What is CHIP and Why Do We Need It?

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Disclosure Statement

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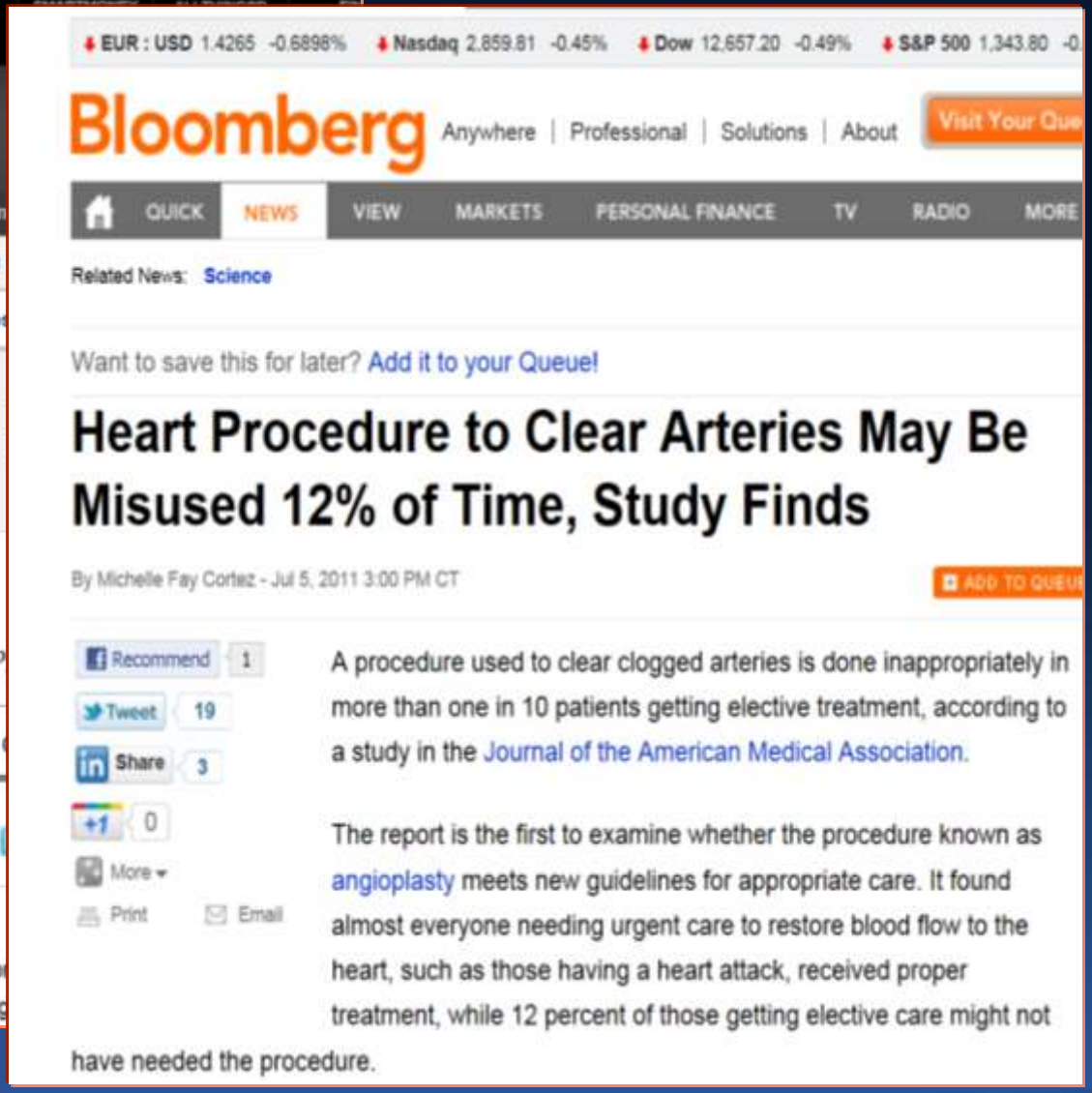
Thanks to the CUMC/NYP CHIP Team:
Jeff Moses, Dimitri Karmpaliotis, Mike Collins, Manish Parikh, Martin Leon

