

The Year In Cardiology

John Coyle, M.D.

October 8, 2010

The Year In Review Series: The American College Of Cardiology

Atherothrombosis

Cardiac Electrophysiology

Cardiac Imaging

Cardiovascular Surgery

Congenital Heart Disease

Epidemiology, Health Services Research and Outcomes Research

Heart Failure

Hypertension

Interventional Cardiology

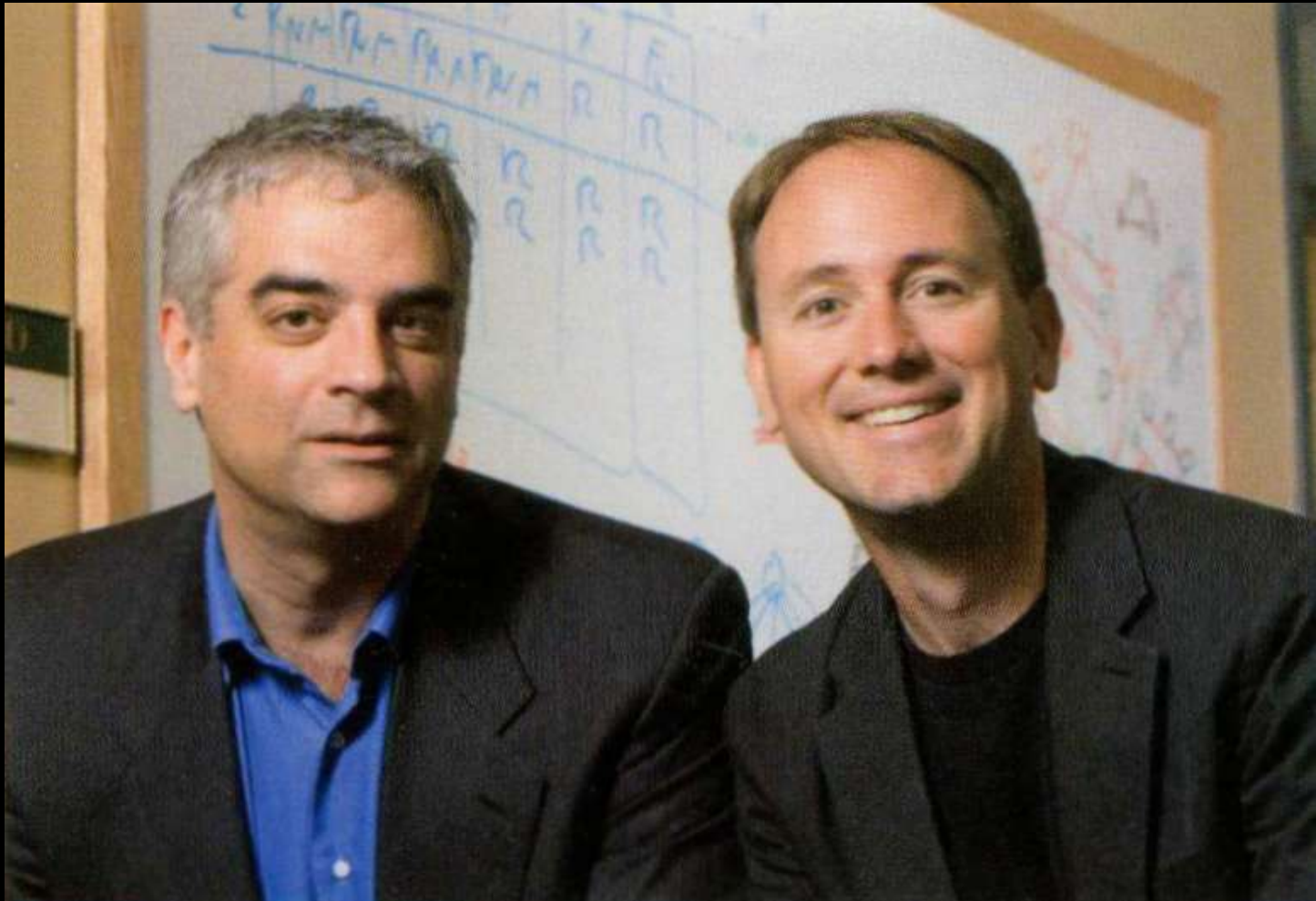
Non-ST-Segment Elevation Acute Coronary Syndrome

Valvular Heart Disease

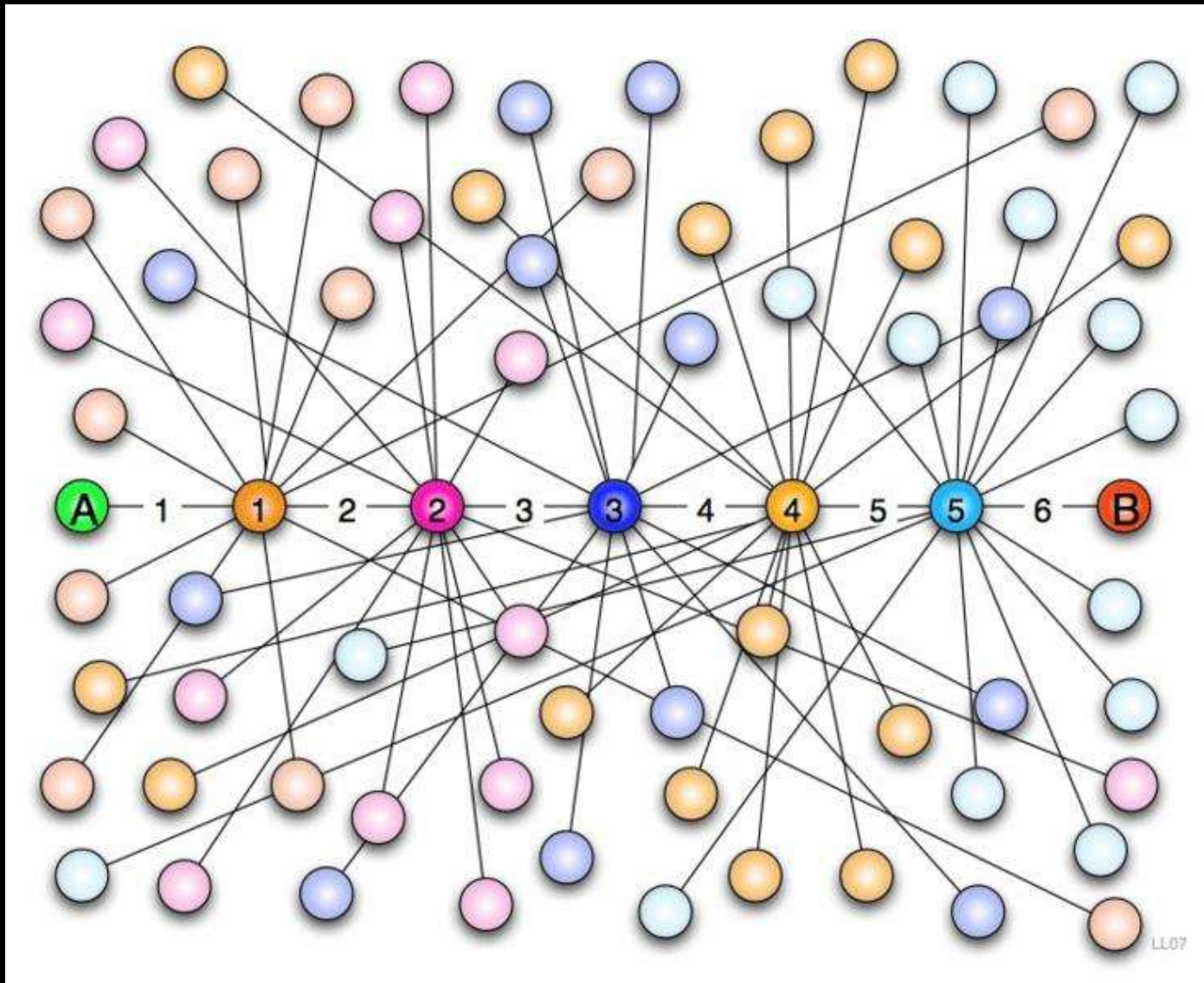
ACC/AHA Guidelines: New and Revised

Epidemiology, Health Services Research and Outcomes Research

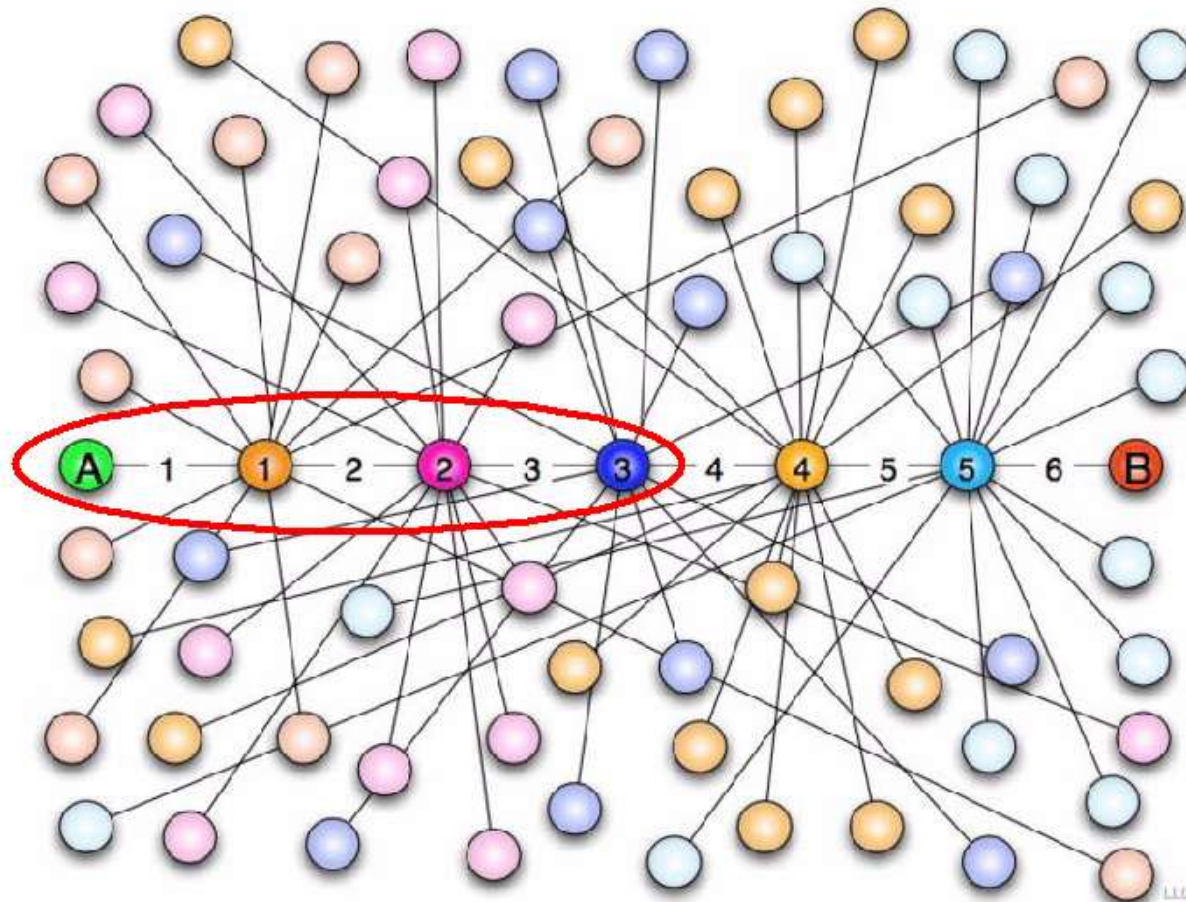
The Firm Of Christakis And Fowler



Six Degrees Of Separation



Three Degrees Of Influence



2007

The NEW ENGLAND JOURNAL of MEDICINE

SPECIAL ARTICLE

The Spread of Obesity in a Large Social Network over 32 Years

Nicholas A. Christakis, M.D., Ph.D., M.P.H., and James H. Fowler, Ph.D.

2008

The NEW ENGLAND JOURNAL of MEDICINE

SPECIAL ARTICLE

The Collective Dynamics of Smoking in a Large Social Network

Nicholas A. Christakis, M.D., Ph.D., M.P.H., and James H. Fowler, Ph.D.

2008

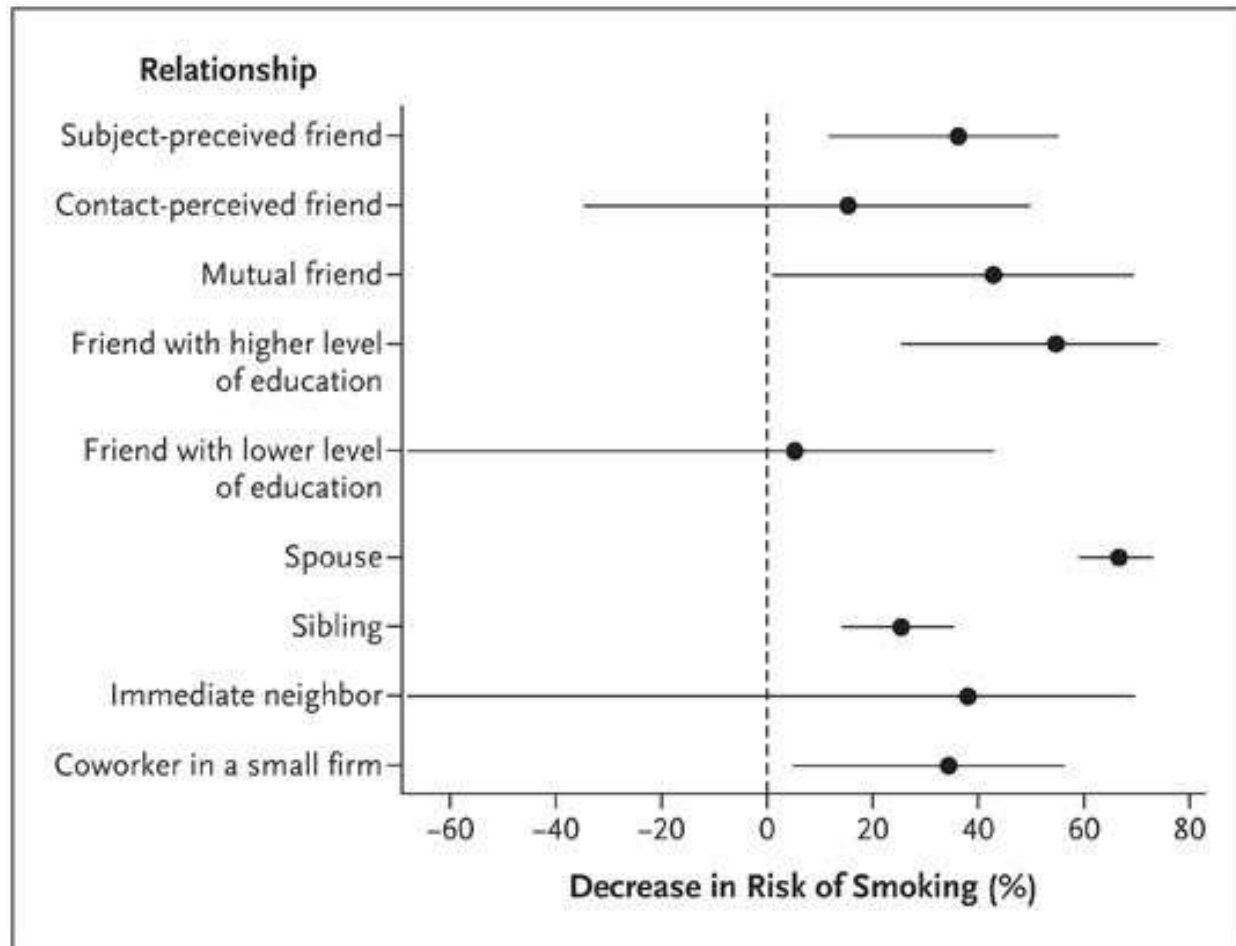
BMJ

RESEARCH

Dynamic spread of happiness in a large social network: longitudinal analysis over 20 years in the Framingham Heart Study

James H Fowler, associate professor,[†] Nicholas A Christakis, professor²

Probability That a Subject Will Quit Smoking According to the Type of Relationship with a Contact Who Quits Smoking, in the Social Network of the Framingham Heart Study



ACC/AHA Guidelines

... And thirdly, the code is *more* what you'd call
"*guidelines*" than actual rules...

Captain Jack Sparrow



Guidelines And The Law

In the United States Court of Appeals For the Seventh Circuit

No. 96-3450

NICHOLAS KNAPP,

Plaintiff-Appellee,

v.

NORTHWESTERN UNIVERSITY, an Illinois not-for-profit corporation, and RICK TAYLOR,

Defendants-Appellants.

Appeal from the United States District Court for the Northern District of Illinois, Eastern Division. No. 95 C 6454--James B. Zagel, Judge.

ARGUED NOVEMBER 7, 1996--DECIDED NOVEMBER 22, 1996

Before BAUER, DIANE P. WOOD, and EVANS, Circuit Judges.

EVANS, Circuit Judge. Nicholas Knapp wants to play NCAA basketball for Northwestern University--so badly that he is willing to face an increased risk of death to do so. Knapp is a competent, intelligent adult capable of assessing whether playing intercollegiate basketball is worth the risk to his heart and possible death, and to him the risk is acceptable. Usually, competent, intelligent adults are allowed to make such decisions. This is especially true when, as here, the individual's family approves of the decision and the individual and his parents are willing to sign liability waivers regarding the worst-case scenario should it occur.

