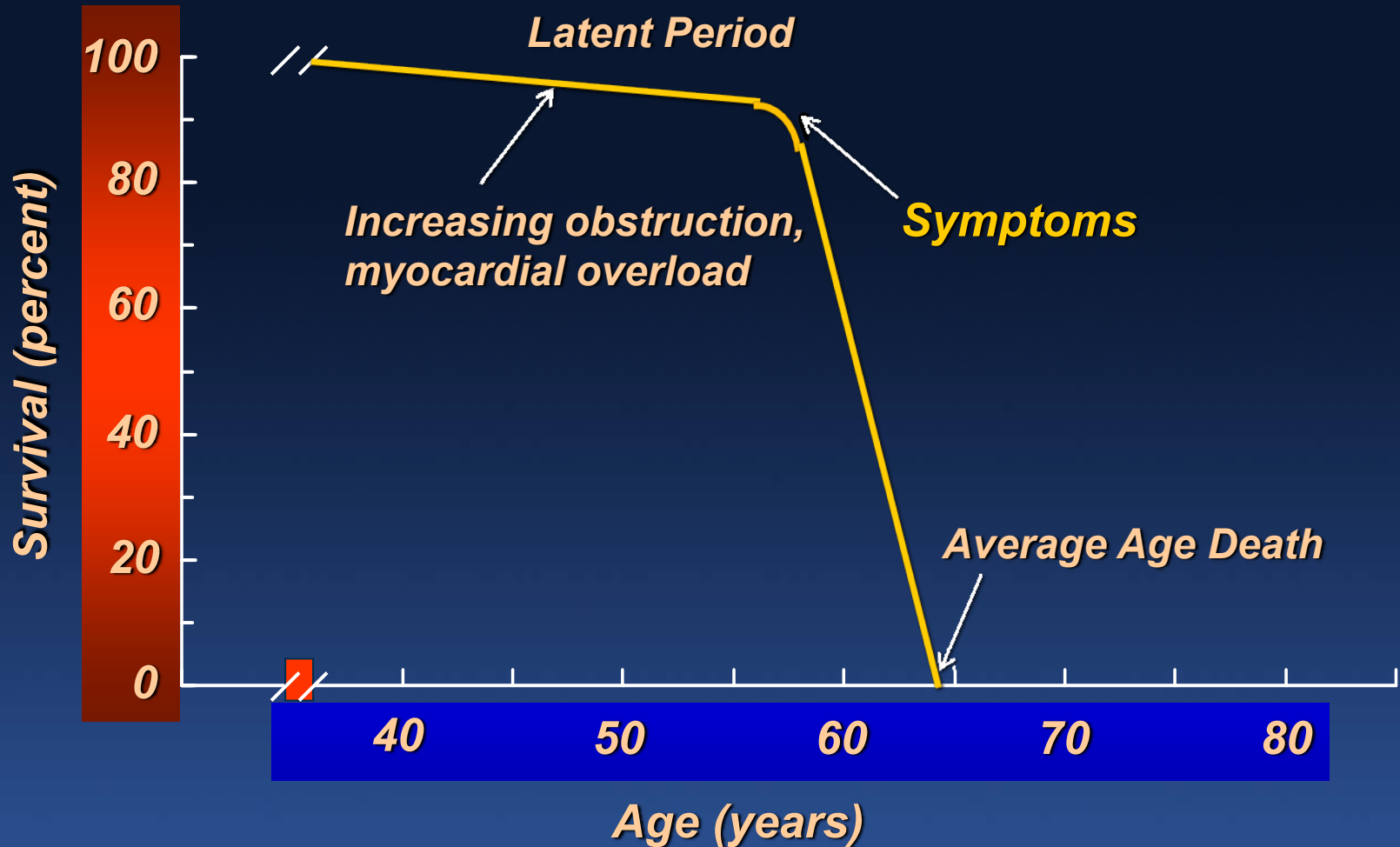
All catheter-based interventional therapies which are not associated with vascular pathology requiring “endoluminal” endovascular treatment.

STRUCTURAL Heart Disease

What is it?