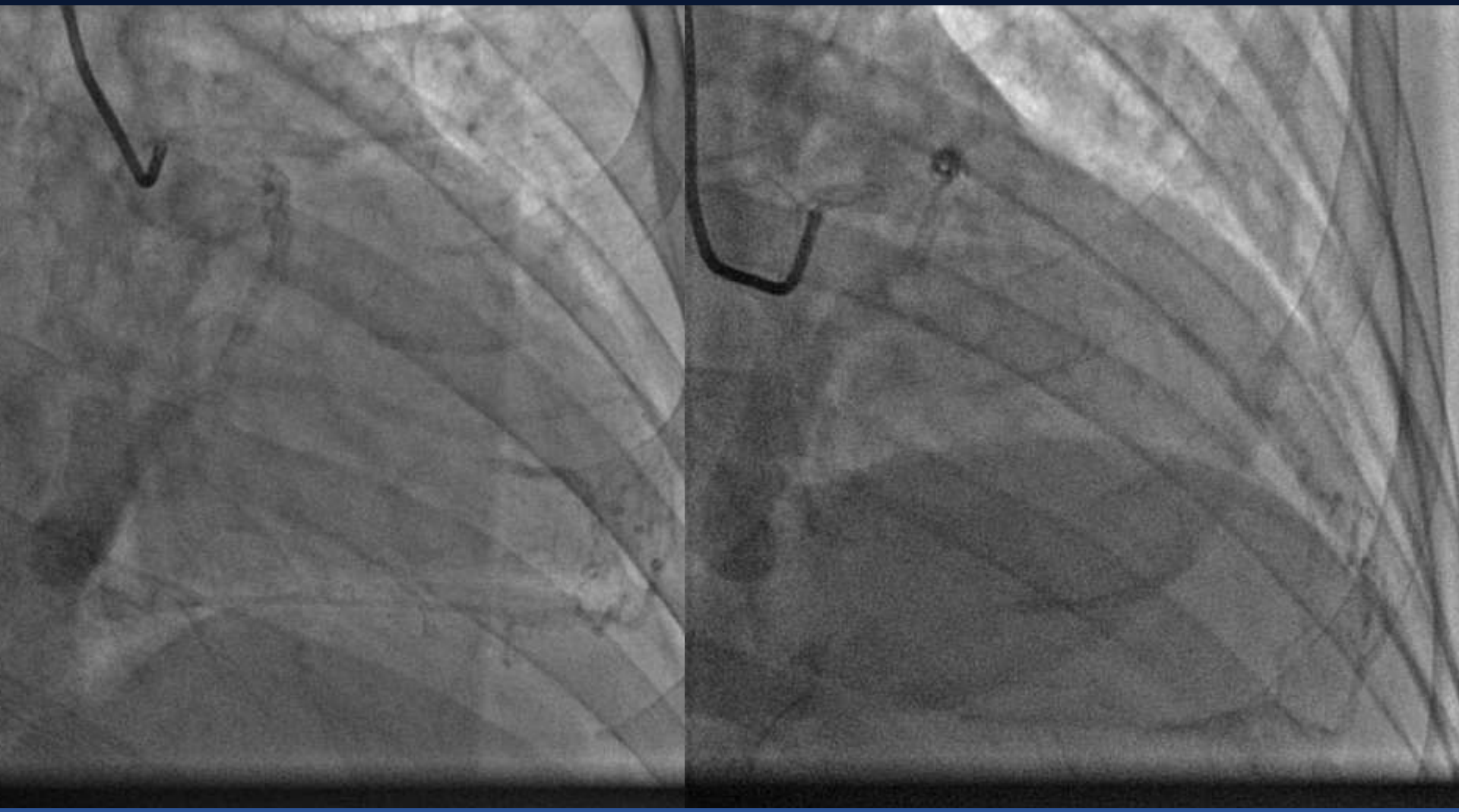
Is PCI Overused?



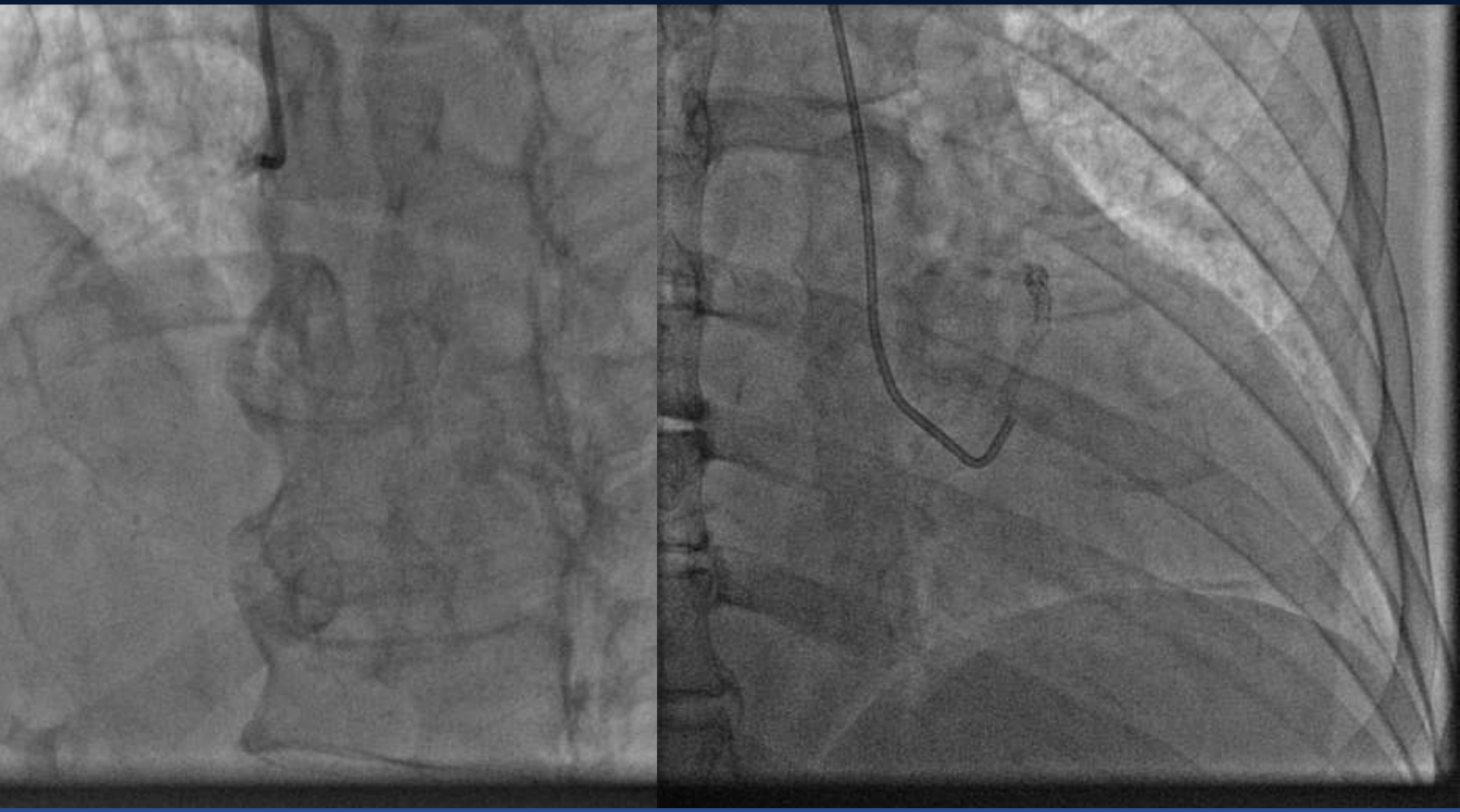
Why We Needed to Evolve: Illustrative Case