We do not believe that, in cases where medical experts disagree in their assessment of the extent of a real risk of serious harm or death, Congress intended that the courts--neutral arbiters but generally less skilled in medicine than the experts involved--should make the final medical decision. Instead, in the midst of conflicting expert testimony regarding the degree of serious risk of harm or death, the court's place is to ensure that the exclusion or disqualification of an individual was individualized, reasonably made, and based upon competent medical evidence.

2

Two national medical conferences were held in Bethesda, Maryland, for the specific purpose of establishing prudent consensus recommendations among cardiologists and sports medicine physicians regarding the eligibility of athletes with cardiovascular abnormalities to compete in sports. The first, known as the 16th Bethesda Conference, was held in 1984 and titled "Cardiovascular Abnormalities in the Athlete: Recommendations Regarding Eligibility for Competition." The consensus recommendations from that conference were published in the Journal of the American College of Cardiology in December 1985. The second, known as the 26th Bethesda Conference and titled "Recommendations for Determining Eligibility for Competition in Athletes with Cardiovascular Abnormalities," was held in January 1994. The consensus recommendations of that conference were published in the Journal of the American College of Cardiology in October 1994.

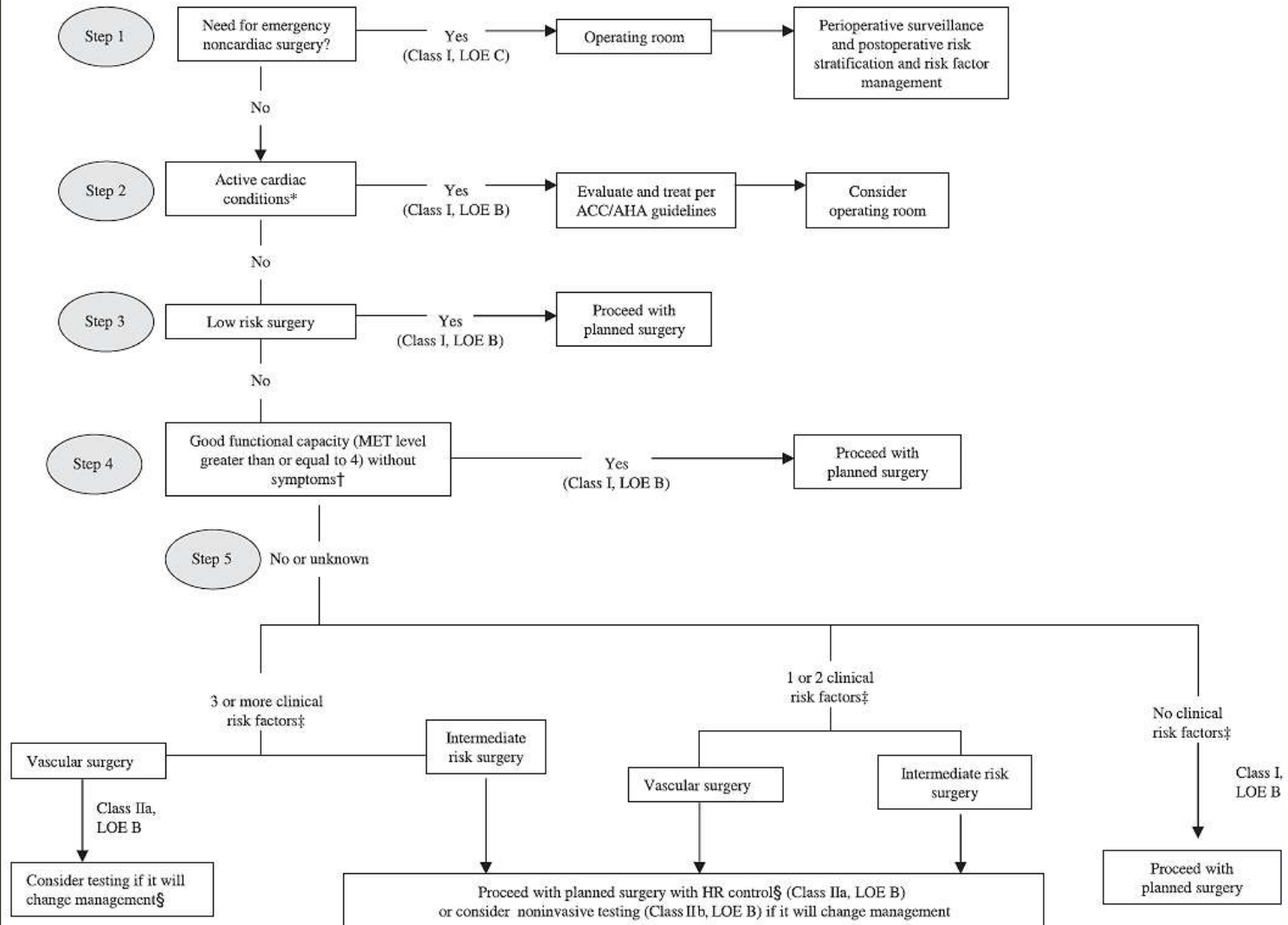
The 26th Bethesda Conference's task force on arrhythmias addressed conditions like Knapp's and implanted cardioverter-defibrillators. This task force recommended that athletes with ventricular fibrillation "that result in cardiac arrest in the presence or absence of structural heart disease cannot participate in any moderate or high intensity competitive sports." 24 Journal of the American College of Cardiology 845, 897 (1994). "For athletes with implantable defibrillators . . . all moderate and high intensity sports are contraindicated." Id.

The Guidelines At Your Fingertips

Guidelines Example: Pre-Op Cardiac Evaluation

Note: This Guidelines page is interactive. To gain more information, click on the box that contains the item in question.

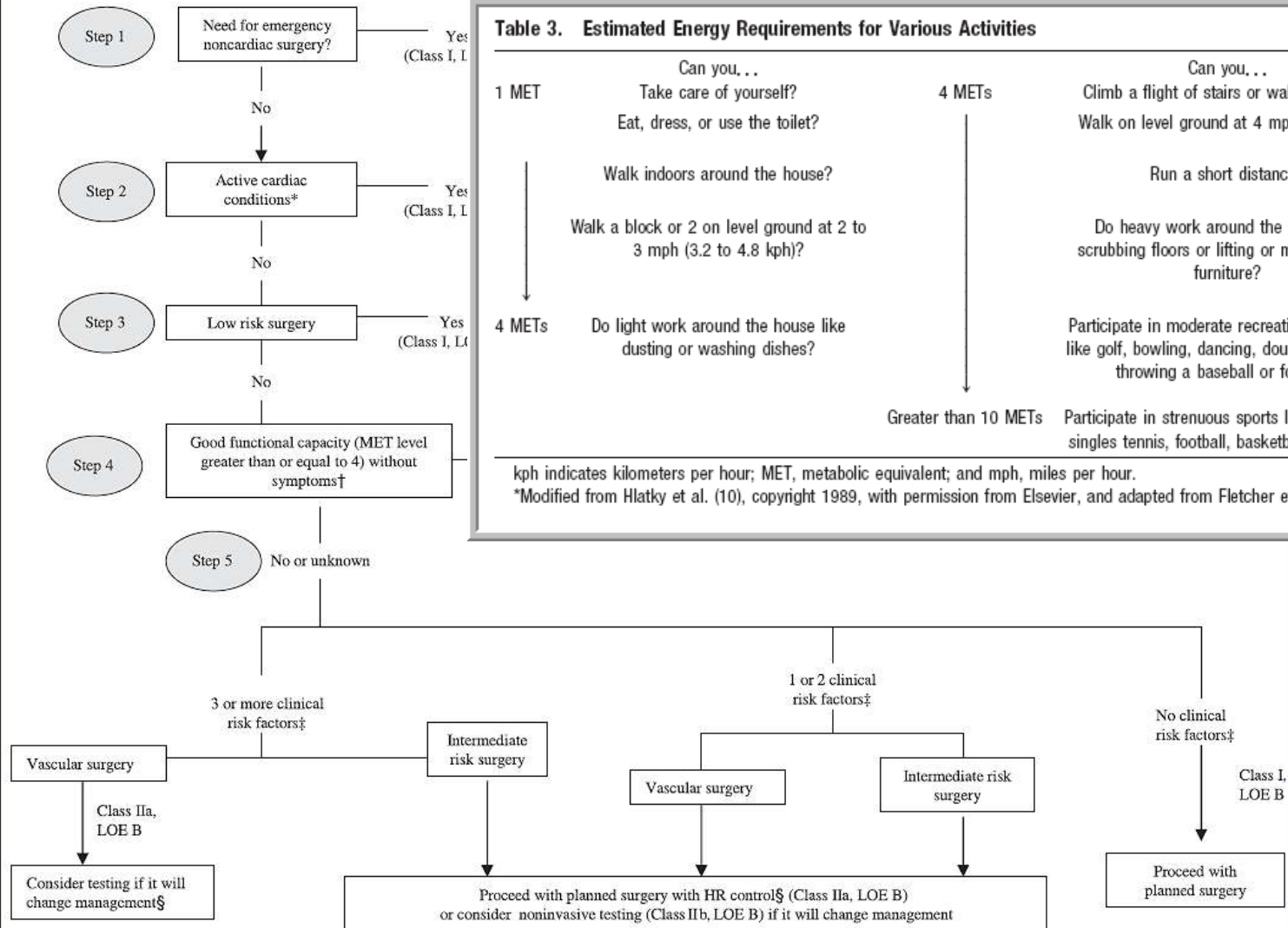
ACC/AHA 2007 Perioperative Guidelines



Guidelines Example: Pre-Op Cardiac Evaluation

Note: This Guidelines page is interactive. To gain more information, click on the box that contains the item in question.

ACC/AHA 2007 Perioperative Guidelines



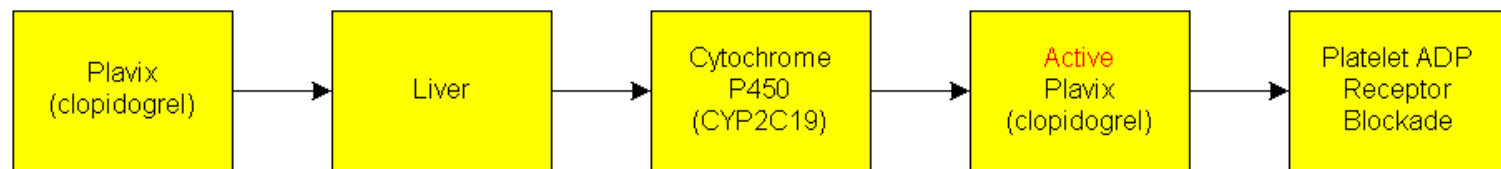
New Guidelines: Plavix

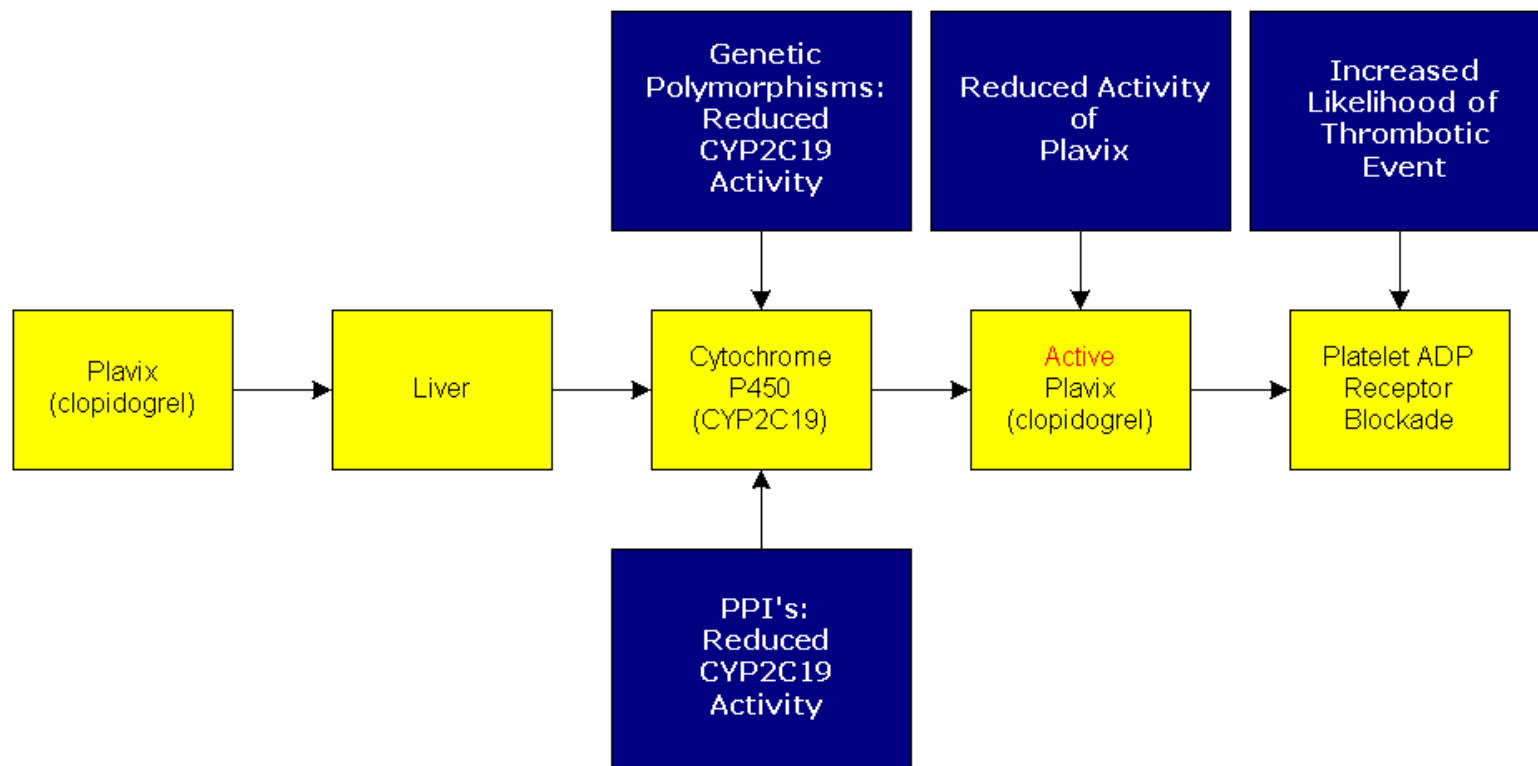
ACC/AHA Joint Guidelines

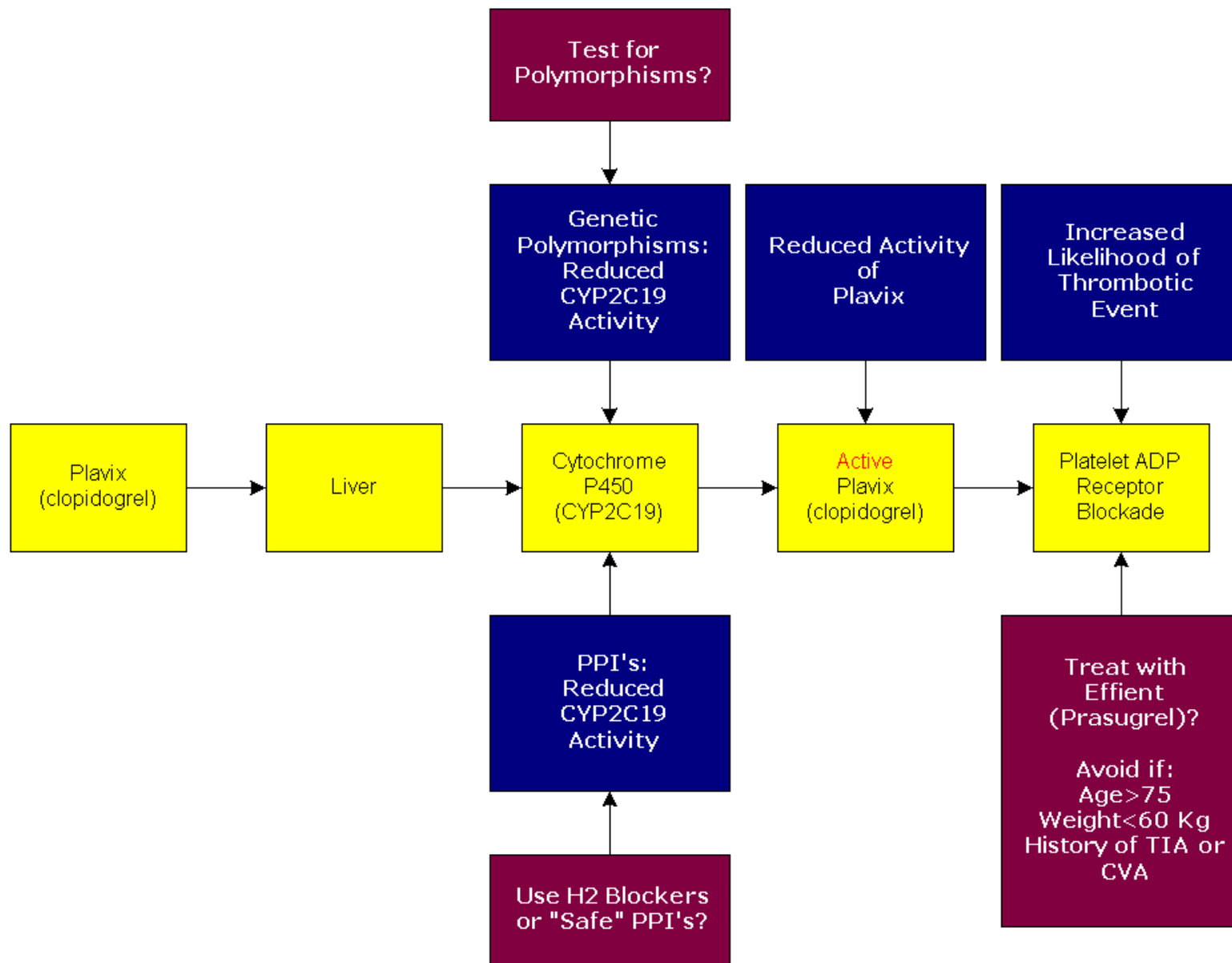
Title	Year Published	Product Code
<u>ACC/AHA Clopidogrel Clinical Alert: Approaches to the FDA "Boxed Warning"</u>	2010	KB-0074
<u>2009 Focused Updates: ACC/AHA Guidelines for the Management of Patients With ST-Elevation Myocardial Infarction (Updating the 2004 Guideline and 2007 Focused Update) and ACC/AHA/SCAI Guidelines on Percutaneous Coronary Intervention (Updating the 2005 Guideline and 2007 Focused Update)</u>	2009	KJ-0734
<u>2009 ACCF/AHA Focused Update on Perioperative Beta Blockade Incorporated Into the ACC/AHA 2007 Guidelines on Perioperative Cardiovascular Evaluation and Care for Noncardiac Surgery</u>	2009	KJ-0736
<u>2009 ACCF/AHA Focused Update on Perioperative Beta Blockade</u>	2009	KJ-0735
<u>ACCF/ASNC/ACR/AHA/ASE/SCCT/SCMR/SNM 2009 Appropriate Use Criteria for Cardiac Radionuclide Imaging</u>	2009	LS-2095
<u>2009 Focused Update: ACCF/AHA Guidelines for the Diagnosis and Management of Heart Failure in Adults</u>	2009	LS-2013
<u>2009 Focused Update Incorporated Into the ACC/AHA 2005 Guidelines for the Diagnosis and Management of Heart Failure in Adults</u>	2009	LS-2014
<u>ACCF/SCAI/STS/AATS/AHA/ASNC 2009 Appropriateness Criteria for Coronary Revascularization</u>	2009	LS-1938

ACC/AHA Joint Guidelines

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A New Anti-Platelet Steps Up To The Plate

COMING ATTRACTIONS

Ticagrelor (Brilinta)

Plus:

Ticagrelor is the first reversibly binding oral P2Y₁₂ adenosine diphosphate (ADP) receptor antagonist.