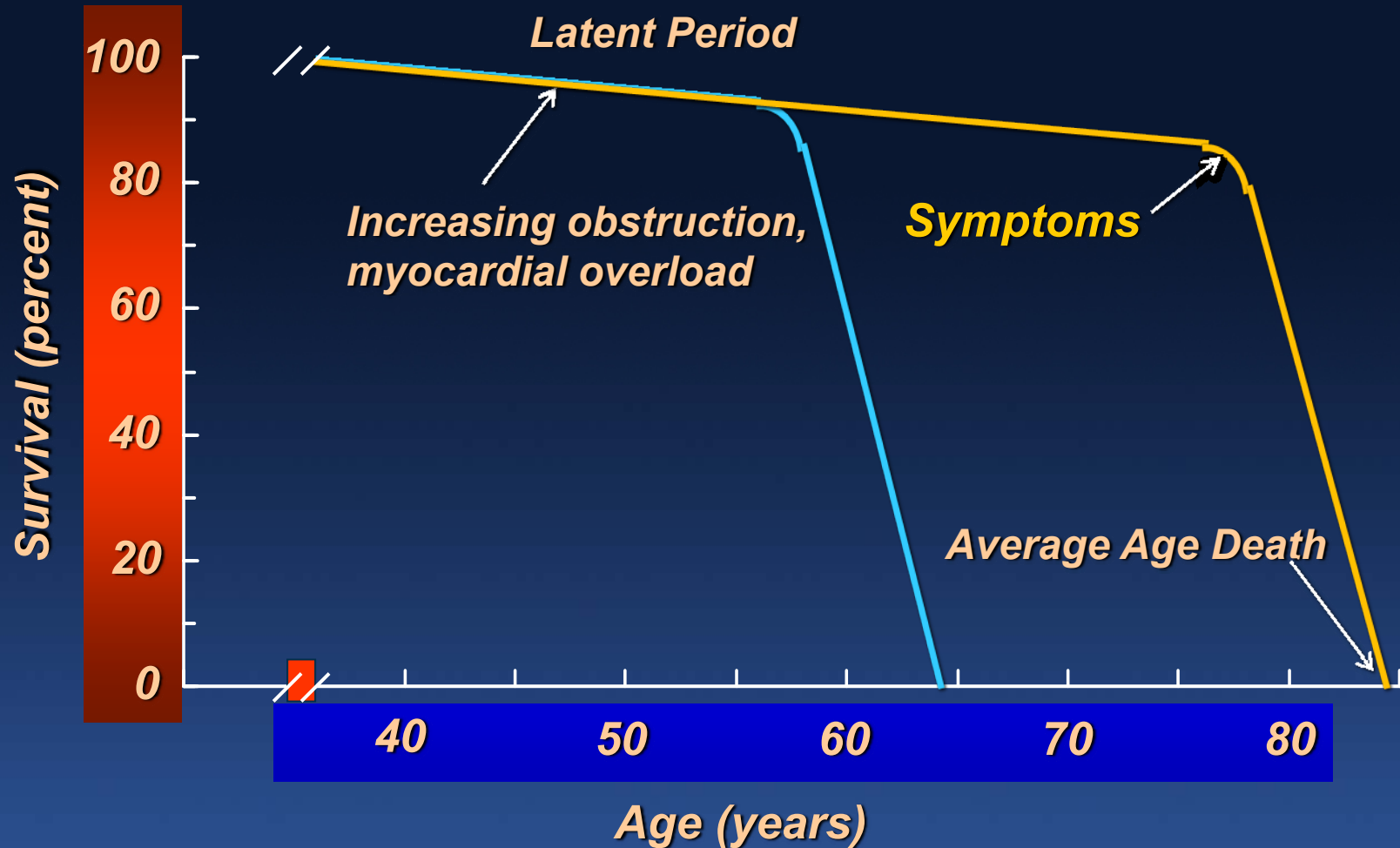
- **Transcatheter valve therapies (esp. aortic and mitral)**
- **Left atrial appendage closure**
- **Adult congenital heart disease**
- **Renal denervation for hypertension (and other sympathetic overdrive syndromes)**
- **Heart failure and advanced hemodynamic support**
- **Out-of-the box concepts (from impotence to obesity to multiple sclerosis)**