- 77 y/o male Neurologist with HTN, HLD, DM2 on oral agents
  - CAD s/p DES x3 to LCx
- Asymptomatic, but underwent stress testing as part of a pre-operative evaluation for a colonoscopy
  - ETT demonstrated 3-4 mm ST depressions inferiorly, 1-2 mm ST depressions laterally but no SPECT ischemia at 10:15
  - Referred for coronary angiography at an OSH

Diagnostic Angiography



Diagnostic Angiography



Management

- Official read of cath report:
  - 50-55% LMCA stenosis
  - 30-40% mid-LAD stenosis
  - 60% D1 stenosis (diffuse)
  - 40% ISR of dLCx
  - 30-40% mid and distal-RCA

- **Referred to CT surgery at our institution for CABG but asking about PCI as a possibility**

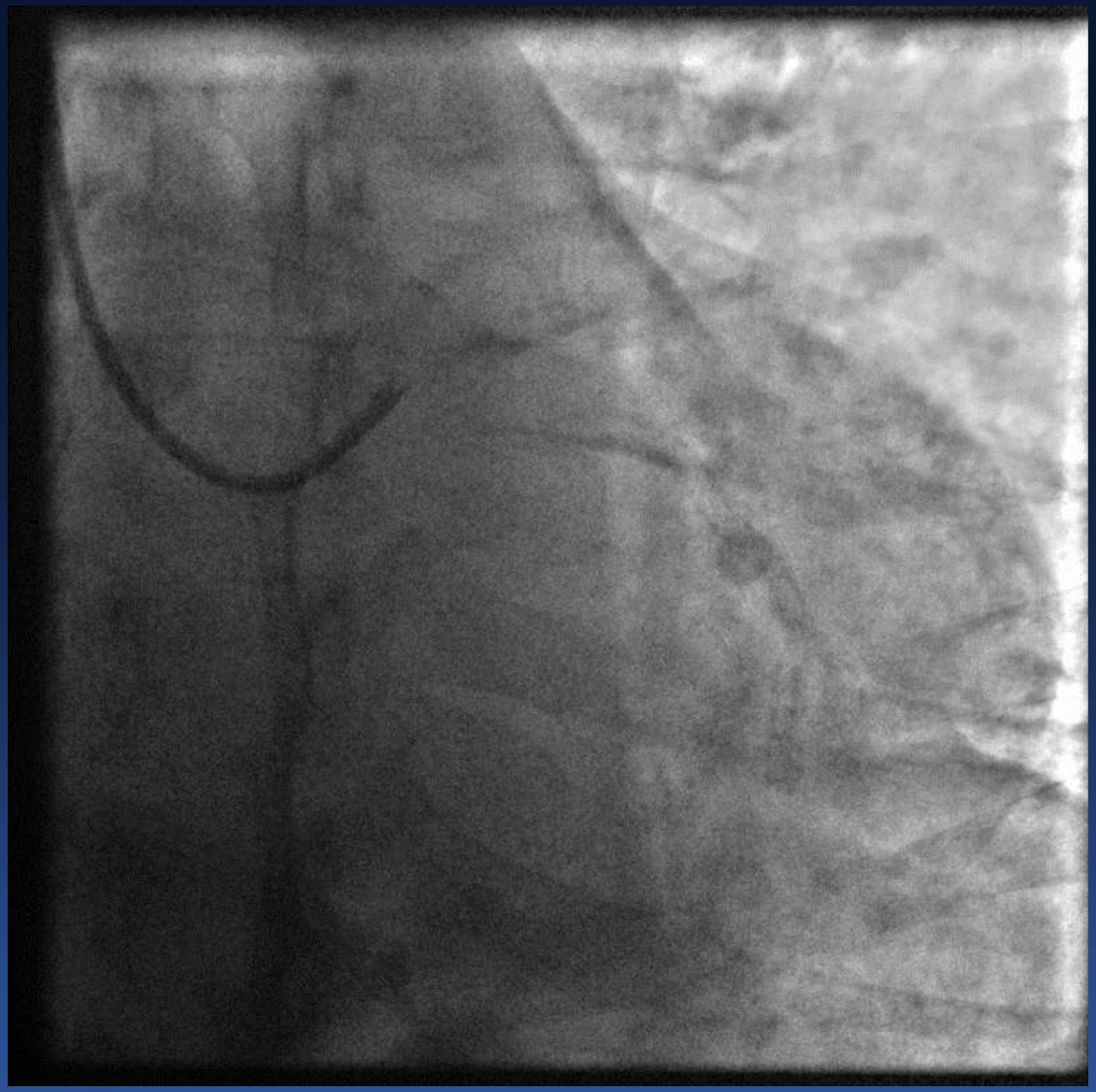
WHAT????