Ticagrelor should be administered with low doses (75 to 100 mg daily) of aspirin.

An FDA advisory panel has voted overwhelmingly to recommend approval of AstraZeneca's investigational antiplatelet drug ticagrelor (July 28, 2010). The FDA usually follows the recommendations of its advisory committees. Better outcomes than Plavix in patients with Acute Coronary Syndrome, except in US patients. Onset and offset of platelet effect are far superior.

Minus:

Twice-a-day dosing.

No benefit over Plavix in US patients in the PLATO trial. (High-dose ASA?)

Rapid offset of effect is hazardous in irresponsible patients with uncertain lives. (Should be GREAT in-hospital.)

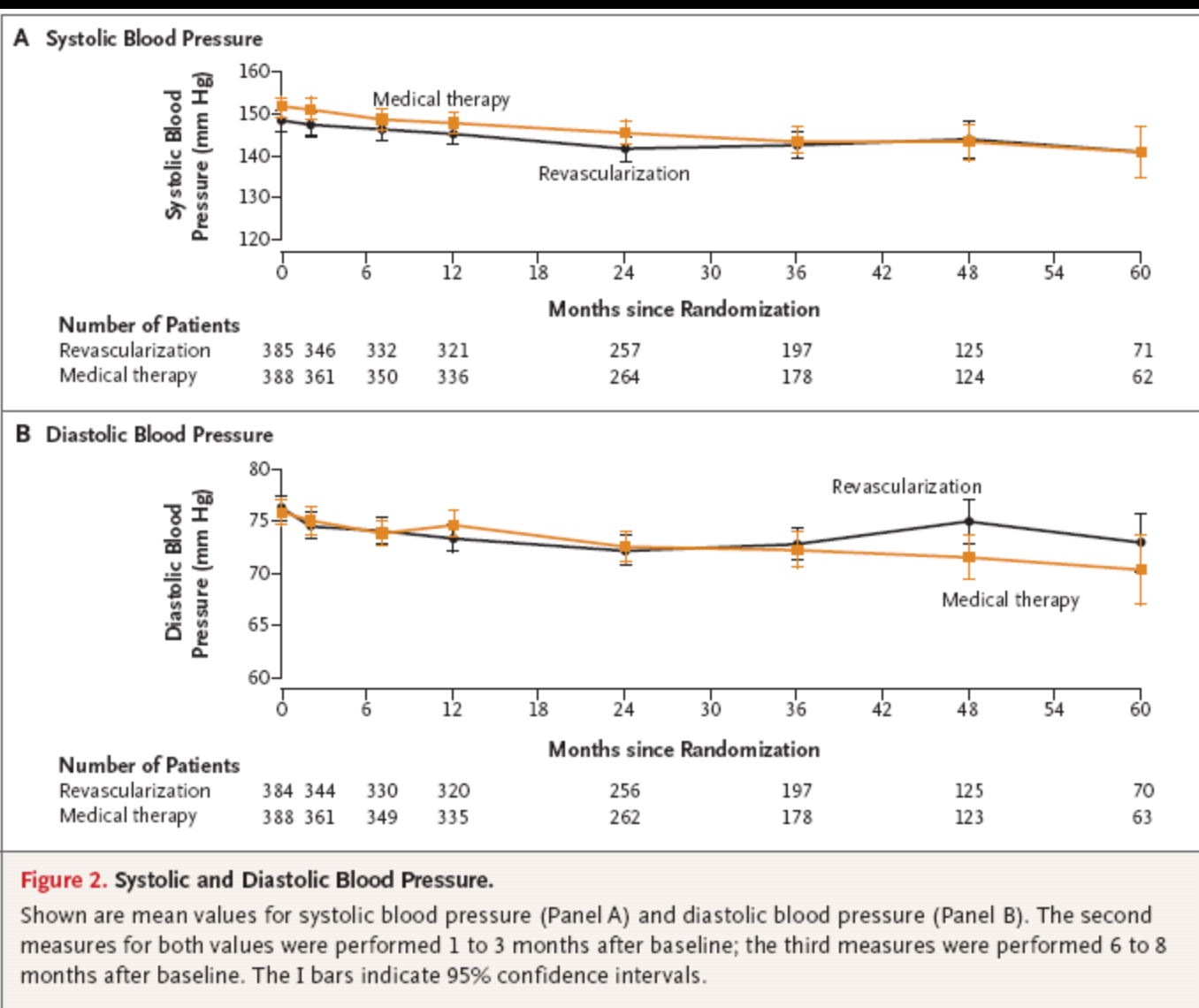
Dyspnea in 39% of patients, usually transient. 5% of patients stop drug.

Price not yet announced, but inevitably will be higher than Plavix, especially in 2012. (Plavix goes full generic.)

Hypertension

Hypertension And The Renal Artery

Angioplasty For Treatment Of Atherosclerotic Renal Artery Stenosis



Renal Radiofrequency Sympathetic Ablation For Treatment Of Refractory Hypertension

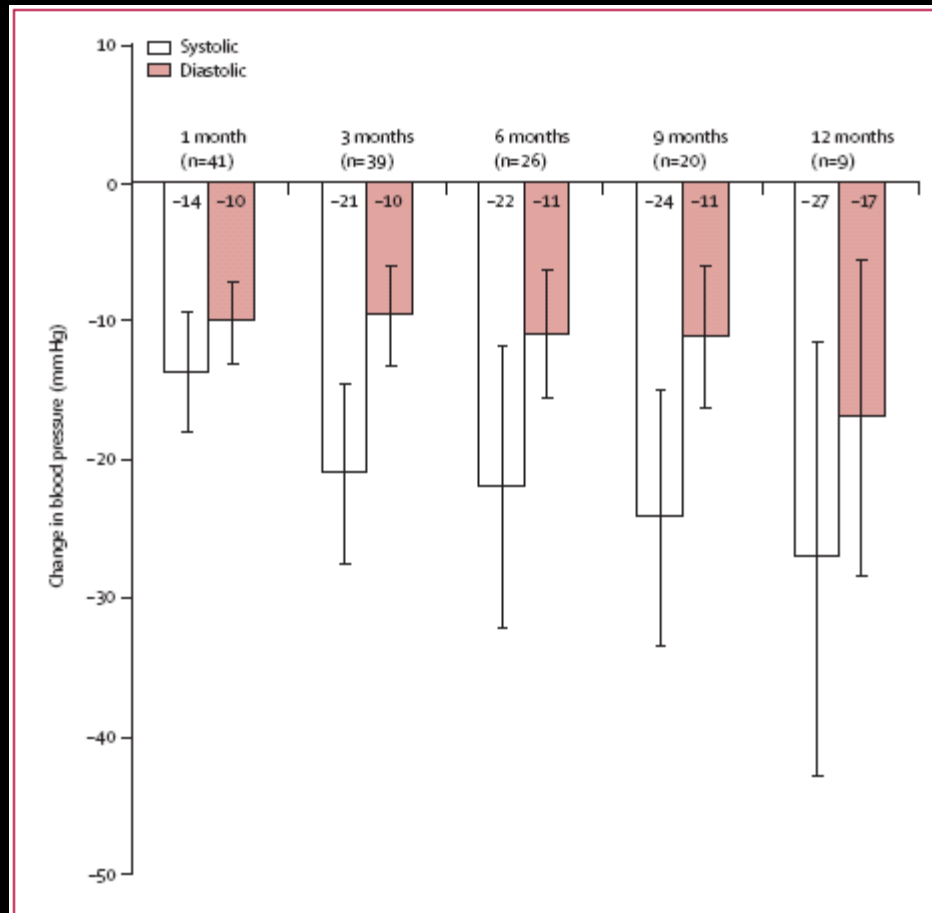


Figure 2: Change in office blood pressure (95% CI) at 1, 3, 6, 9, and 12 months
Numbers in parentheses indicate patients who had attended each predefined visit at the time of submission of this publication.

Brevity Is The Soul Of
Efficacy

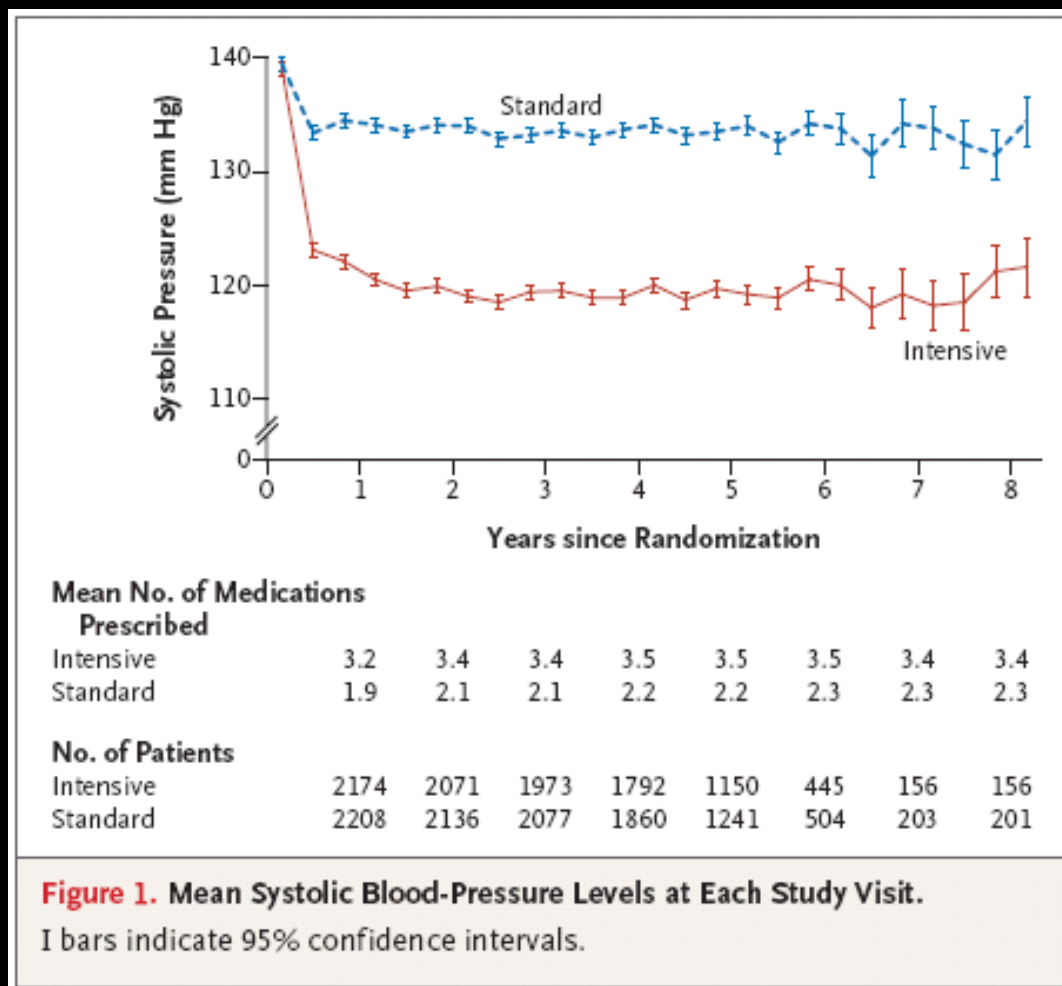
ACCOMPLISH Supports Single-Pill Combination Therapy For Patients With More Resistant Hypertension



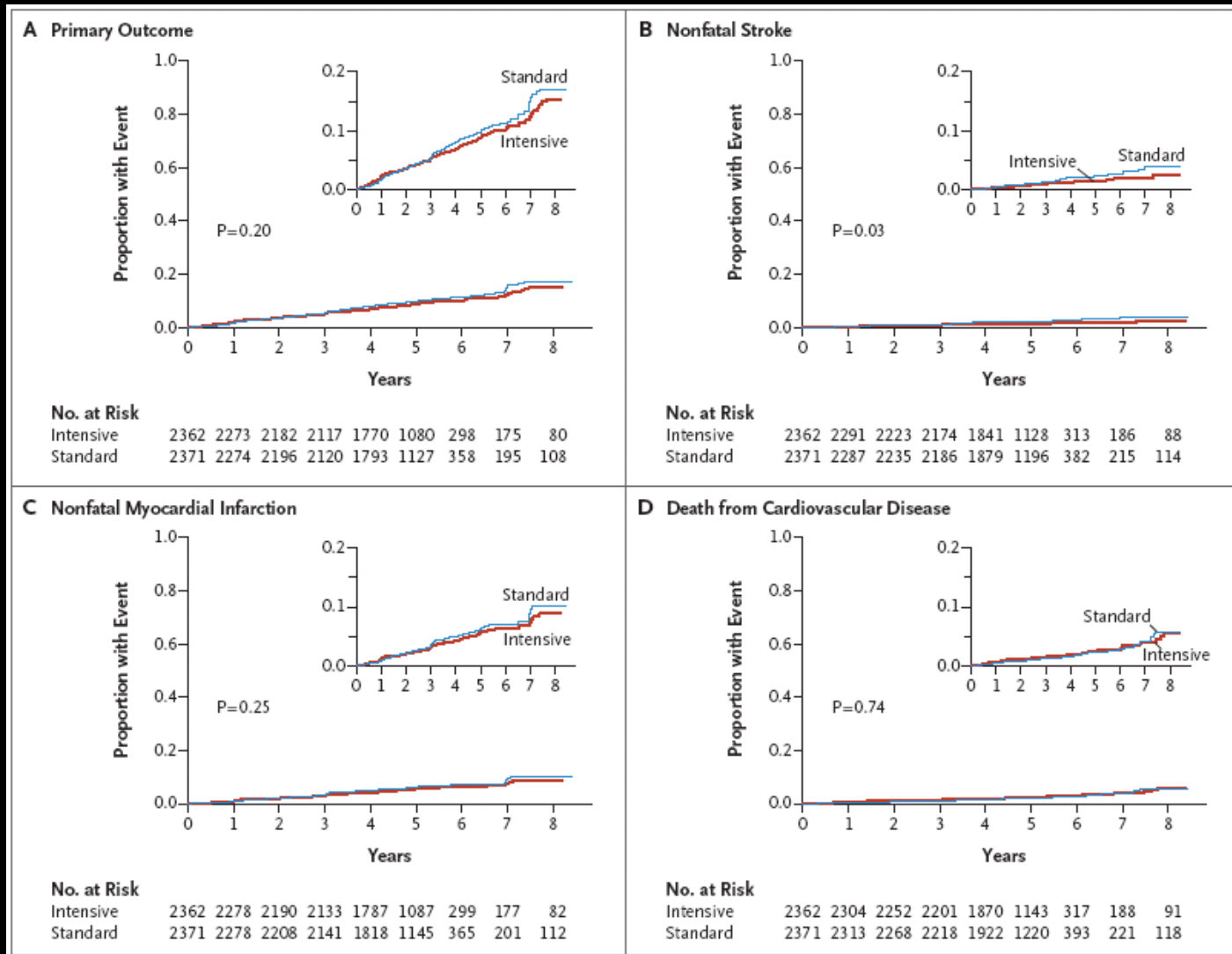
“The data from the ACCOMPLISH study also showed that when patients were transferred to either of the single-pill combinations tested in that study, there was a dramatic improvement in BP control, with >70% achieving their BP target. The reasons for this are not immediately obvious but may in part relate to improved concordance with therapy in a clinical trial setting. It does lend some support to current guideline recommendations of initial therapy with a low-dose, single-pill combination for patients whose BP is >20/10 mm Hg above their target BP.”