Natural History of Aortic Stenosis



from Ross and Braunwald, *Circulation* 1968;38:V-61

Natural History of Aortic Stenosis

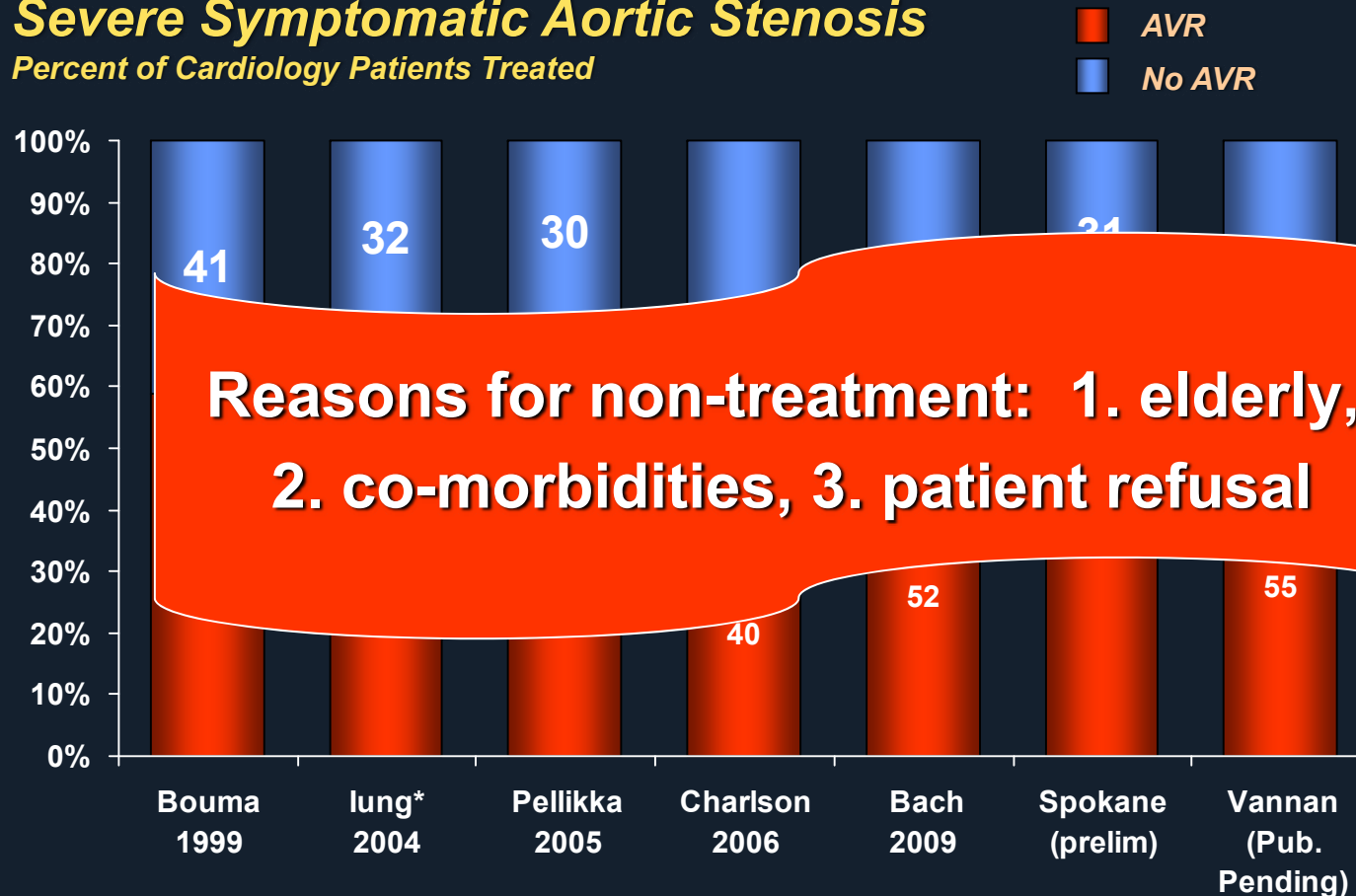


from Ross and Braunwald, *Circulation* 1968;38:V-61

At Least 30% of Patients with Severe Symptomatic AS are “Untreated”!

Severe Symptomatic Aortic Stenosis

Percent of Cardiology Patients Treated



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

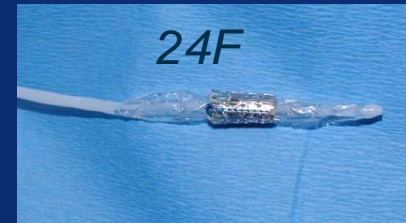
PVT - The Foundation...



Percutaneous Valve Technologies Aortic Heart Valve



Polyurethane



23mm max diameter

Bovine pericardium / Stainless steel stent

Dr. Alain Cribier

First-in-Man PIONEER

Circulation American Heart Association
JOURNAL OF THE AMERICAN HEART ASSOCIATION
Learn and Live.



Percutaneous Transcatheter Implantation of an Aortic Valve Prosthesis for Calcific Aortic Stenosis

First Human Case Description

Alain Cribier, MD; Helene Eltchaninoff, MD; Assaf Bash, PhD; Nicolas Borenstein, MD; Christophe Tron, MD; Fabrice Bauer, MD; Genevieve Derumeaux, MD; Frederic Anselme, MD; François Laborde, MD; Martin B. Leon, MD

Conclusions— *Nonsurgical implantation of a prosthetic heart valve can be successfully achieved with immediate and midterm hemodynamic and clinical improvement.*

April 16, 2002

TAVR Arrives

Current Generation Devices

***>75,000 patients treated thru 2013
in >750 interventional centers
around the world!***



Edwards Lifesciences



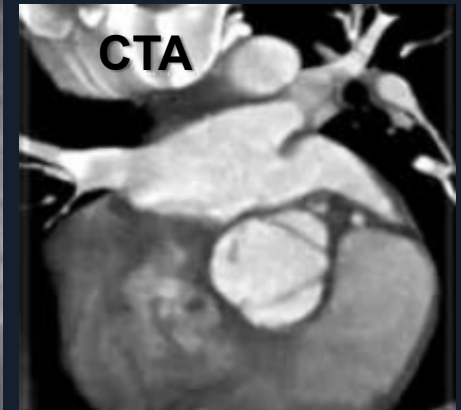
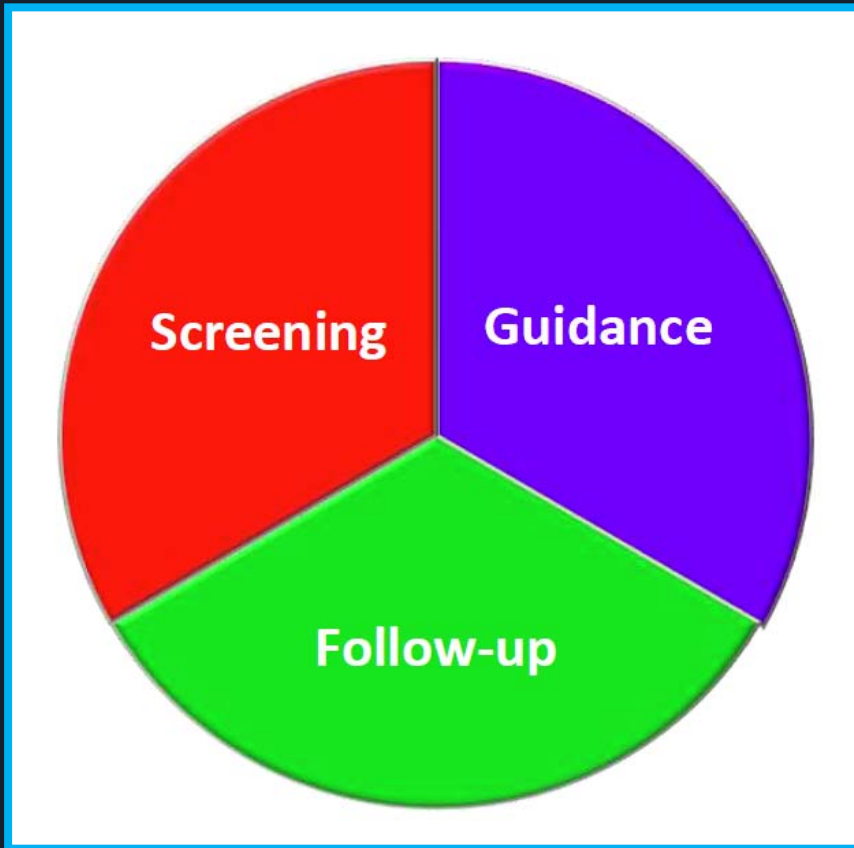
Medtronic CoreValve