Evolution of Modern-Day PCI

Things HAVE actually gotten more complex

- Advances in core and adjunctive therapies (stents, imaging/physiology, wires/microcatethers, specialty devices, hemodynamic support, pharmacotherapy)
- Advanced coronary techniques (e.g. CTO, bifurcations, calcium)
- Patient-centered approach to case selection; more judicious use of PCI for ischemia-producing lesions but with focus on functionally complete revascularization

Post FFR of all 3 Vessels (all non-significant)



CABG Deferred!

PCI Deferred!

Back to (Asymptomatic!) Clinical Practice with Intensification of Medical Therapy

Modern/Current View of Cath and PCI

But what about Underuse?
Can it be Measured?

Newsweek 8/17/11

Goals of the CHIP Initiative

- Identifying a potentially underserved population (shift away from overuse)
- Raise awareness in the general and specialized cardiovascular community of this high-risk population
  - Enlist collaborative support to promote this initiative based on the overall initiative and not merely “device specific events”
- Education and Teaching / Best Practices
- Initiate research and clinical programs

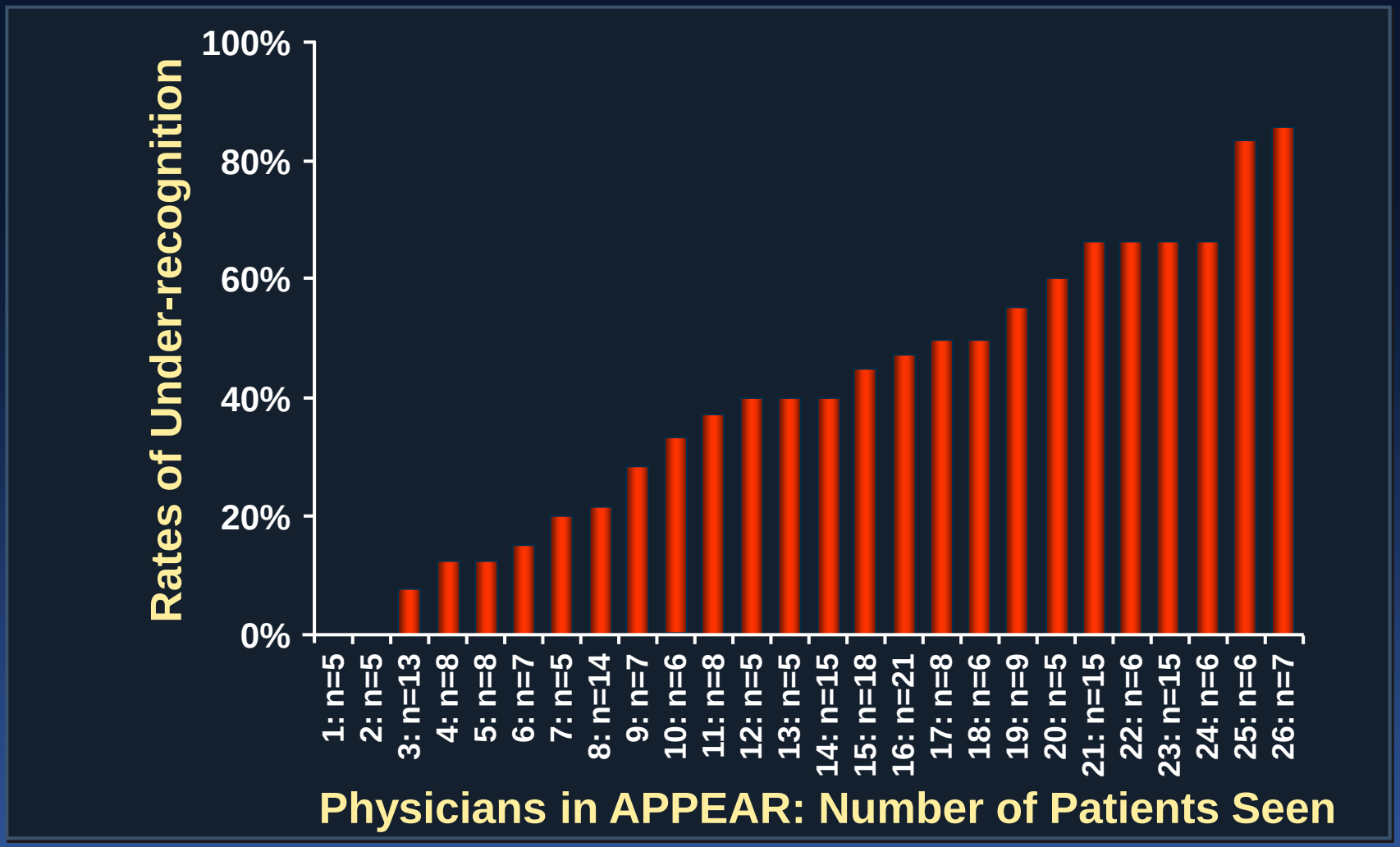
Rule #1 for Success

Understand the diseases you are treating

Understanding the disease process and knowing what should be done is often as challenging as performing the intervention