Is Lower Better?

ACCORD Does *Not* Support More Aggressive BP Treatment In High-Risk Diabetics



ACCORD Does *Not* Support More Aggressive BP Treatment In High-Risk Diabetics



Cardiac Electrophysiology

Freezing Atrial Fibrillation To Death

Arctic Front Cryocatheter and Ablation Methods

Cryoballoon design

Cryoballoon sizes

23 and 28 mm

Structure

Double balloon

Cooling (in balloon)

Liquid → gas transition



Balloon delivery

Catheter

Steerable

Sheath

14 French
deflectable

Ablation

PVI w / no lines



Focal Catheter

9 Fr, 8mm tip

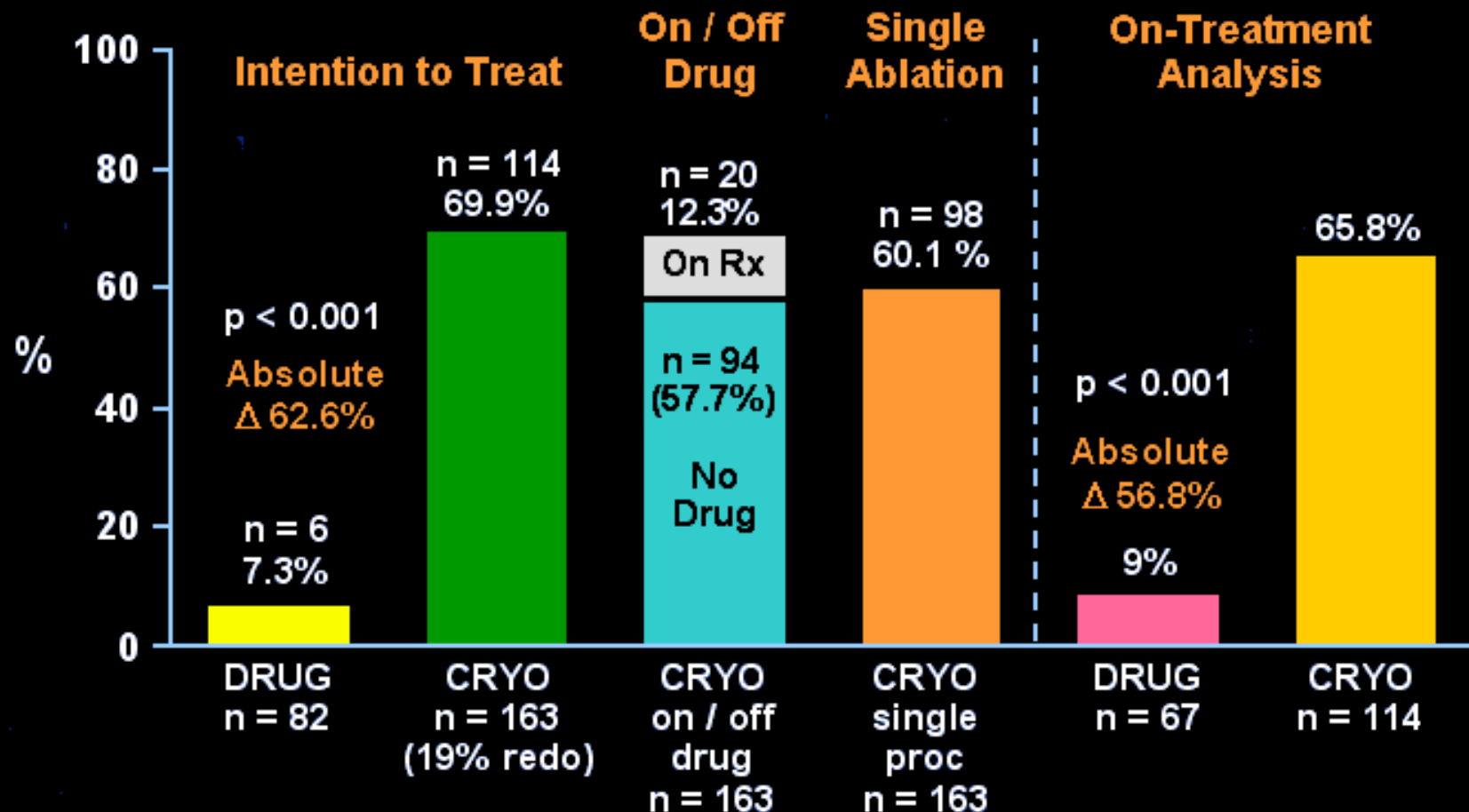


Baseline Characteristics

Baseline/demographic	ALL	DRUG	CRYO	p value*
Age (years)	56.6	56.4	56.7	0.80
Male (%)	77%	78%	76%	0.87
Left atrial AP diameter (mm)	40.5	40.9	40.3	0.35
LV ejection fraction (%)	60%	61%	60%	0.41
NYHA				
None / Class I (%)	94%	94%	93%	1.00
Class II (%)	6.5%	6.1%	6.7%	1.00
AF episodes within 2 mo (no.)	23.2	21.2	24.3	0.54
Previous cardioversion (%)	22%	21%	23%	0.87
History of atrial flutter (%)	45%	44%	46%	0.79
Efficacy-failed AF drugs				
Flecainide (%)	36%	35%	37%	0.87
Propafenone (%)	47%	44%	49%	0.50
Sotalol (%)	29%	31%	29%	0.88
CHADS2	0.6	0.6	0.6	0.92
Overall SF-36 (v2) score	70.6	70.4	70.8	0.87

* p value for comparison between DRUG and CRYO subjects

Treatment Success By Analysis Method



Conclusions

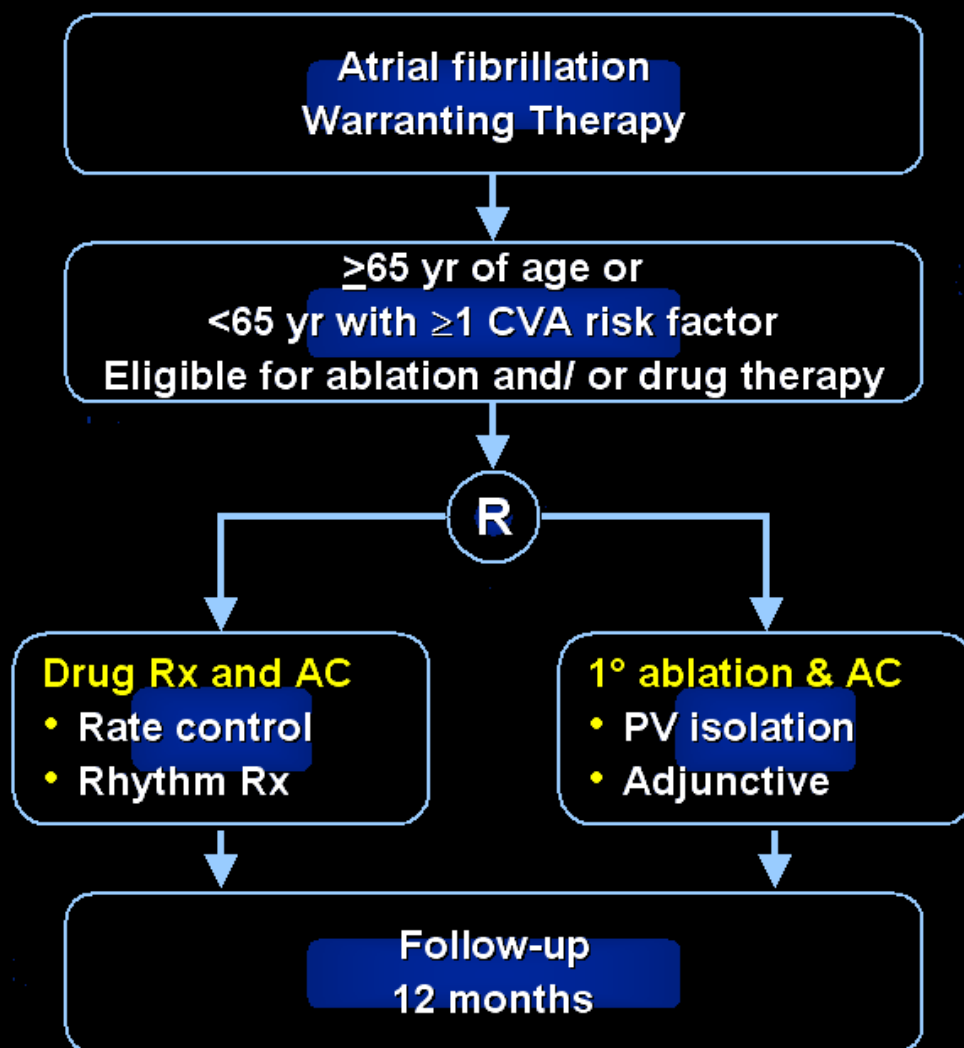
- **Cryoballoon ablation is effective for treating recurrent drug-refractory paroxysmal AF in symptomatic patients**
- **Balloon-only ablation is feasible in the majority of patients**
- **Pulmonary vein stenosis may occur with cryoablation**
- **Phrenic nerve injury occurring with cryoablation is largely reversible**
- **The STOP-AF Trial endpoints were all reached**

Closer, But Still Not A
“Real World” Trial

Purpose of CABANA Pilot Study

- **Determine the freedom from AF with ablation vs drug therapy in patients with more problematic AF and accompanying co-morbidities**
- **Test the feasibility of a long-term pivotal trial for assessing mortality, stroke, hospitalization and cost outcomes**

Design of the CABANA Pilot Study

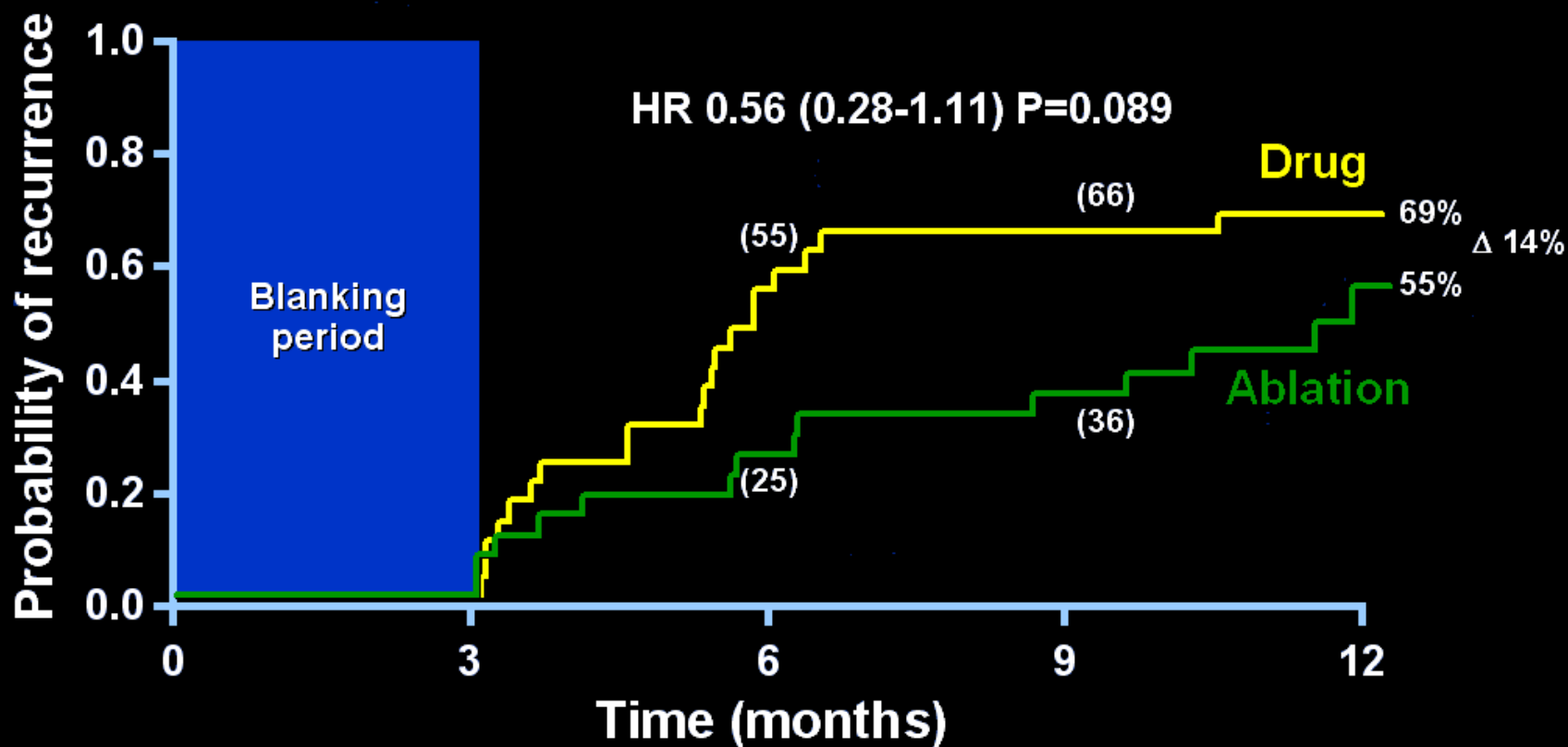


Inclusion Criteria

- ≥2 paroxysmal AF episodes (≥1 hour) over 4 mos or ≥1 persistent AF episode (>1 week)
- ≥65 yr of age, or <65 yr with ≥1 risk factors
 - Hypertension
 - Diabetes
 - Heart failure
 - Prior CVA or TIA
 - LA size >5.0 cm (Vol In ≥40 cc/m²)
 - EF ≤35 %
- Eligible for ablation and ≥2 rhythm control and/or ≥3 rate control drugs

CABANA Pilot Study

Recurrence of Any Atrial Fibrillation



Abla Rx	28	26	21	18	5
Drug Rx	31	30	13	10	6

Conclusion of the CABANA Pilot Study

- Ablative intervention was more effective than drug therapy for preventing recurrent *symptomatic* atrial fibrillation
- Treatment success rates in this population, which include a significant percentage with persistent and long-standing persistent AF, were lower than observed in other randomized clinical trials
- Late recurrence of AF may reduce long-term effectiveness of ablation
- This pilot study establishes the feasibility and importance of conducting a pivotal trial for establishing long-term outcome, mortality, quality of life, and cost of therapy for AF

Au Revoir, Coumadin?

COMING
SOON

Pradaxa[®]
dabigatran etexilate

 **Boehringer
Ingelheim**

Dabigatran: The End Of Warfarin?

Plus:

A direct thrombin inhibitor. It eliminates the middle-man.

No need for coagulation monitoring with blood tests.

Reduced risk of intracranial bleeding.

No apparent dietary restrictions.

As good as warfarin (or better) for prevention of stroke with about the same overall bleeding risk.

Minus:

Twice-a-day dosing.

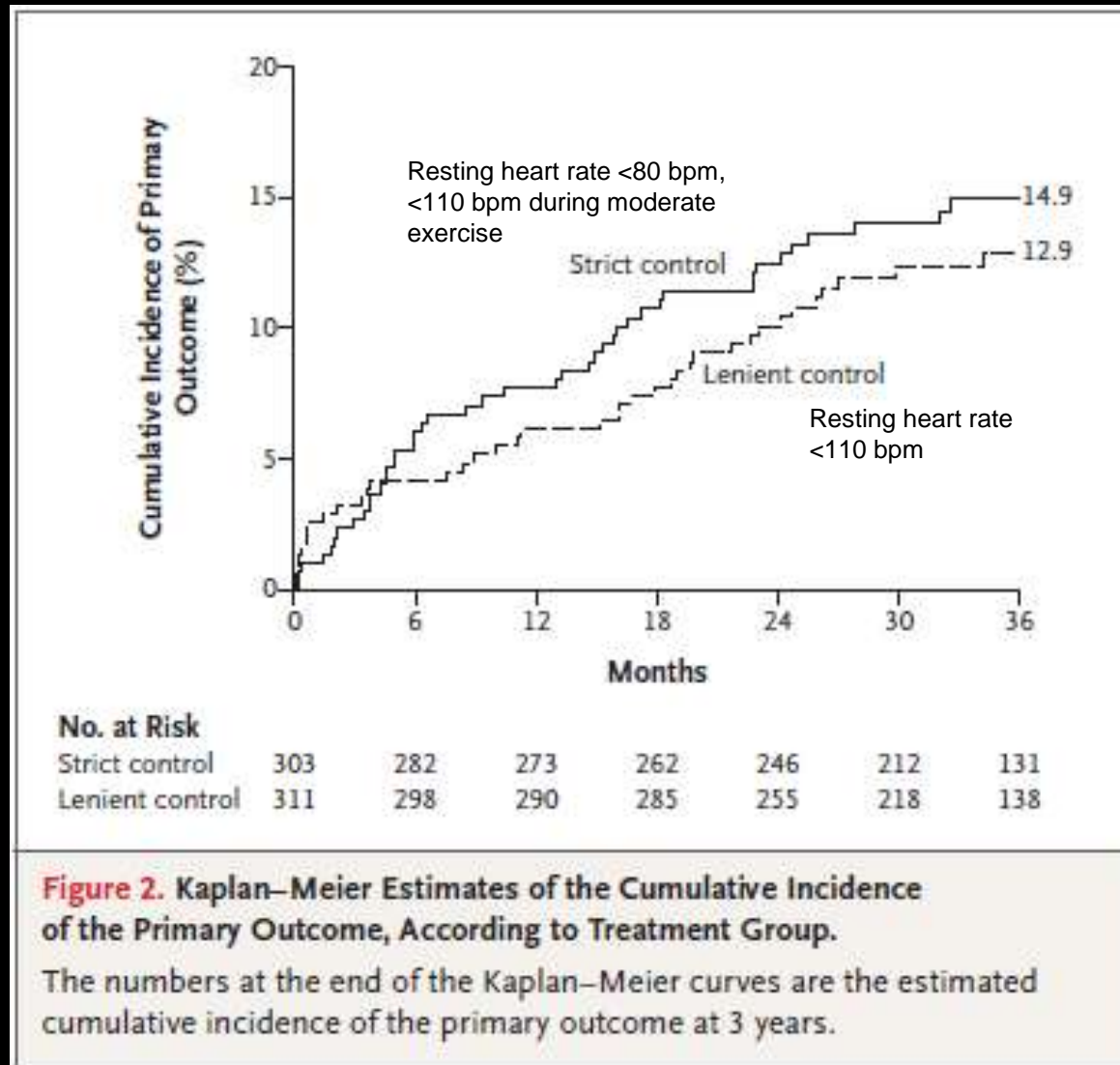
Needs an acidic environment for absorption. Wrapped in tartaric acid. Risk of GI upset.