Columbia University Medical Center Heart Valve Team



Adjunctive Imaging for TAVR

Multi-modality Imaging is the RULE



A Dedicated TAVR Milieu

Hybrid Cath Lab/OR



Cath Lab

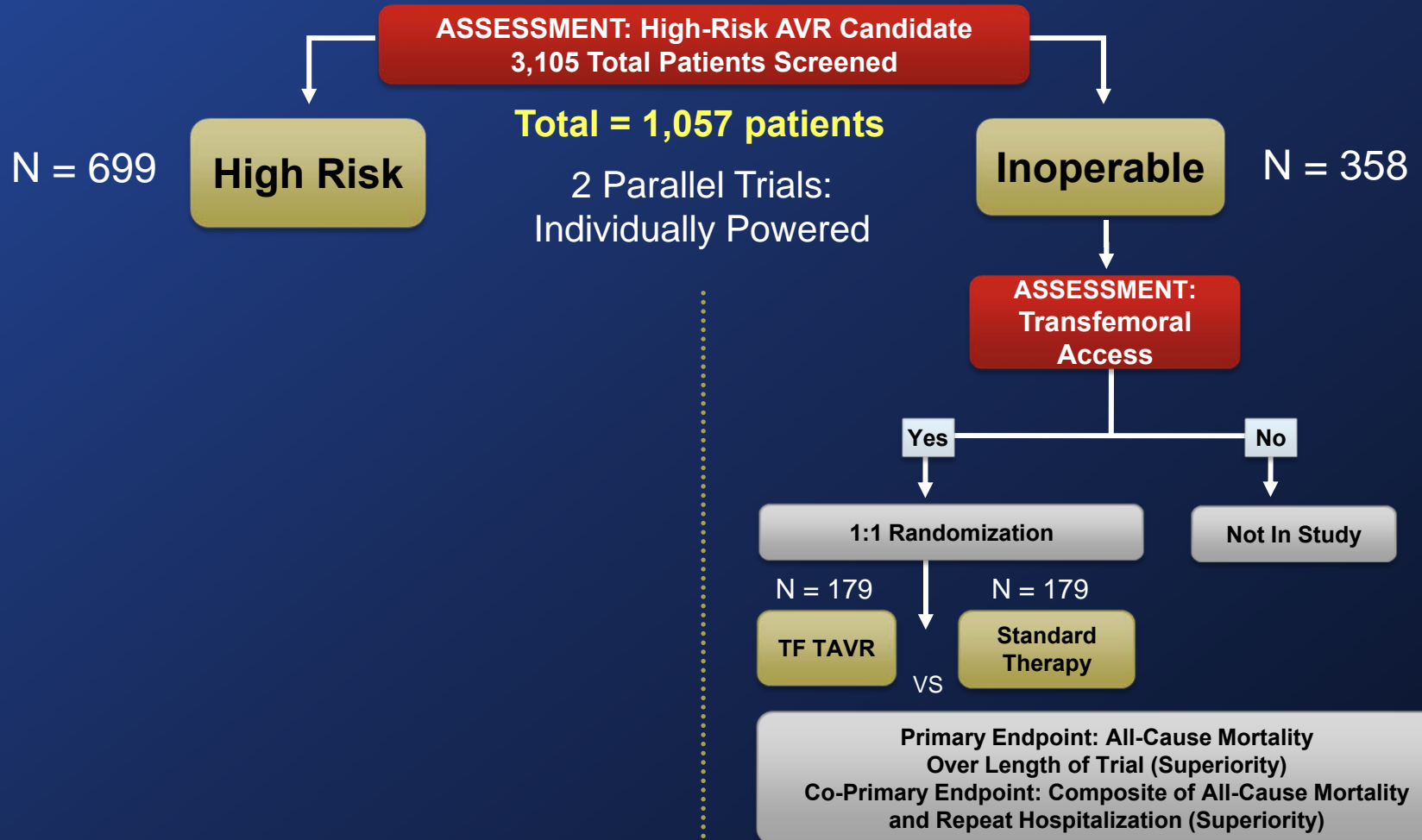
Multi-Disciplinary
Collaboration

OR

PARTNER Study Design



Symptomatic Severe Aortic Stenosis



PARTNER Study Design



Symptomatic Severe Aortic Stenosis

ASSESSMENT: High-Risk AVR Candidate
3,105 Total Patients Screened

N = 699

High Risk

Total = 1,057 patients

2 Parallel Trials:
Individually Powered

Inoperable

N = 358

**ASSESSMENT:
Transfemoral
Access**

Yes

No

**ASSESSMENT:
Transfemoral
Access**

Yes

No

Transfemoral (TF)

Transapical (TA)

1:1 Randomization

1:1 Randomization

N = 244

N = 248

N = 104

N = 103

TF TAVR

AVR

VS

TA TAVR

AVR

VS

1:1 Randomization

Not In Study

N = 179

N = 179

TF TAVR

**Standard
Therapy**

VS

**Primary Endpoint: All-Cause Mortality at 1 yr
(Non-inferiority)**

**Primary Endpoint: All-Cause Mortality
Over Length of Trial (Superiority)**
**Co-Primary Endpoint: Composite of All-Cause Mortality
and Repeat Hospitalization (Superiority)**

The severe AS-T

- Old...very old...
- Frail...very frail
- Lots of co-morbidities
 - Prior CABG (poor)
 - CKD
 - Severe COPD
 - PVD
 - Chronic AF
 - Cancer in remission



But still enjoying life !