APPEAR: Under-recognition of Angina

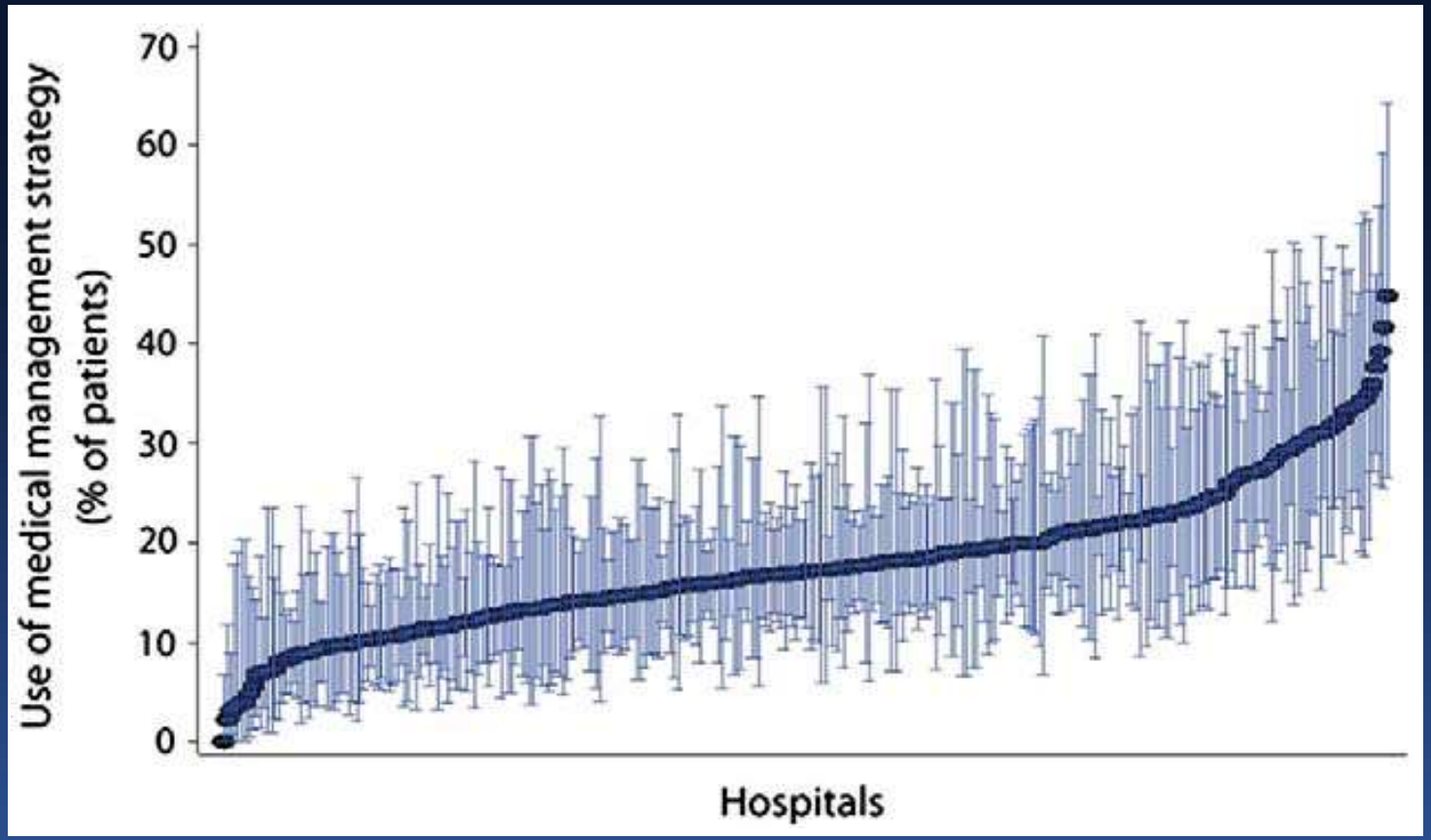
Individual Physician Reporting compared with SAQ



Arnold, S. et al. *Circ Cardiovasc Qual Outcomes.* 2016; 9:00-00

NSTEMI with LMCA/3VD: A Role for Medical Management?