Increased risk of GI bleeding.

Price not yet announced, but inevitably will be higher than warfarin.

Atrial Fibrillation: Is Slower
Better?

Lenient Versus Strict Rate Control in Patients with Atrial Fibrillation



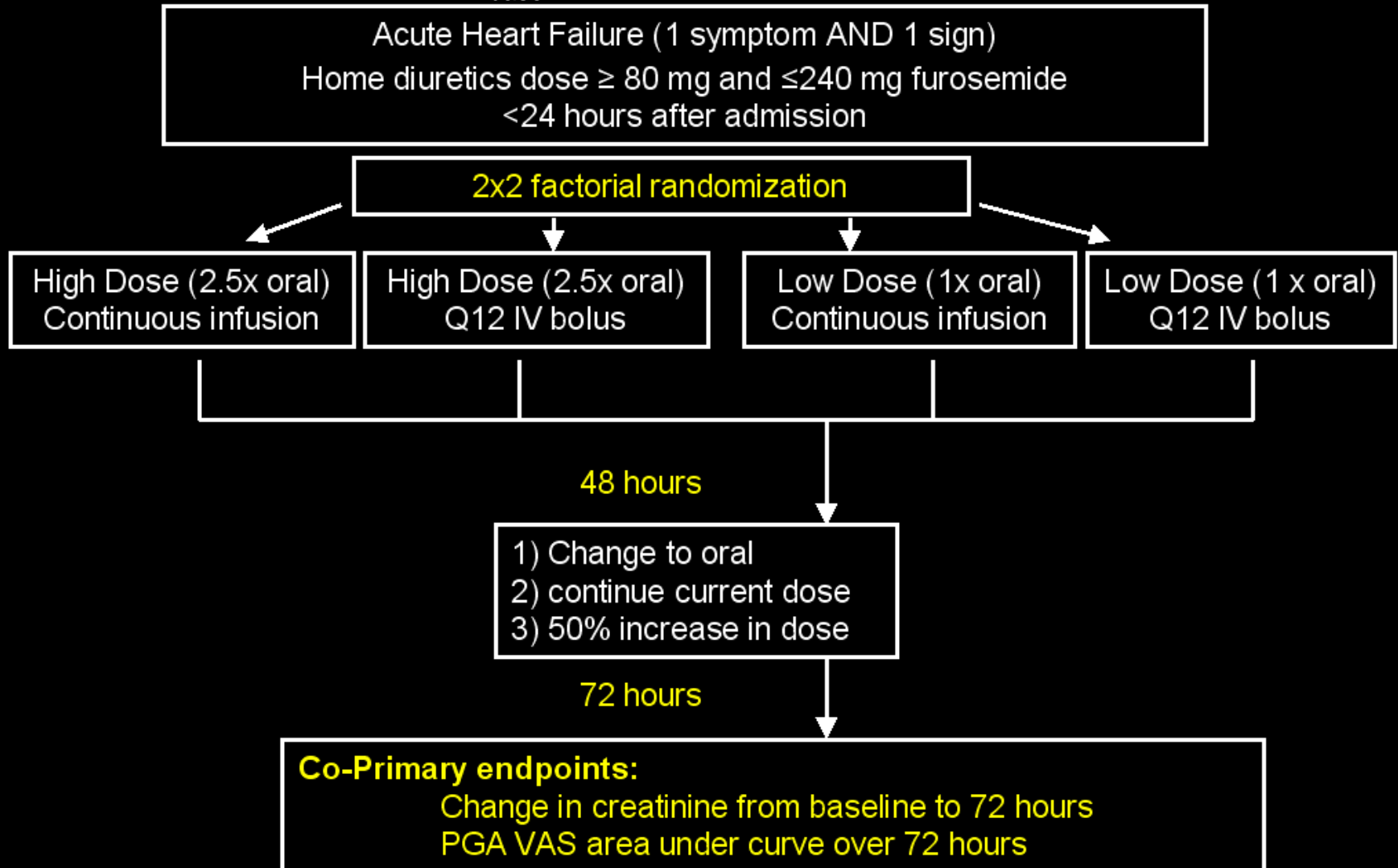
The primary outcome was a composite of death from cardiovascular causes, hospitalization for heart failure, and stroke, systemic embolism, bleeding, and life-threatening arrhythmic events.

Heart Failure

When To Say When With Lasix

The DOSE Trial: Quantity And Timing Of Furosemide Therapy In Acute CHF

- Dosing strategies get an evidence base -



The DOSE Trial: Quantity And Timing Of Furosemide Therapy In Acute CHF

- There was no statistically significant difference in global symptom relief or change in renal function at 72 hours for either:
 - Intermittent bolus vs. continuous infusion
 - Low intensification vs. high intensification
- High intensification was associated with trends towards greater improvement in multiple domains:
 - Symptom relief (global assessment and dyspnea)
 - Weight loss and net volume loss
 - Proportion free from signs of congestion
 - Reduction in NT-proBNP
- High intensification was associated with higher incidence of worsening renal function at 72 hrs but these changes did not persist over time
- **A high intensification diuretic strategy (2.5 x oral dose) with careful monitoring of renal function may be a preferred initial strategy in ADHF**

Interventional Cardiology

Clipping The Leaky Mitral Valve

Simple medical device, MitraClip, could save millions from open-heart surgery

BY [HELEN KENNEDY](#)

DAILY NEWS STAFF WRITER

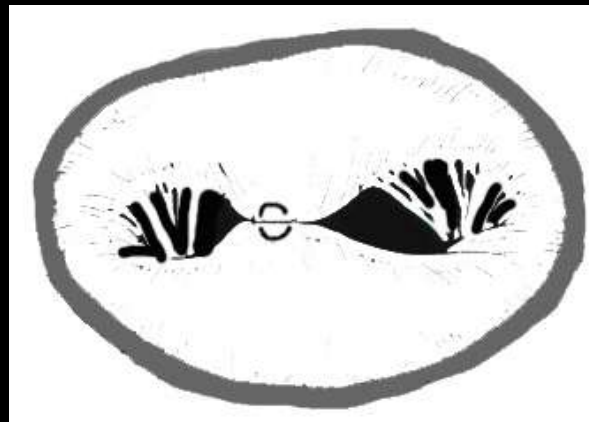
Sunday, March 14th 2010, 12:44 PM



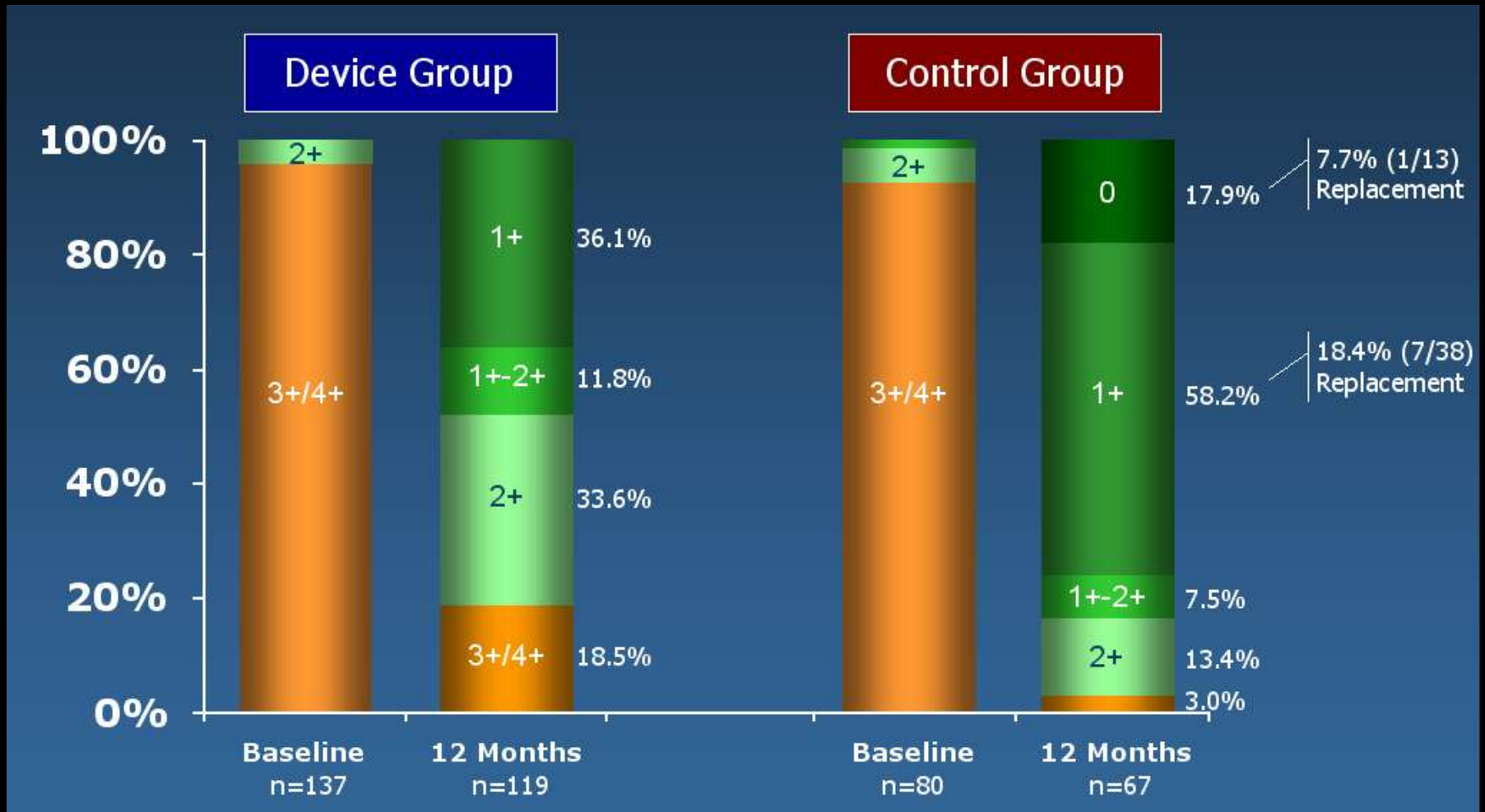
House of Taylor

Elizabeth Taylor told her Twitter followers that she received the Mitraclip, a small device that fixes leaky heart valves.





EVEREST II: Outcomes



**I did not
have six
with that
woman.**

9

AVR: Older, Sicker, Slicker

At 101, Doris Snyder Receives Sapien Aortic Valve Replacement

August 28th, 2010

This is quite interesting...

When Doris Snyder celebrated her 102nd birthday on August 10, she was that much closer to the expected birth of her first great-granddaughter who's due to arrive early September. She is very excited about the milestone, which might not have been possible were it not for a cutting-edge, experimental procedure that replaced one of Doris' heart valves weeks earlier — when she was 101 years old.



Doris' valve had been rendered useless by [aortic valve stenosis](#) — hardening from calcium deposits that restrict the flow of blood from the heart. Her surgeon, Patrick M. McCarthy, MD, chief of the division of cardiothoracic surgery for Northwestern Memorial Hospital and director of the hospital's Bluhm Cardiovascular Institute and the Heller-Sacks professor of Surgery at Northwestern University's Feinberg School of Medicine, noted:

Edwards Sapien THV



- Tri-leaflet bovine pericardial tissue treated with ThermoFix Process



- Balloon expandable stainless steel stent for sutureless implantation

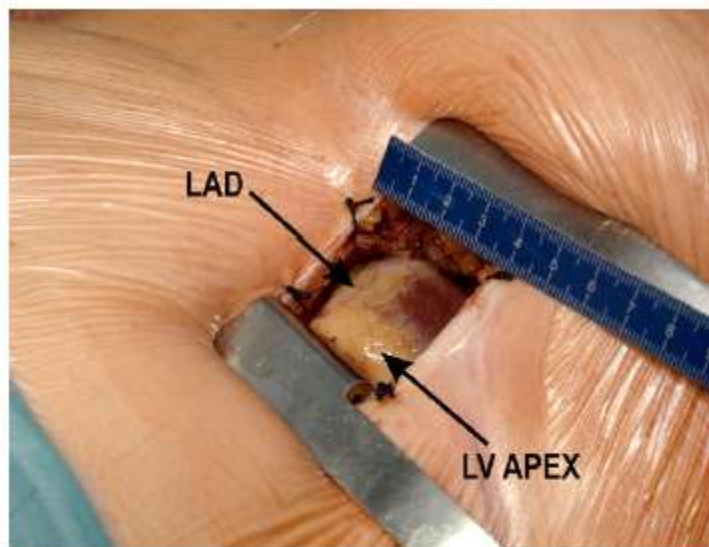


Figure 1 Approach

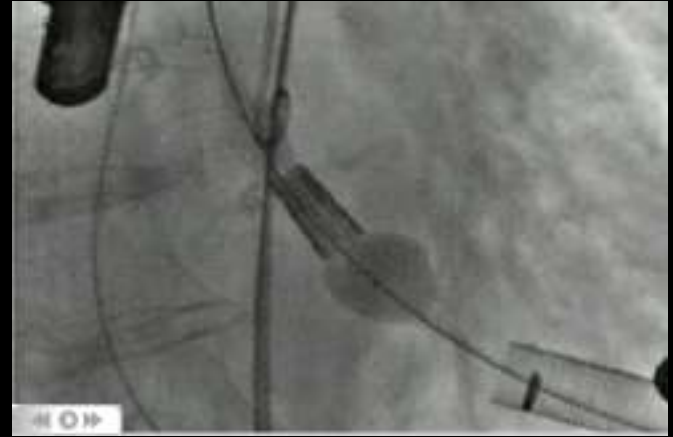
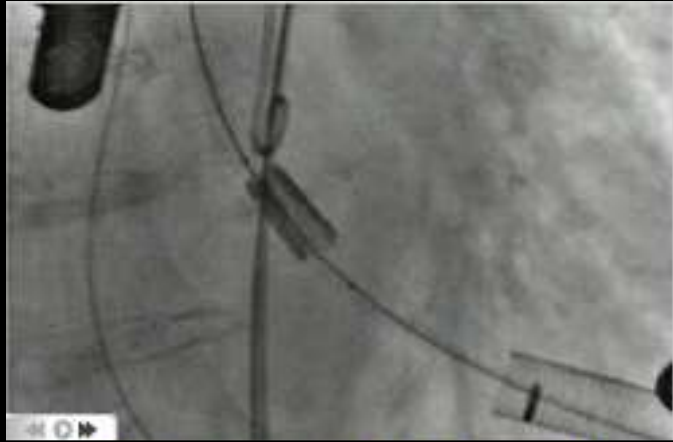
Excellent access to the apex of the heart through the left mini anterior thoracotomy. LAD = left anterior descending artery; LV = left ventricular.