PARTNER Manuscripts in NEJM (October, 2010 – May, 2012)



The NEW ENGLAND JOURNAL of MEDICINE

ESTABLISHED IN 1812

OCTOBER 21, 2010

VOL. 363 NO. 17

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

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

The NEW ENGLAND JOURNAL of MEDICINE

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JUNE 9, 2011

VOL. 364 NO. 23

Transcatheter and Surgical Aortic-Valve Replacement in High-Risk Patients

Craig R. Smith, M.D., Martin B. Leon, M.D., Michael J. Mack, M.D., D. Craig Miller, M.D., Jeffrey W. Moses, M.D., Lars G. Svensson, M.D., Ph.D., E. Murat Tuzcu, M.D., John G. Webb, M.D., Gregory P. Fontana, M.D., Raj R. Makkar, M.D., Mathew Williams, M.D., Todd Dewey, M.D., Samir Kapadia, M.D., Vasilis Babaliaros, M.D., Vinod H. Thourani, M.D., Paul Corso, M.D., Augusto D. Pichard, M.D., Joseph E. Bavaria, M.D., Howard C. Herrmann, M.D., Jodi J. Akin, M.S., William N. Anderson, Ph.D., Duolao Wang, Ph.D., and Stuart J. Pocock, Ph.D., for the PARTNER Trial Investigators*

The NEW ENGLAND JOURNAL of MEDICINE

ORIGINAL ARTICLE

Transcatheter Aortic-Valve Replacement for Inoperable Severe Aortic Stenosis

Raj R. Makkar, M.D., Gregory P. Fontana, M.D., Hasan Jilaihawi, M.D., Samir Kapadia, M.D., Augusto D. Pichard, M.D., Pamela S. Douglas, M.D., Vinod H. Thourani, M.D., Vasilis C. Babaliaros, M.D., John G. Webb, M.D., Howard C. Herrmann, M.D., Joseph E. Bavaria, M.D., Susheel Kodali, M.D., David L. Brown, M.D., Bruce Bowers, M.D., Todd M. Dewey, M.D., Lars G. Svensson, M.D., Ph.D., Murat Tuzcu, M.D., Jeffrey W. Moses, M.D., Mathew R. Williams, M.D., Robert J. Siegel, M.D., Jodi J. Akin, M.S., William N. Anderson, Ph.D., Stuart Pocock, Ph.D., Craig R. Smith, M.D., and Martin B. Leon, M.D., for the PARTNER Trial Investigators*