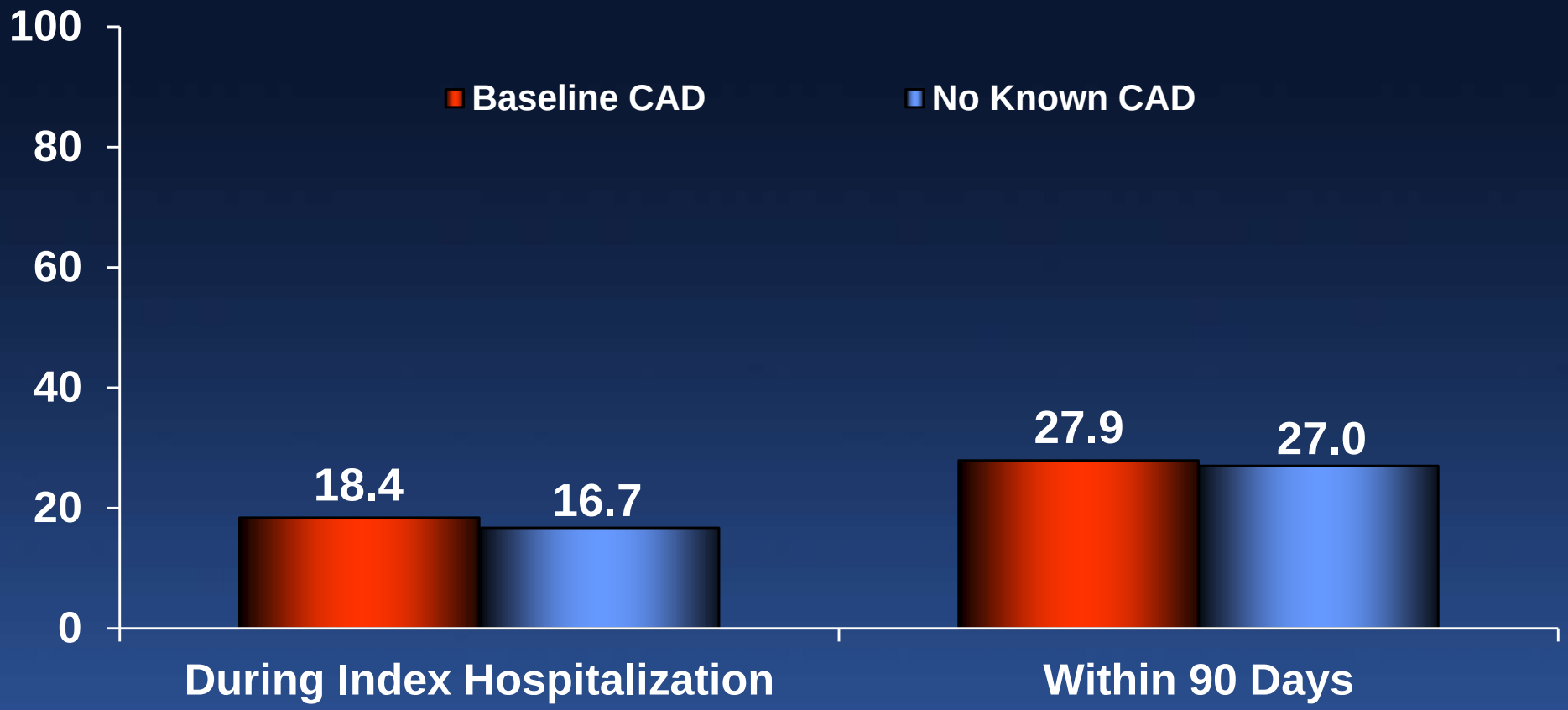
41,310 pts from 316 high-volume hospitals in ACTION-GWTG



Harskamp et al, AHJ 2014

Rates of Invasive / Non-invasive Work-up for CAD in *67,640 Patients with New HF as Principal Diagnosis*

MarketScan Commercial and Medicare Supplemental Databases (1/1/2010-7/31/2014)



Doshi et al, JACC 2016

So…
What is CHIP?

C omplex

H igh risk

I nterventional

P rocedures

C omplex

H igh risk

I ndicated

P atients

C omplete Revasc of

H igh risk

I ndicated

P atients

WHITE PAPER

Treatment of Higher-Risk Patients With an Indication for Revascularization

Evolution Within the Field of Contemporary Percutaneous Coronary Intervention

ABSTRACT: Patients with severe coronary artery disease with a clinical indication for revascularization but who are at high procedural risk because of patient comorbidities, complexity of coronary anatomy, and/or poor hemodynamics represent an understudied and potentially underserved patient population. Through advances in percutaneous interventional techniques and technologies and improvements in patient selection, current percutaneous coronary intervention may allow appropriate patients to benefit safely from revascularization procedures that might not have been offered in the past. The burgeoning interest in these procedures in some respects reflects an evolutionary step within the field of percutaneous coronary intervention. However, because of the clinical complexity of many of these patients and procedures, it is critical to develop dedicated specialists within interventional cardiology who are trained with the cognitive and technical skills to select these patients appropriately and to perform these procedures safely. Preprocedural issues such as multidisciplinary risk and treatment assessments are highly relevant to the successful treatment of these patients, and knowledge gaps and future directions to improve outcomes in this emerging area are discussed. Ultimately, an evolution of contemporary interventional cardiology is necessary to treat the increasingly higher-risk patients with whom we are confronted.

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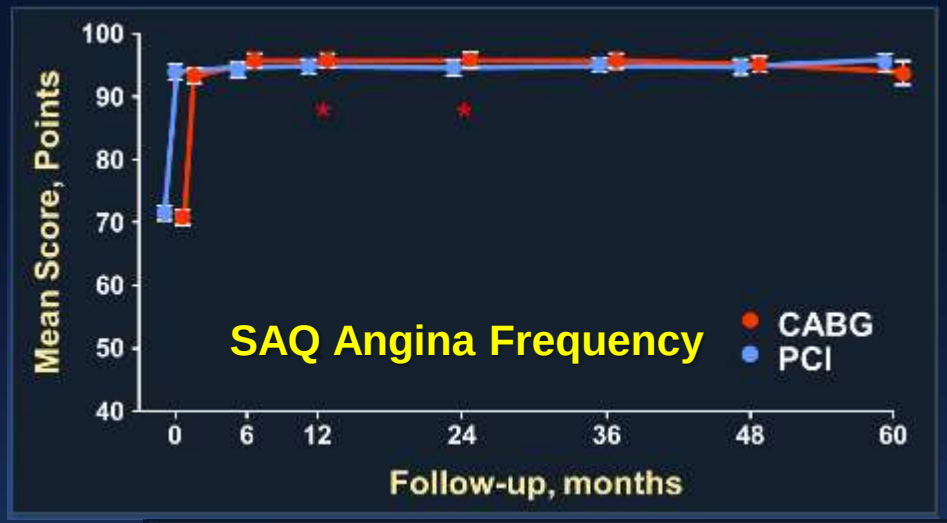
Circulation 2016