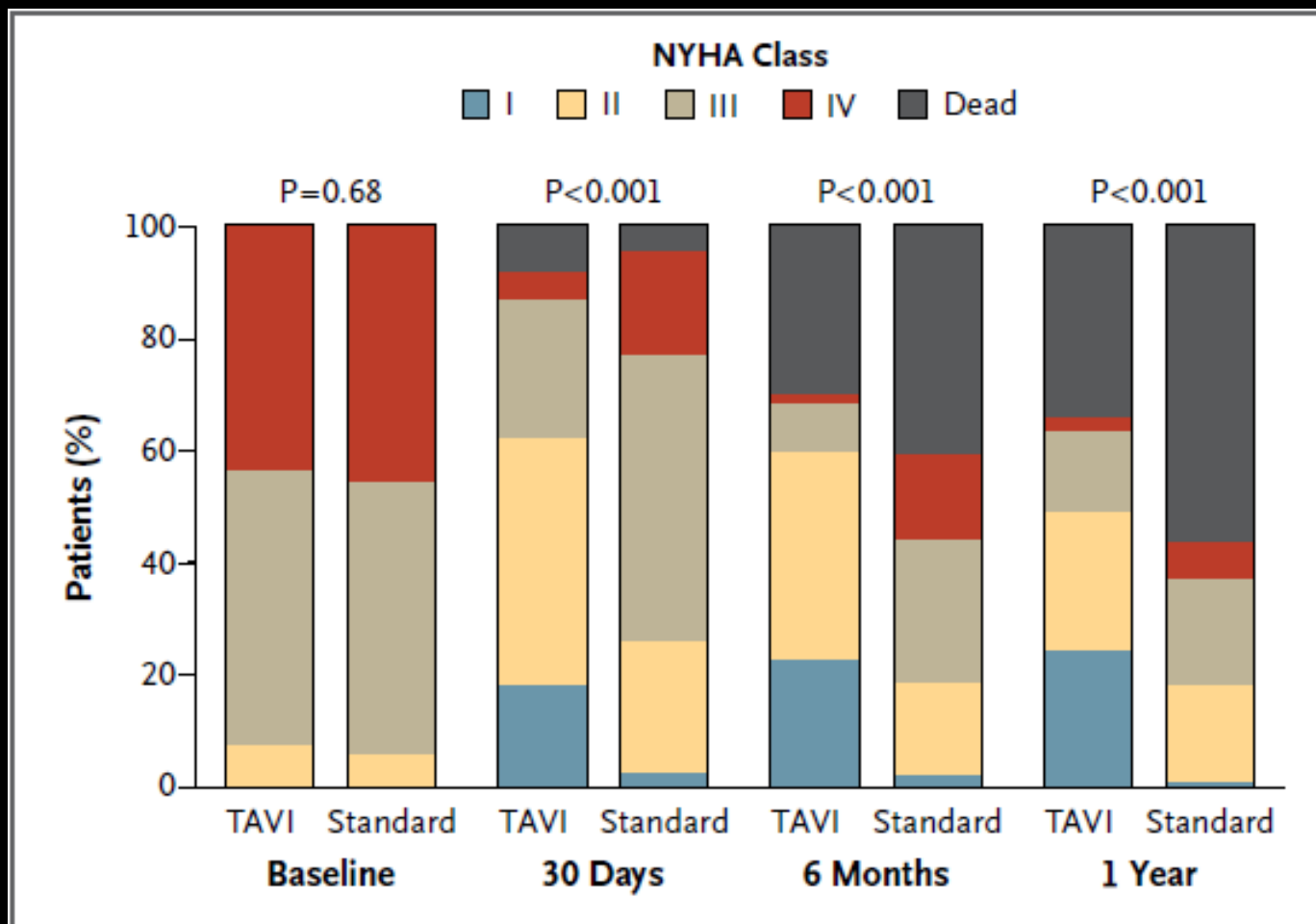
Figure 2 The Hybrid Operating Room

A special operating room that combines a catheter laboratory with the preconditions necessary to perform surgery and sterile valve preparation before implantation, anesthesiologic equipment, appropriate lighting, and the heart-lung machine.

Edwards Sapien Valve: Transapical Approach



The PARTNER Trial: 358 High-Risk Aortic Stenosis Patients, TAVI vs Medical Therapy ± Balloon Valvuloplasty

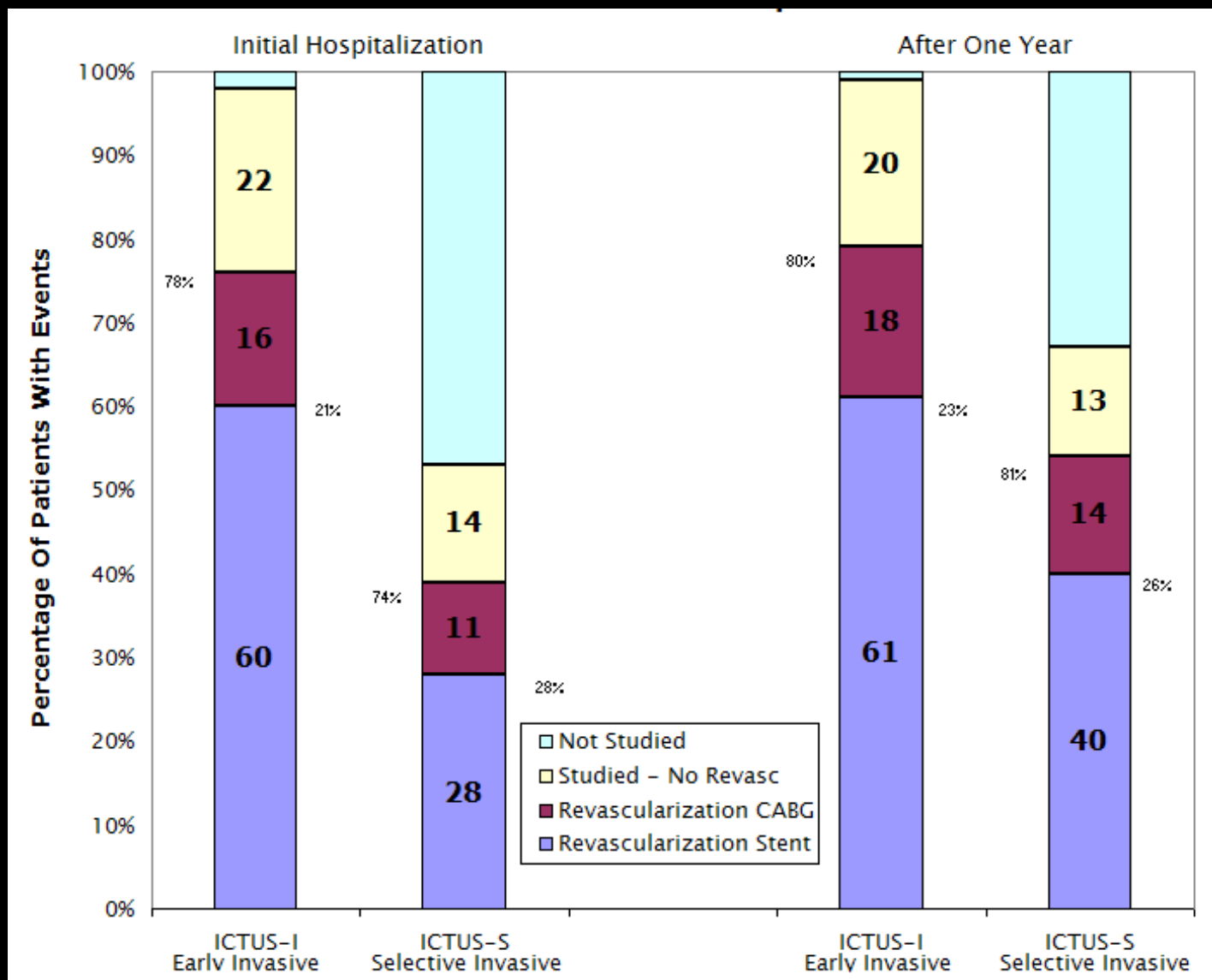


Non-ST-Segment Elevation Acute Coronary Syndrome

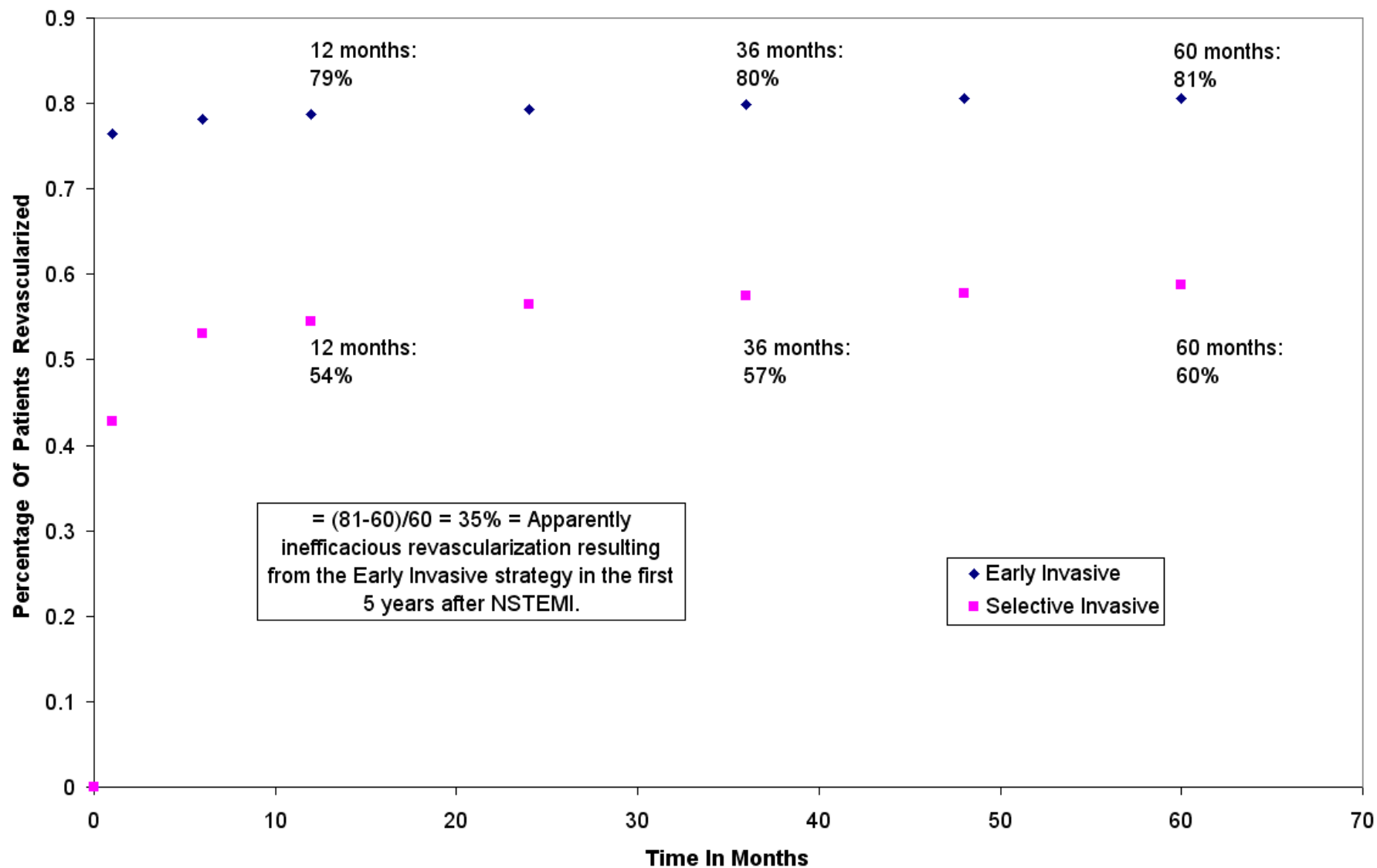
ICTUS



ICTUS: Revascularization At End Of Initial Hospitalization And After 1 Year (n=1200 pts)

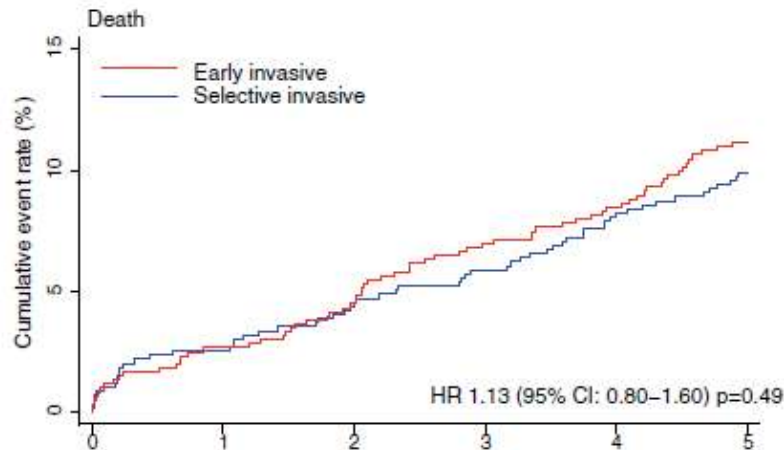


ICTUS: Timing Of First Revascularization After Presentation With Non-St-Elevation MI



ICTUS Outcomes: 5 Years

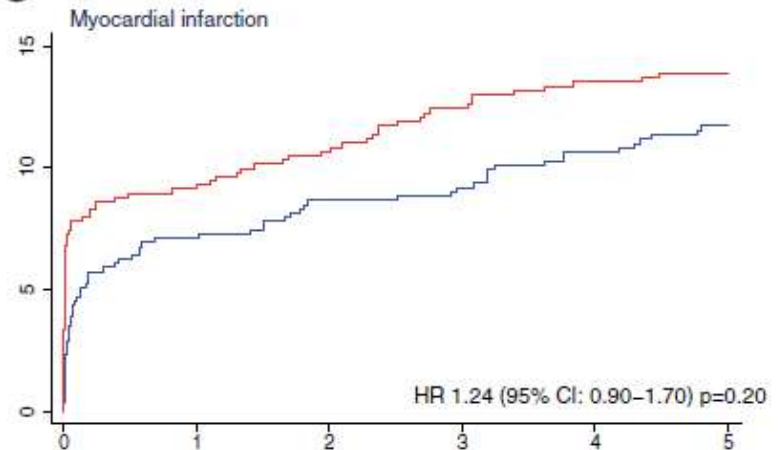
A



No. at risk

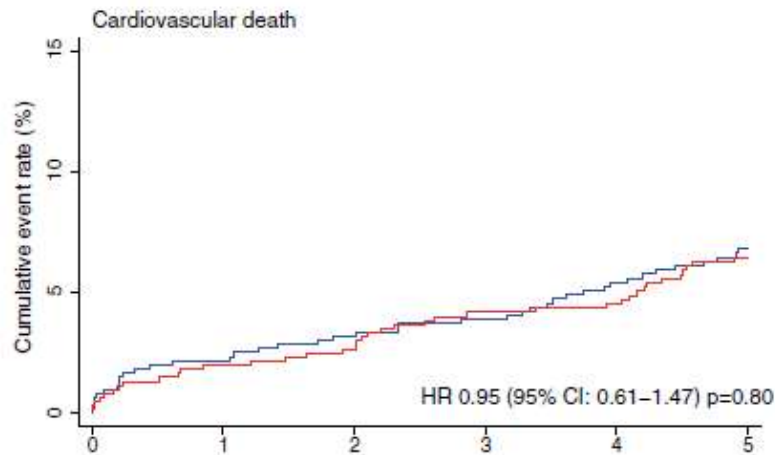
Early invasive	604	588	576	558	547	531
Selective invasive	596	581	570	561	547	536

C



604	533	515	487	469	458
596	542	524	510	490	477

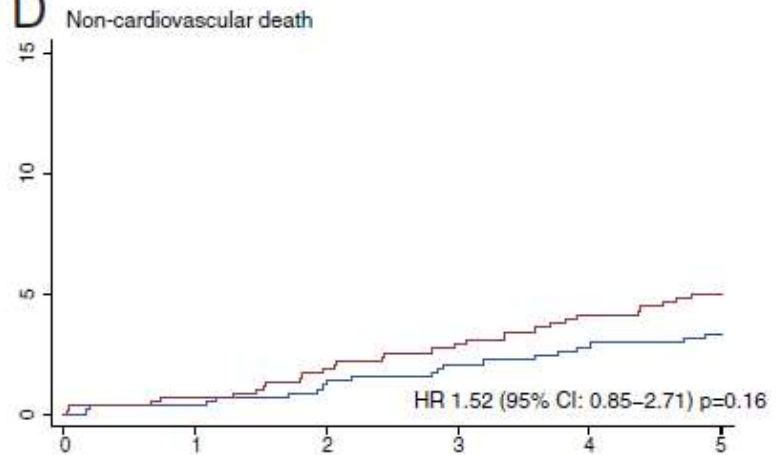
B



No. at risk

Early invasive	604	588	576	558	547	531
Selective invasive	596	581	570	561	547	536

D



604	588	576	558	547	531
596	581	570	561	547	536

Time since randomization (years)

Diseases desperate
grown

By desperate appliance
are reliev'd,

Or not at all

Claudius in “Hamlet”



Diseases desperate
grown

By desperate appliance
are reliev'd,

~~Or not at all~~ About 60% of the time
Claudius in "Hamlet"



Is This Magic?