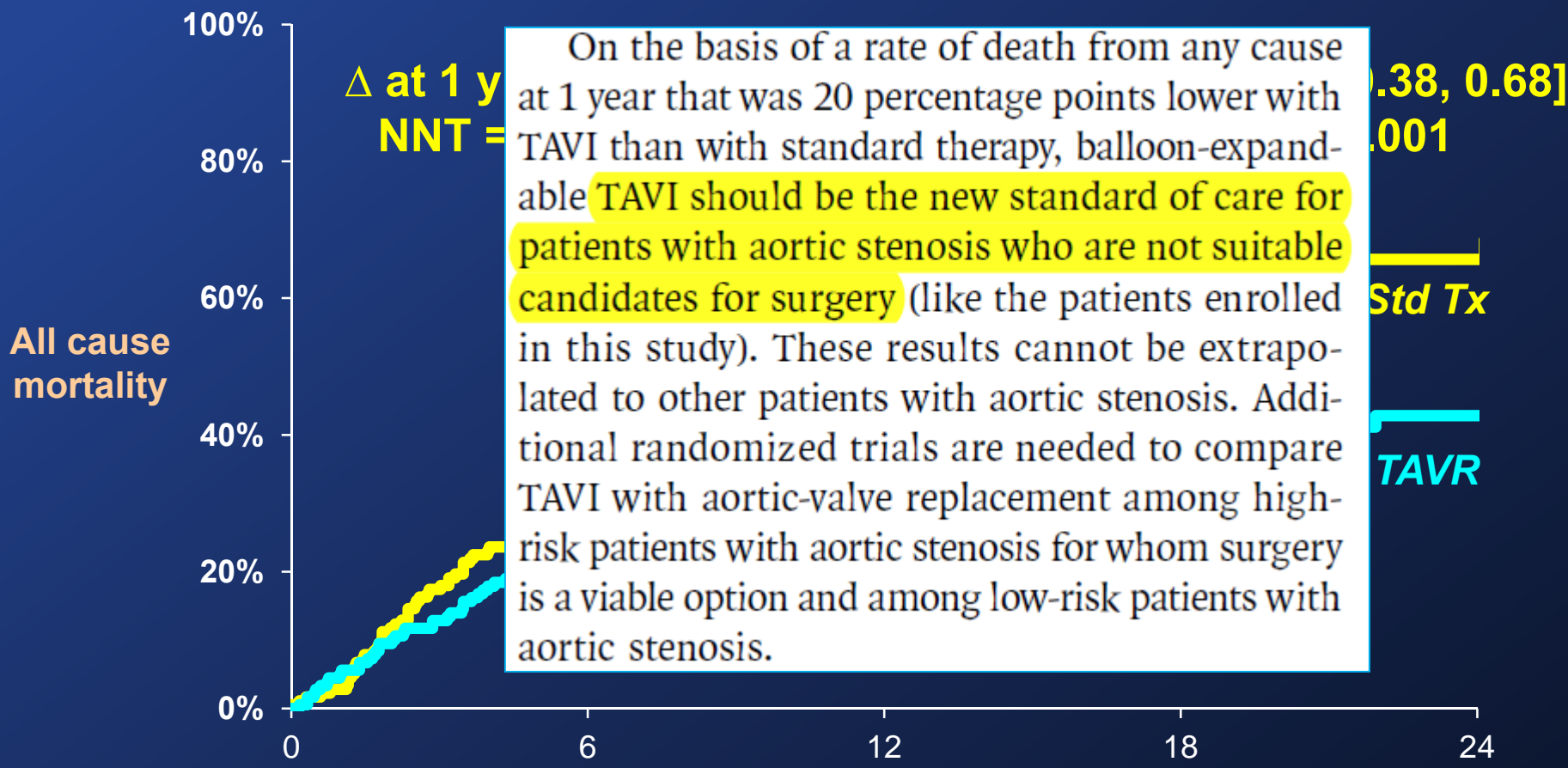
The NEW ENGLAND JOURNAL of MEDICINE

ORIGINAL ARTICLE

Two-Year Outcomes after Transcatheter or Surgical Aortic-Valve Replacement

Susheel K. Kodali, M.D., Mathew R. Williams, M.D., Craig R. Smith, M.D., Lars G. Svensson, M.D., Ph.D., John G. Webb, M.D., Raj R. Makkar, M.D., Gregory P. Fontana, M.D., Todd M. Dewey, M.D., Vinod H. Thourani, M.D., Augusto D. Pichard, M.D., Michael Fischbein, M.D., Wilson Y. Szeto, M.D., Scott Lim, M.D., Kevin L. Greason, M.D., Paul S. Teirstein, M.D., S. Chris Malaisrie, M.D., Pamela S. Douglas, M.D., Rebecca T. Hahn, M.D., Brian Whisenant, M.D., Alan Zajarias, M.D., Duolao Wang, Ph.D., Jodi J. Akin, M.S., William N. Anderson, Ph.D., and Martin B. Leon, M.D., for the PARTNER Trial Investigators*

Primary Endpoint: All Cause Mortality

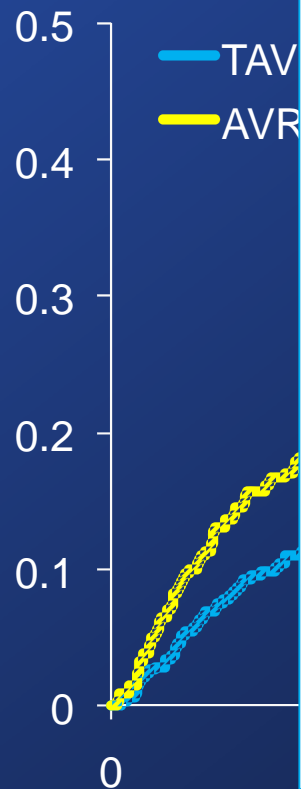


Numbers at Risk

	0	6	12	18	24
Std Tx	179	121	85	56	24
TAVR	179	138	124	103	60

High-Risk Operable PARTNER Cohort

Primary Endpoint: **All-Cause Mortality**



In conclusion, we have shown that in patients with aortic stenosis who are at high risk for operative complications and death, surgical aortic-valve replacement and balloon-expandable transcatheter replacement were associated with similar mortality at 30 days and 1 year and produced similar improvements in cardiac symptoms. Our findings indicate that transcatheter replacement is an alternative to surgical replacement in a well-chosen, high-risk subgroup of patients with aortic stenosis. In the absence of long-term follow-up data, recommendations to individual patients must balance the appeal of avoiding the known risks of open-heart surgery against the less invasive trans-