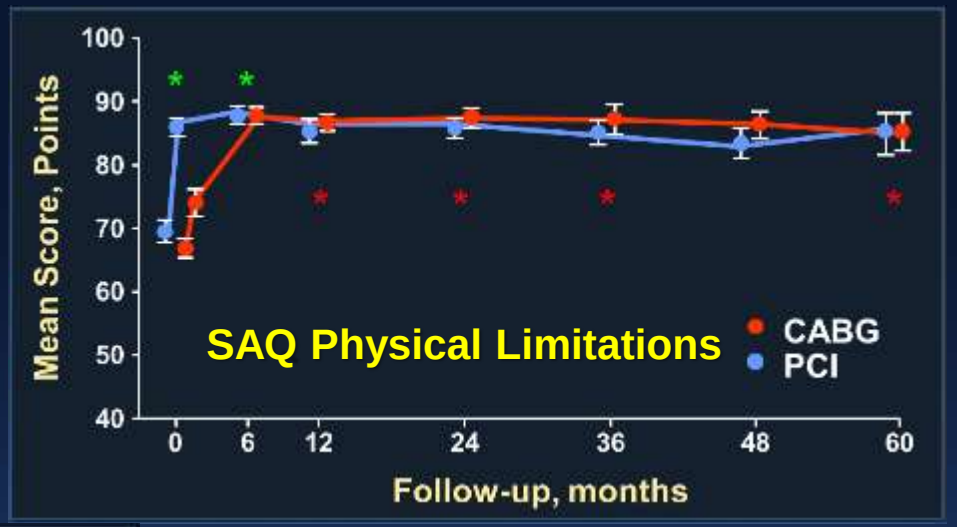
FACT:

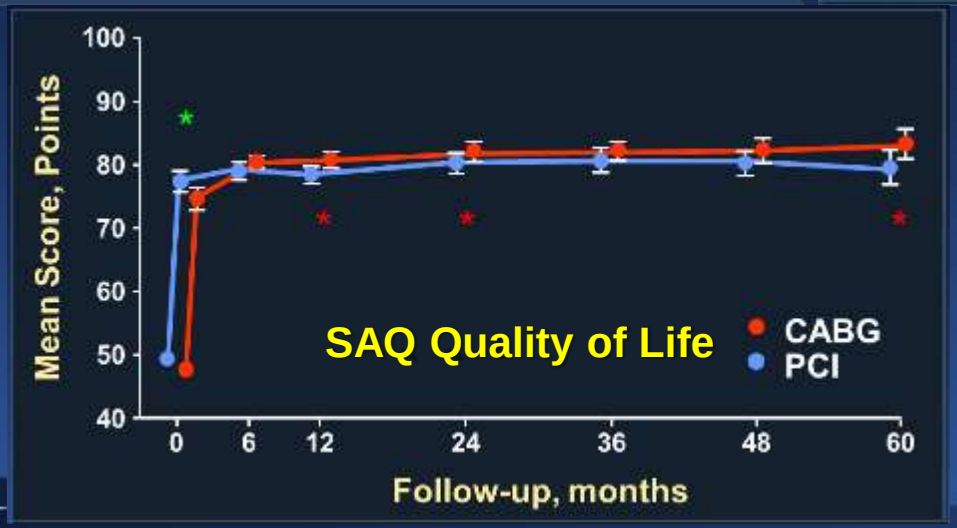
Diagnosing and Treating SEVERE CAD is Clinically Important!

Quality of Life

Angina frequency, physical limitations, and quality-of-life domains of the SAQ assessed at baseline, at 1, 6, and 12 months, and annually thereafter.







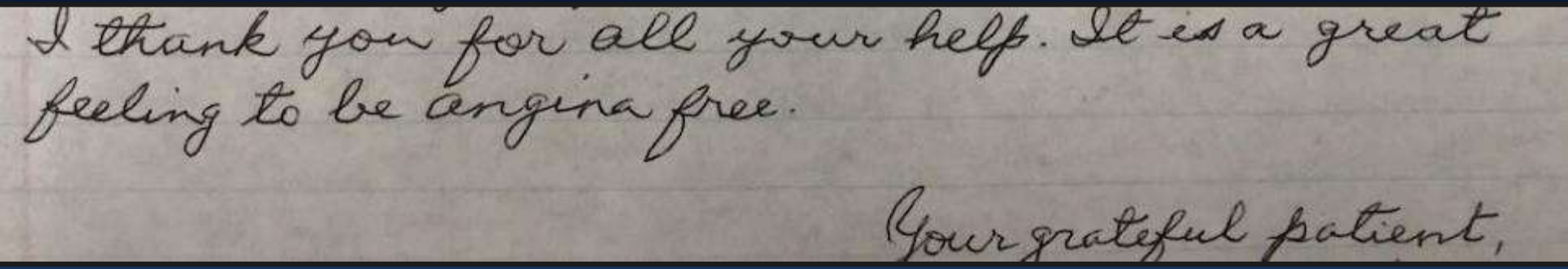
Adjusted:

*** P<0.05 favoring PCI**

***P<0.05 favoring CABG**

Abdallah MS et al. JAMA 2013;on-line

How Do Our Patients *with Real Symptoms* Actually Feel After Revascularization?