FAME Clears It All Up

The NEW ENGLAND JOURNAL of MEDICINE

ESTABLISHED IN 1812

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VOL. 360 NO. 3

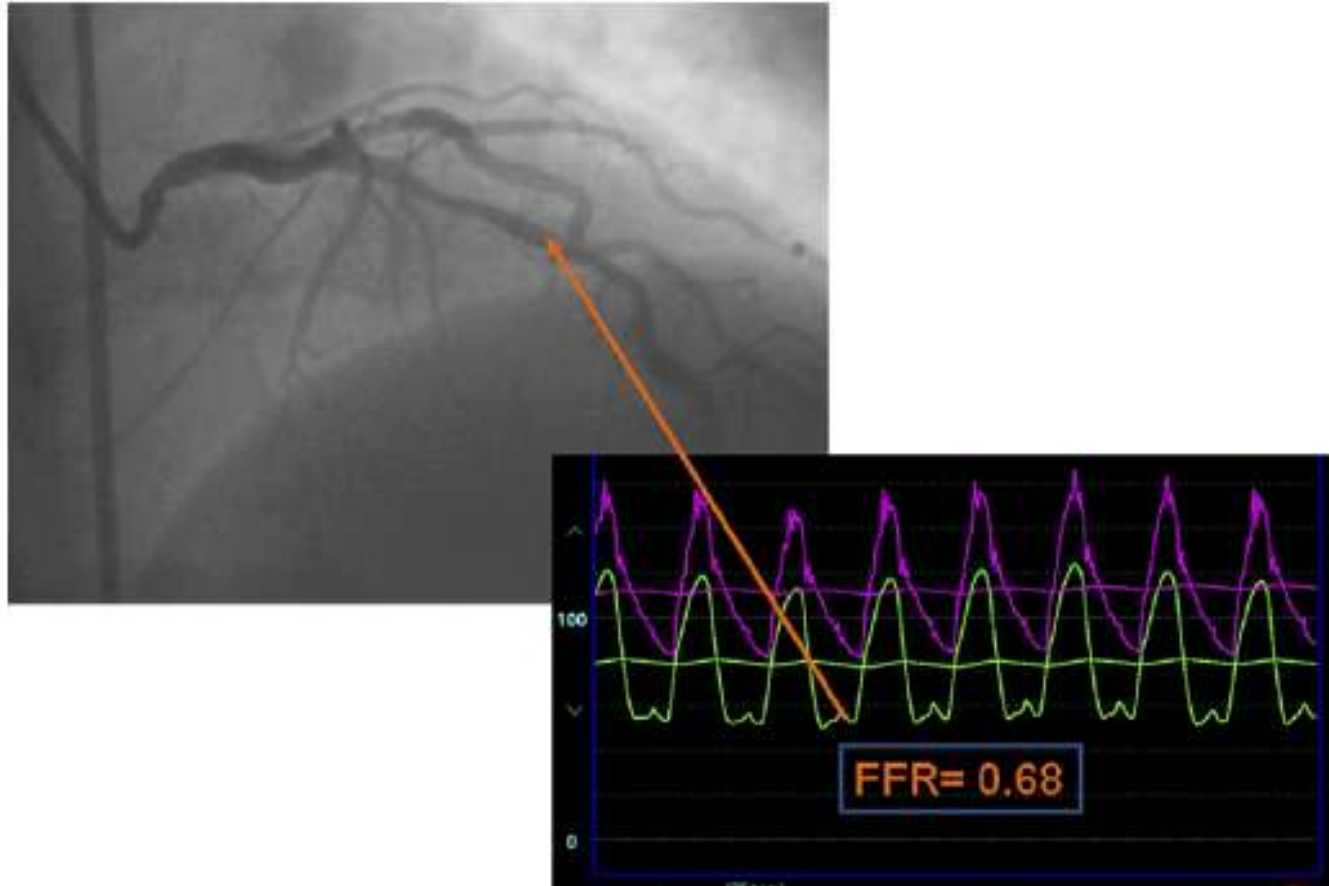
Fractional Flow Reserve versus Angiography for Guiding Percutaneous Coronary Intervention

Pim A.L. Tonino, M.D., Bernard De Bruyne, M.D., Ph.D., Nico H.J. Pijls, M.D., Ph.D.,
Uwe Siebert, M.D., M.P.H., Sc.D., Fumiaki Ikeno, M.D., Marcel van 't Veer, M.Sc., Volker Klauss, M.D., Ph.D.,
Ganesh Manoharan, M.D., Thomas Engström, M.D., Ph.D., Keith G. Oldroyd, M.D., Peter N. Ver Lee, M.D.,
Philip A. MacCarthy, M.D., Ph.D., and William F. Fearon, M.D., for the FAME Study Investigators*

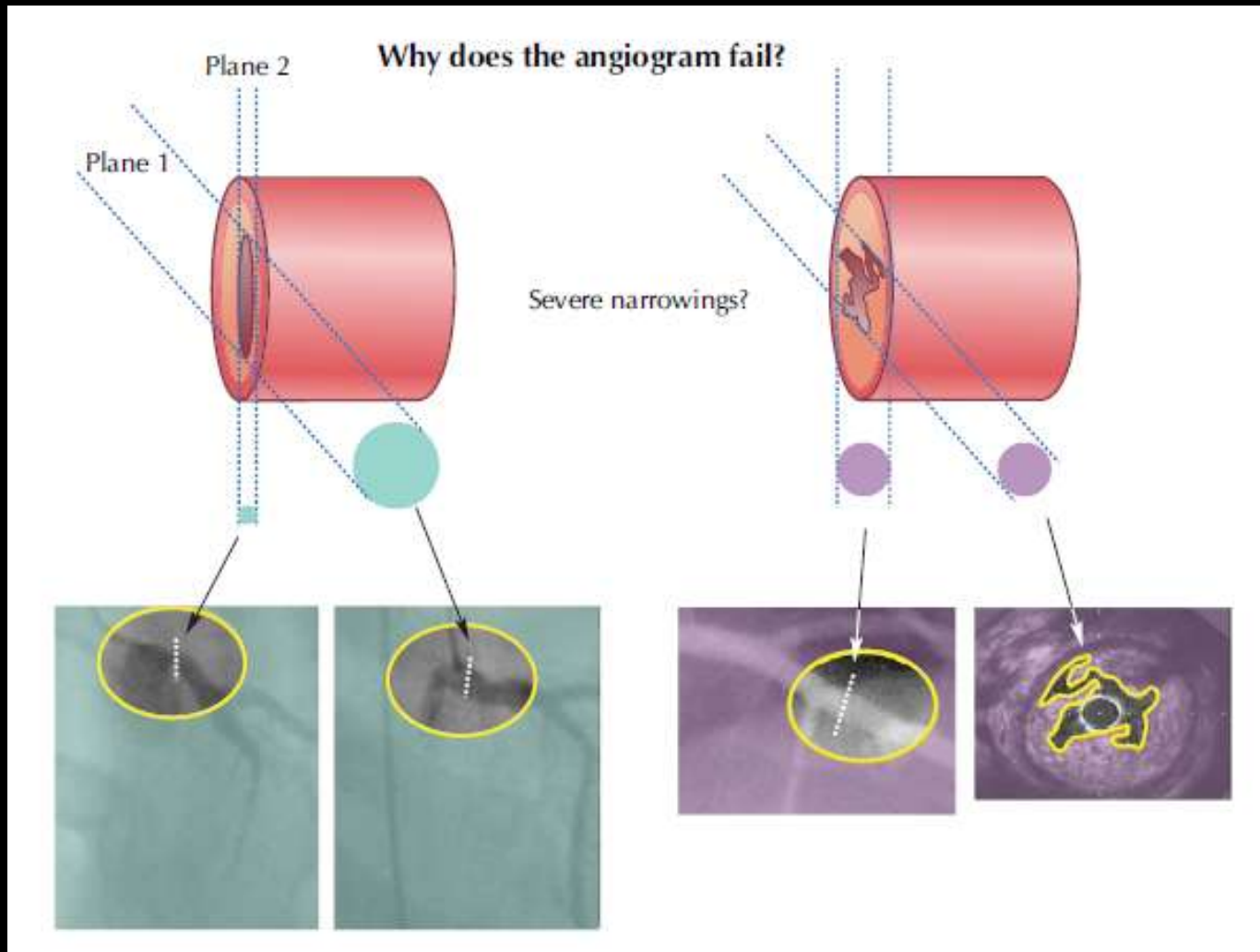
Characteristic	Angiography Group (N=496)	FFR Group (N=509)	P Value†
Angiographic Findings			
Indicated lesions per patient — no.‡	2.7±0.9	2.8±1.0	0.34
No. of stents per patient			
Mean	2.7±1.2	1.9±1.3	<0.001

$$0.8/2.7 = 30\%$$

Understanding The Results Of FAME

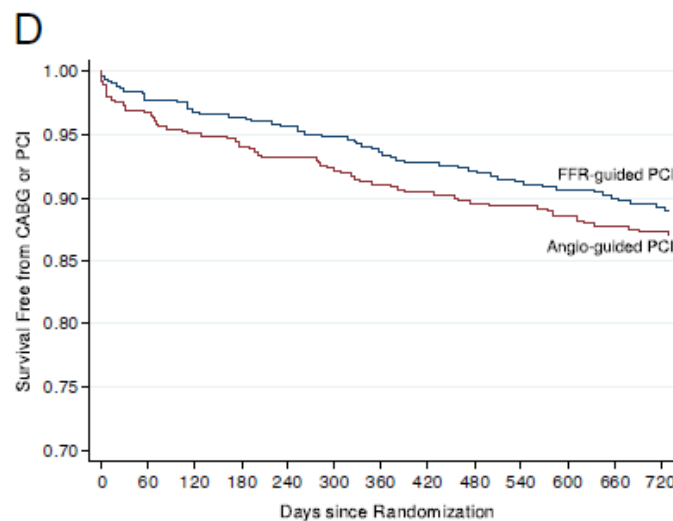
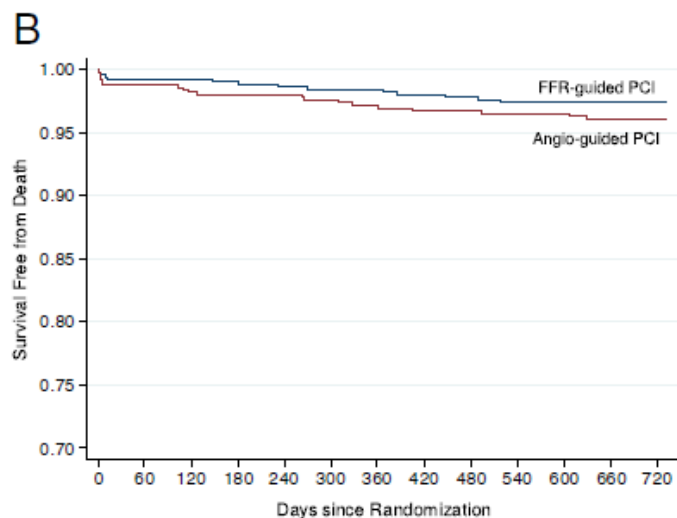
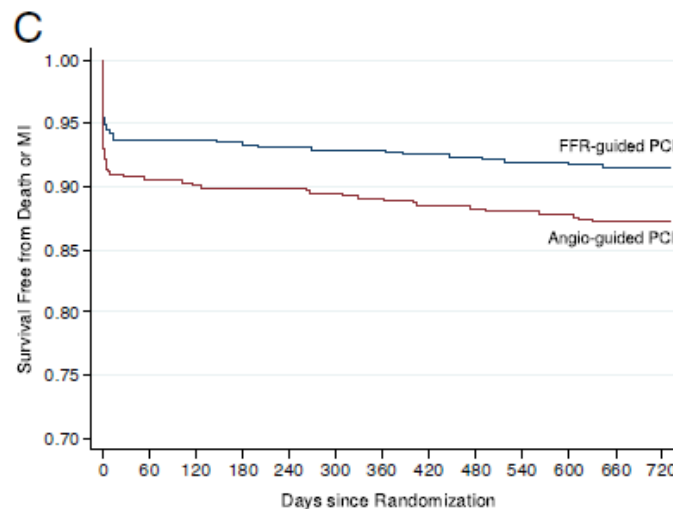
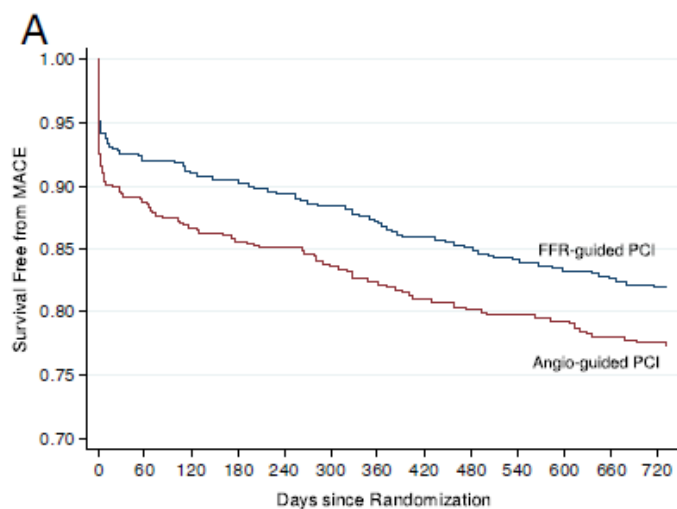


Understanding The Results Of FAME

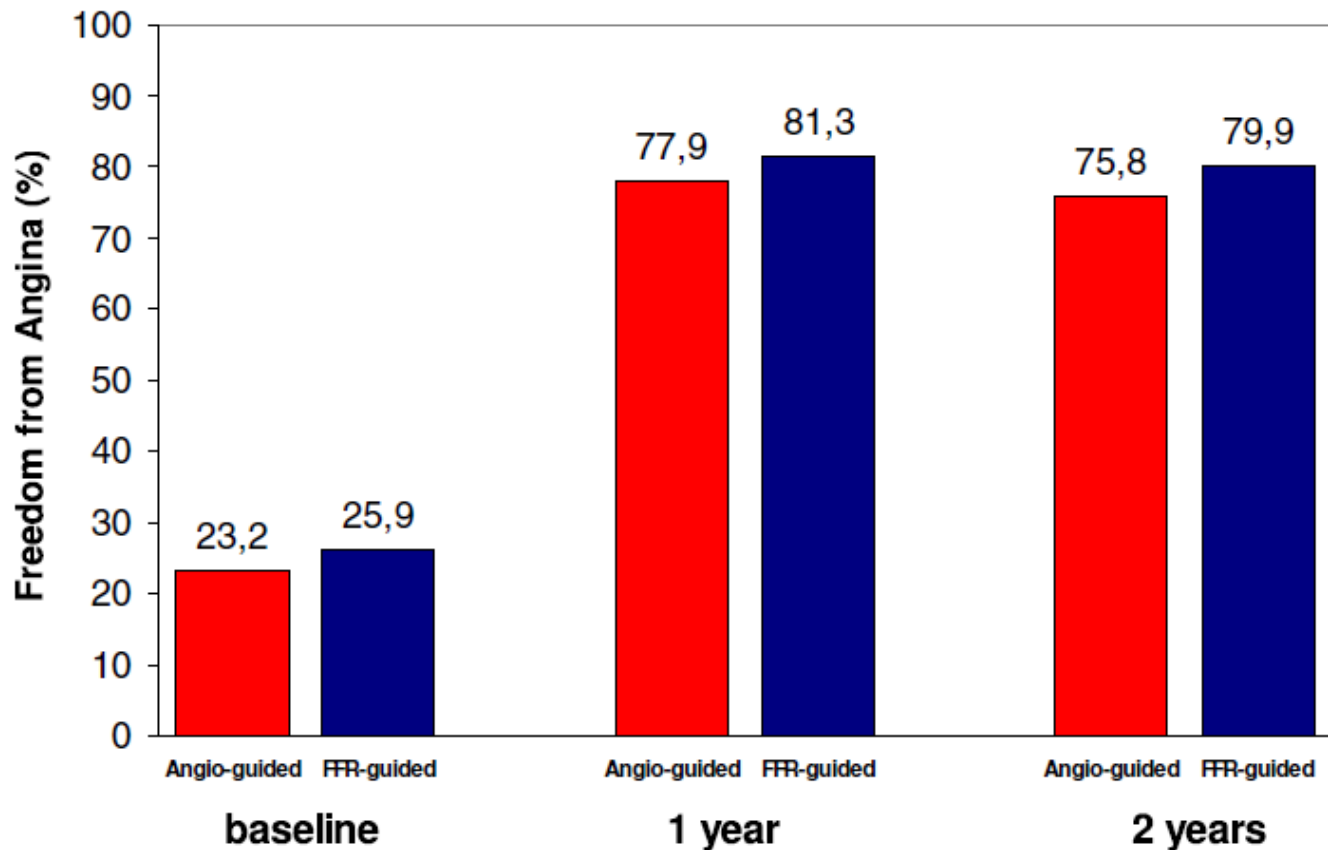


Using FFR to assess all 3 vessels, Sant'Anna et al. (Am J Cardiol 2007;99:504–8.) have shown that the incidence of “significant” 3-vessel angiographic CAD drops from 27% to 9%, 2-vessel drops from 43% to 17%, and single-vessel disease increases from 30% to 60%, simplifying decision making in this difficult patient group.

FAME: 2-Year Outcomes



FAME: Patients Entirely Free From Angina



FAME: Is Deferral Of Stenting An Invitation To Preventable MI?