No. at Risk

Months

TAVR

348

298

260

147

67

AVR

351

252

236

139

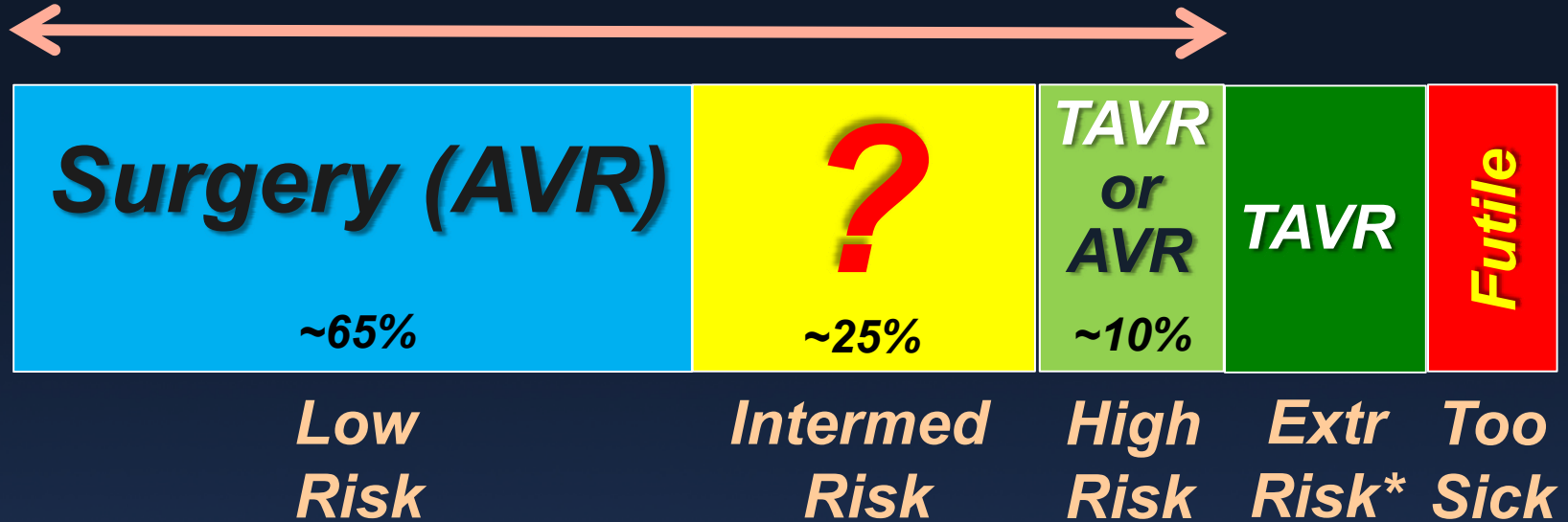
65

24

TAVR Categories

(risk is a continuum)

Operable AS patients





TAVR in 2013

irresponsible, reckless

“equipoise” OK preferred No

** Extreme risk = “inoperable”*

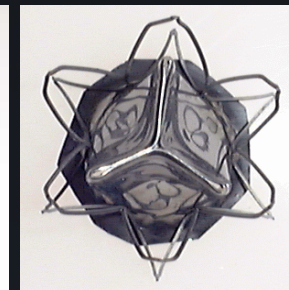
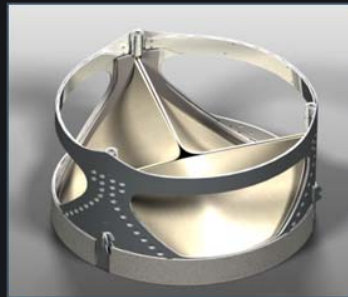
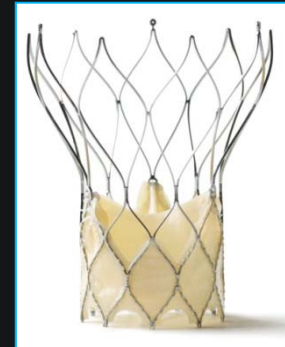
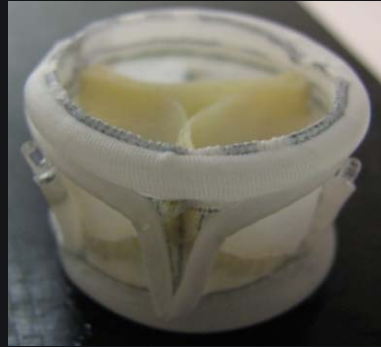
TVT U.S. National Registry

STS/ACC TVT Registry™  		TVT Registry™ v1.1 – Data Collection Form For Transcatheter Valve Replacement Procedures	
A. DEMOGRAPHICS			
Last Name ²⁰⁰⁰ :		First Name ²⁰¹⁰ :	
Middle Name ²⁰²⁰ :			
SSN ²⁰³⁰ : - - <input type="checkbox"/> SSN N/A ²⁰³¹	Patient ID ²⁰⁴⁰ : (auto)		Other ID ²⁰⁴⁵ :
Birth Date ²⁰⁵⁰ : mm / dd / yyyy	Sex ²⁰⁶⁰ : <input type="radio"/> Male <input type="radio"/> Female	Hispanic or Latino Ethnicity ²⁰⁷⁶ : <input type="radio"/> No <input type="radio"/> Yes	
Race: (check all that apply)	<input type="checkbox"/> White ²⁰⁷⁰ <input type="checkbox"/> American Indian/Alaskan Native ²⁰⁷³	<input type="checkbox"/> Black/African American ²⁰⁷¹ <input type="checkbox"/> Native Hawaiian/Pacific Islander ²⁰⁷⁴	<input type="checkbox"/> Asian ²⁰⁷²
B. EPISODE OF CARE			
Arrival Date/Time ^{3000,3001} : mm / dd / yyyy HH:MM			
Insurance Payors: (check all that apply)			
<input type="checkbox"/> Private Health Insurance ³⁰⁰⁵	<input type="checkbox"/> Medicare ³⁰⁰⁶	<input type="checkbox"/> Medicaid ³⁰⁰⁷	<input type="checkbox"/> Military Health Care ³⁰⁰⁸
<input type="checkbox"/> State-Specific Plan (non-Medicaid) ³⁰⁰⁹	<input type="checkbox"/> Indian Health Service ³⁰¹⁰	<input type="checkbox"/> Non-US Insurance ³⁰¹¹	<input type="checkbox"/> None ³⁰¹²
HIC ³⁰¹⁵ :	Research Study ³⁰³⁰ : <input type="radio"/> No <input type="radio"/> Yes → If Yes, Study Patient ID ³⁰³² :		

- Comprehensive prospective observational database (7-page CRF)
- FU includes 30-days, 1-year (incl. QOL measures)
- TVT compliance linked to reimbursement