FAME "Deferred" Lesions: MI at 2 years	1/500 = 0.1%/year
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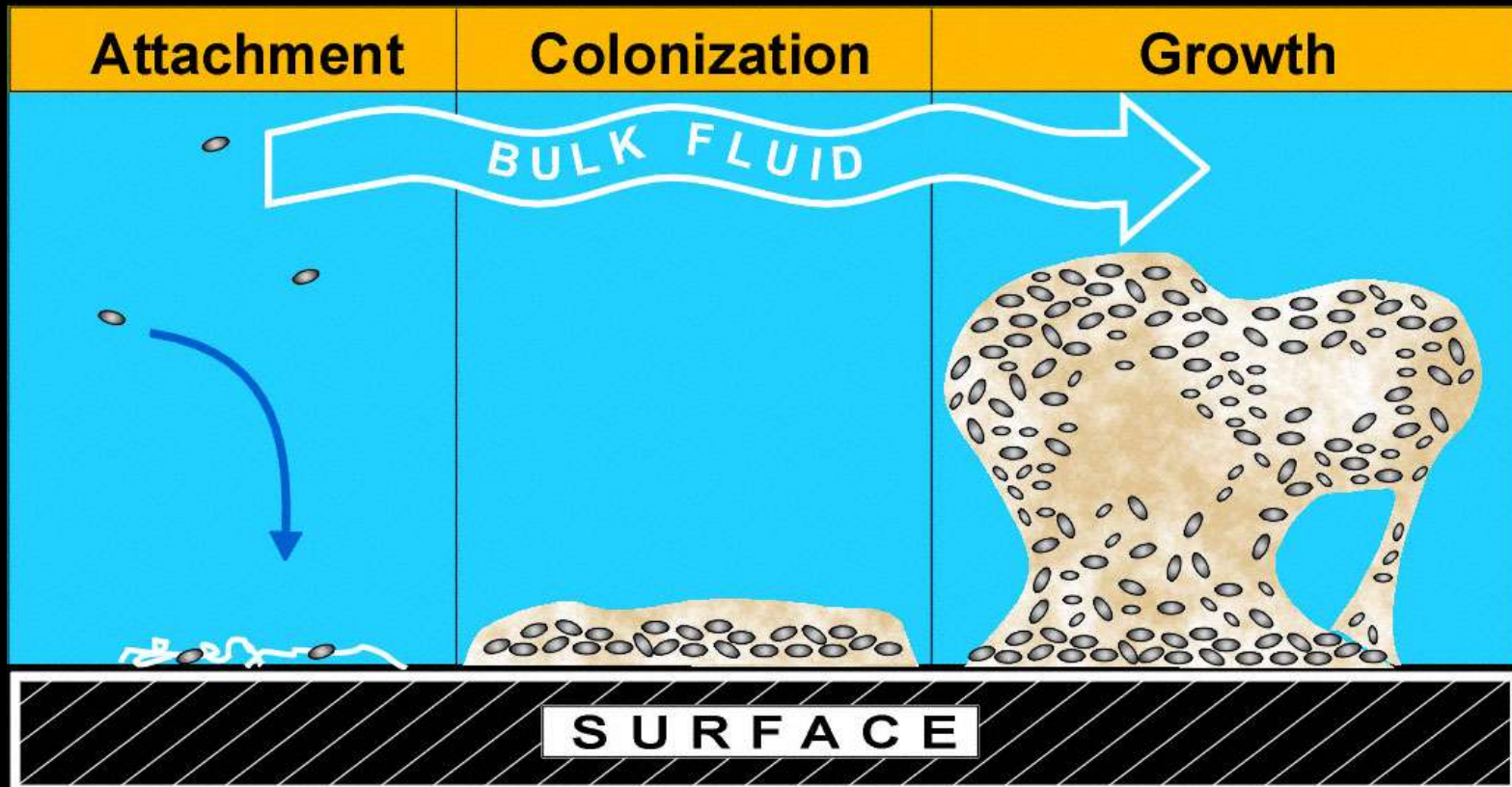
Bare metal and drug-eluting stent thrombosis rate per year (N Engl J Med 2007;356:1020-9)	0.4% to 0.6%/year
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Mortality rate with stent thrombosis and MI	30% to 45%
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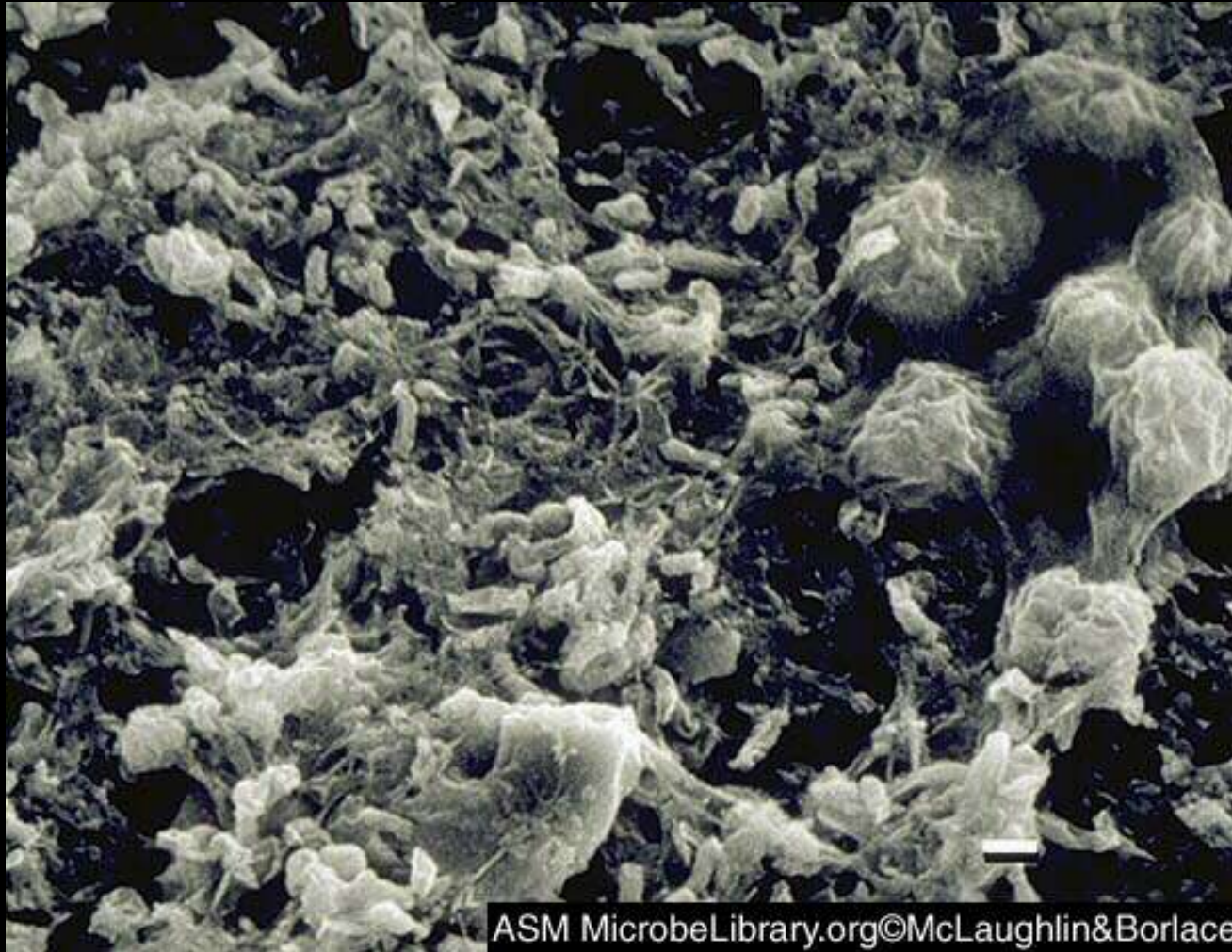
Bacteria 1, Eukaryocytes 0

Asymptomatic Bacterial Colonization Of Intravascular Devices/Generators

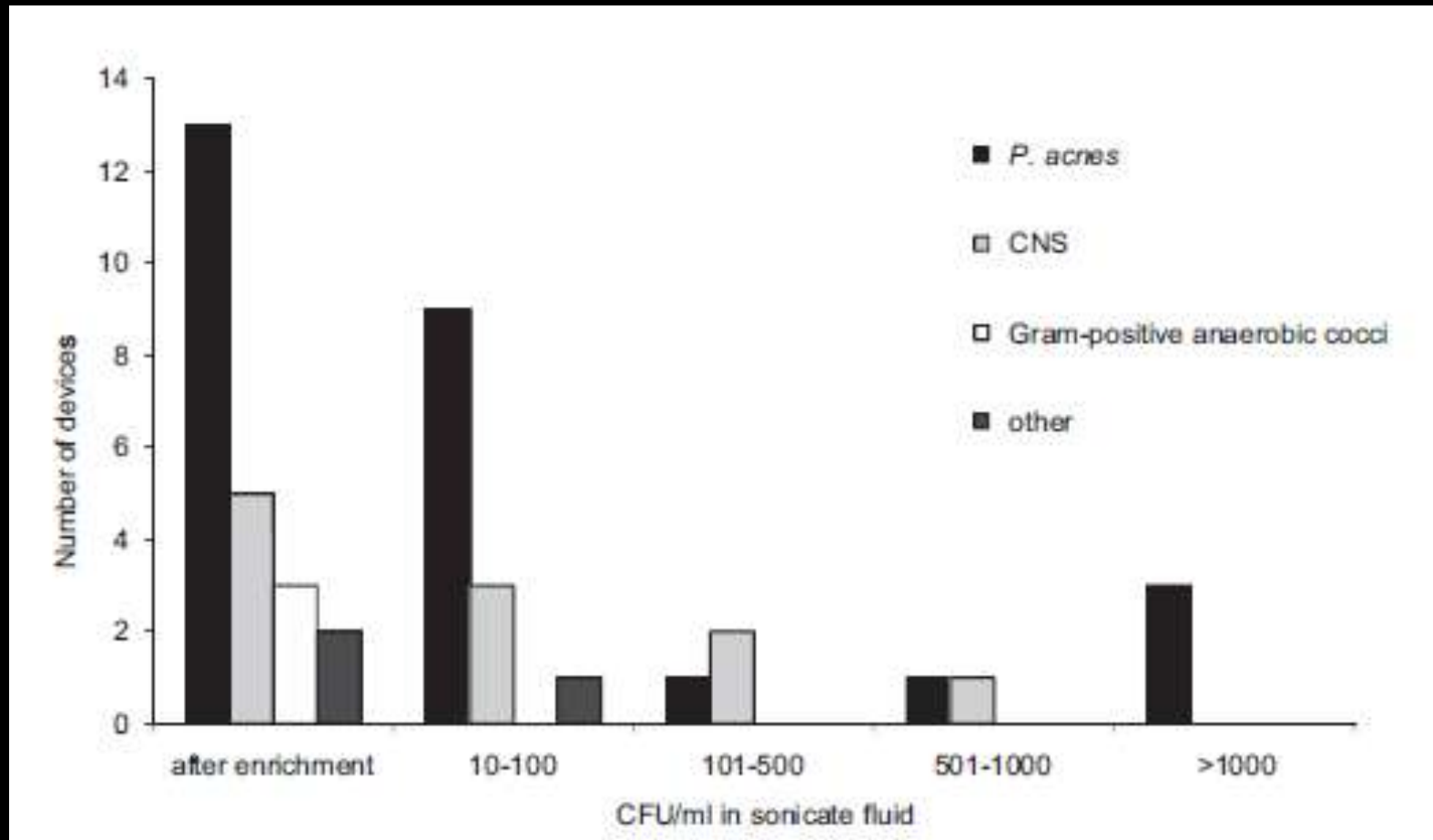
Biofilm formation:

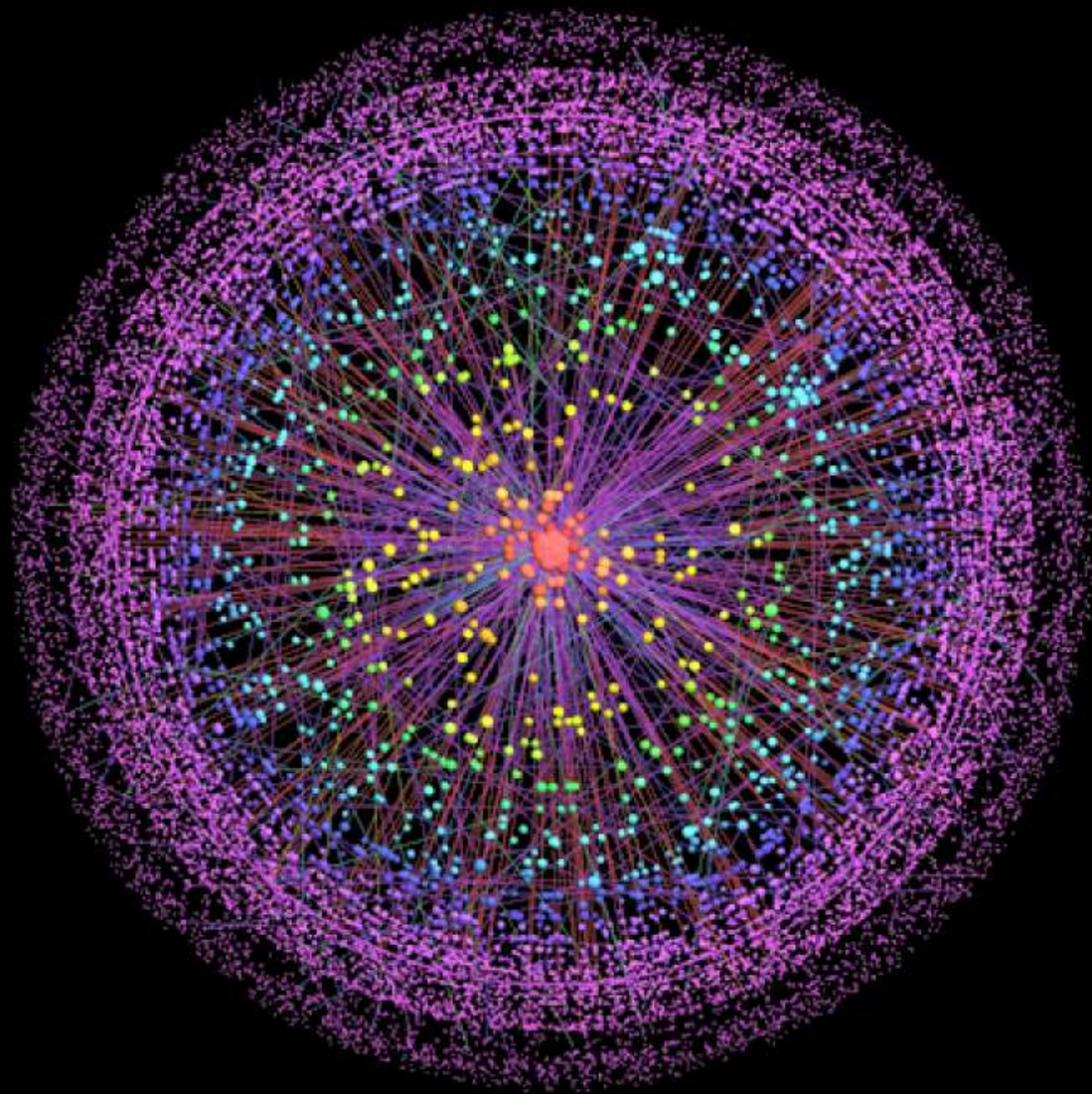


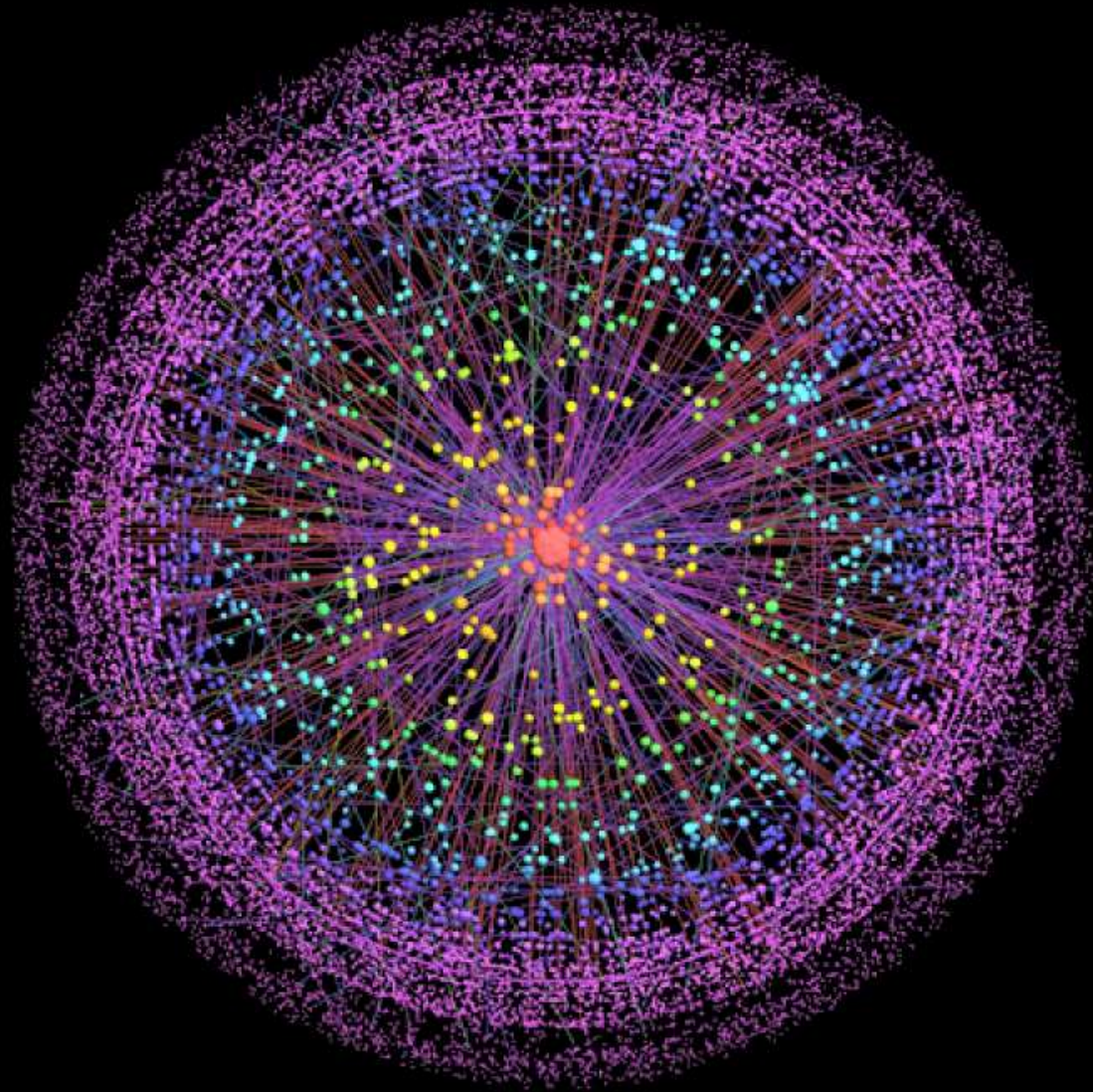
Asymptomatic Bacterial Colonization Of Intravascular Devices/Generators



Asymptomatic Bacterial Colonization Of Intravascular Devices/Generators







The Internet

THANK

YOU