New TAVI Systems - *Transfemoral*

- Direct Flow
- Sadra
- St. Jude
- AorTx
- HLT
- EndoTech
- ABPS PercValve



TAVR... Fulfilling Gruentzig's Dream

- Favorable balance of safety and efficacy
- Treatment focuses on most appropriate high-risk patients
- Generalizable to the interventional community
- Rigorous evidence-based medicine clinical studies
- Innovative technology (incl. accessory devices)
- Emphasizes advanced imaging and a well characterized treatment milieu
- Multi-disciplinary collaborations (e.g. the Heart Valve Team)

From PTCA to TAVR

**Final
Thoughts**

Heritage of Intervention

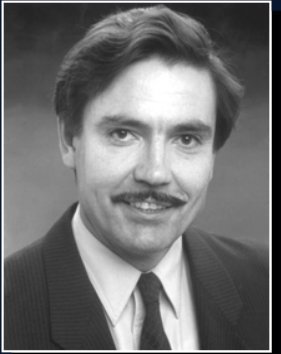
- **We believe that “less invasive” is better** (certainly for patients and also for the healthcare system in general; and less-invasive means catheter-based, non-surgical, whenever possible)
- **We are technology addicts** (esp. new gizmos which can shorten procedures, improve outcomes, and expand treatment indications)
- **We are passionate about experimental and clinical research and evidence-based medicine** (fundamental to every important therapy change and to the interventional device development process)

Heritage of Intervention

- **We rely heavily on adjunctive imaging - a visual subspecialty** (a growing trend...echo/IVUS, MR/CT, “fusion” imaging, and other new invasive imaging modalities)
- **We are passionate about the interface of clinical medicine and the rapid communication of ideas** (educational meetings, physician training, new IT developments, patient care initiatives, and marketing opportunities)
- **We have a vibrant entrepreneurial spirit, are risk-takers, and rapidly embrace new therapies**
- **We strongly support and promote global and multi-disciplinary collaborations**

Heritage of Intervention

- ***We have a cultural identity ... innovation, strong industry partnerships, impatience leading to evolution and forward motion; we have a need to stimulate change and to continually re-invent ourselves, in pace with advances in bio-medical science and technology!***



What Would Andreas Think? of What's Become of Interventional Cardiology?

I think he would be...

Approving of the mandate to generate and utilize evidence-based medicine in clinical decision-making

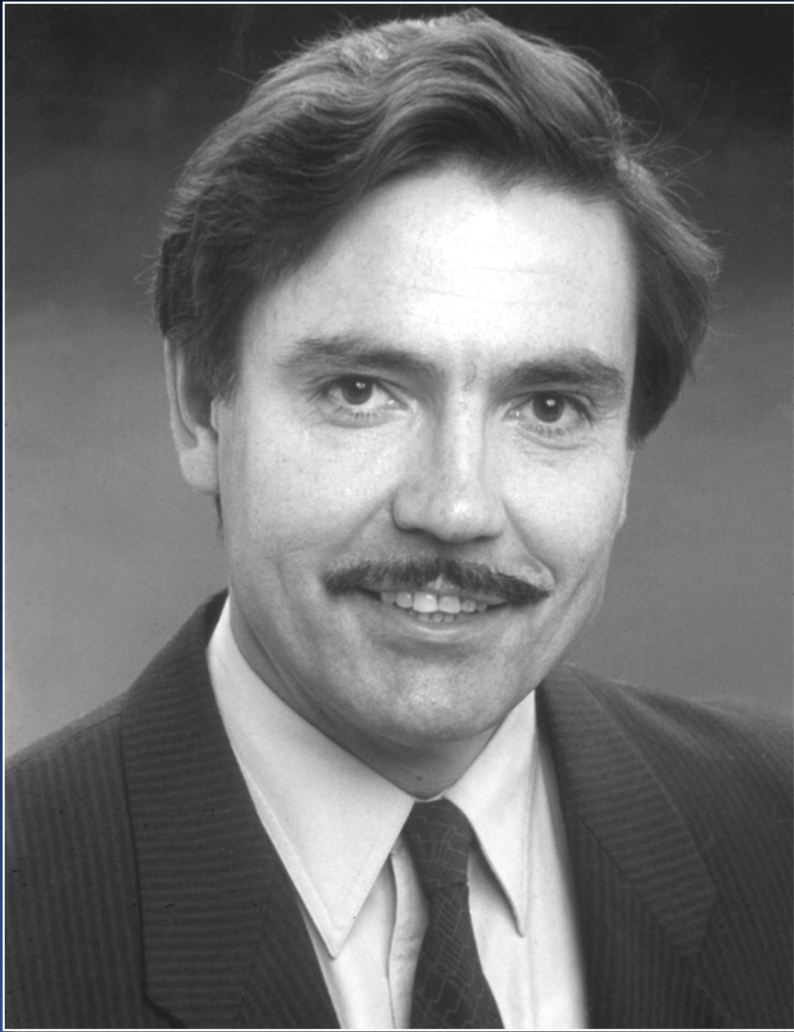
Ecstatic and overwhelmed with the technology explosion that has overcome many of the limitations of PTCA

Enthralled with the extension of catheter-based treatment to non-vascular disease states (e.g. structural/valvular)

Appalled with the sometimes inappropriate use of devices, and **concerned** about operators who don't practice with the highest standards of quality and ethics

Distressed by the myriad external social, economic and political forces that are interfering with the practice of medicine

Celebrating >30 Years!



**Andreas Gruentzig
1939 - 1985**

*On the shoulders of
pioneers, we've witnessed
the birth of a subspecialty.
Cardiovascular medicine
has been forever
transformed and patient
outcomes have never been
better!*