I thank you for all your help. It is a great feeling to be angina free.

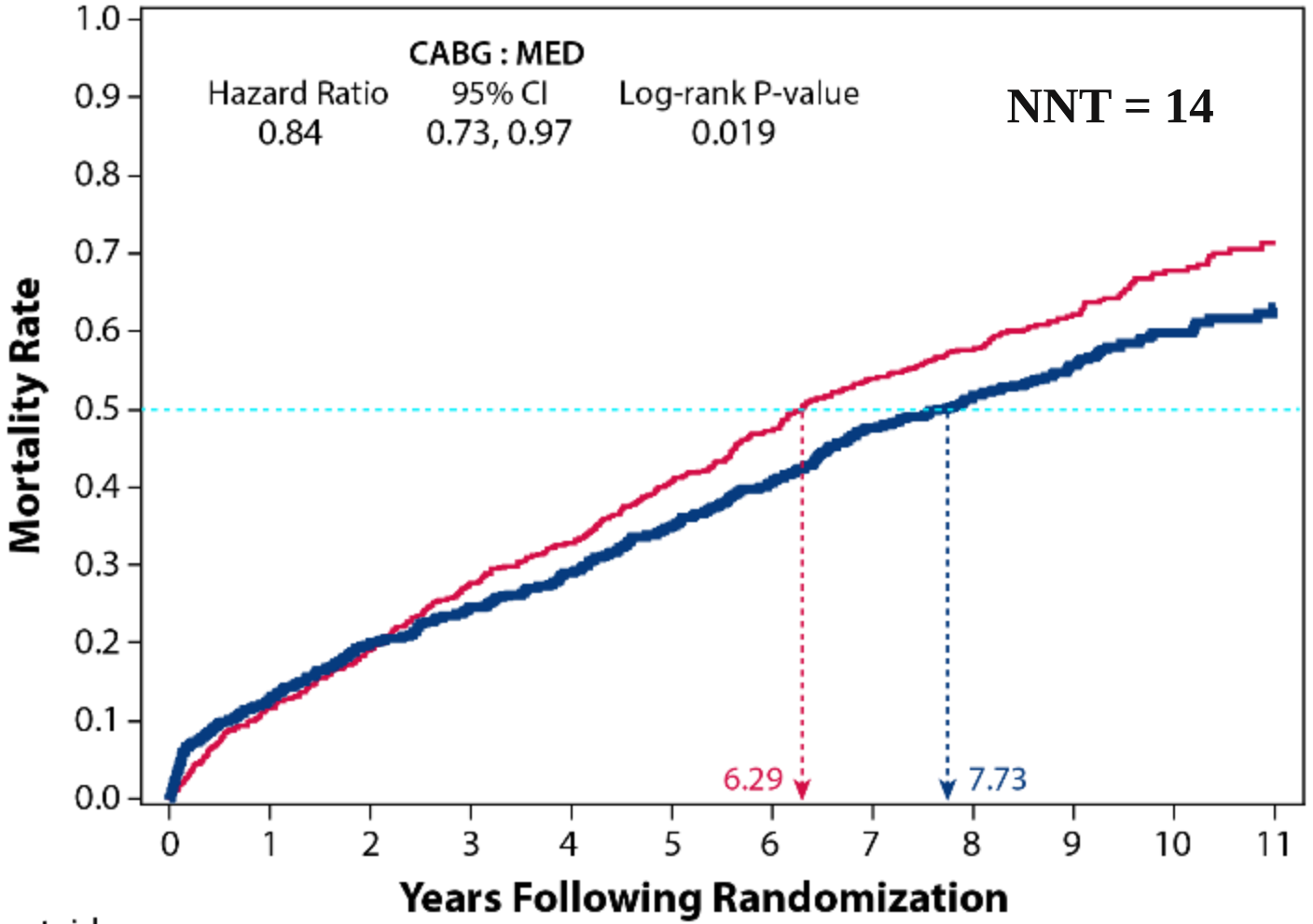
Your grateful patient,

CAD Prognostic Index

Extent of CAD	Prognostic Weight (0–100)	5-Year Survival Rate (%)*
1-vessel disease, 75%	23	93
1-vessel disease, 50% to 74%	23	93
1-vessel disease, ≥95%	32	91
2-vessel disease	37	88
2-vessel disease, both ≥95%	42	86
1-vessel disease, ≥95% proximal LAD artery	48	83
2-vessel disease, ≥95% LAD artery	48	83
2-vessel disease, ≥95% proximal LAD artery	56	79
3-vessel disease	56	79
3-vessel disease, ≥95% in ≥1 vessel	63	73
3-vessel disease, 75% proximal LAD artery	67	67
3-vessel disease, ≥95% proximal LAD artery	74	59

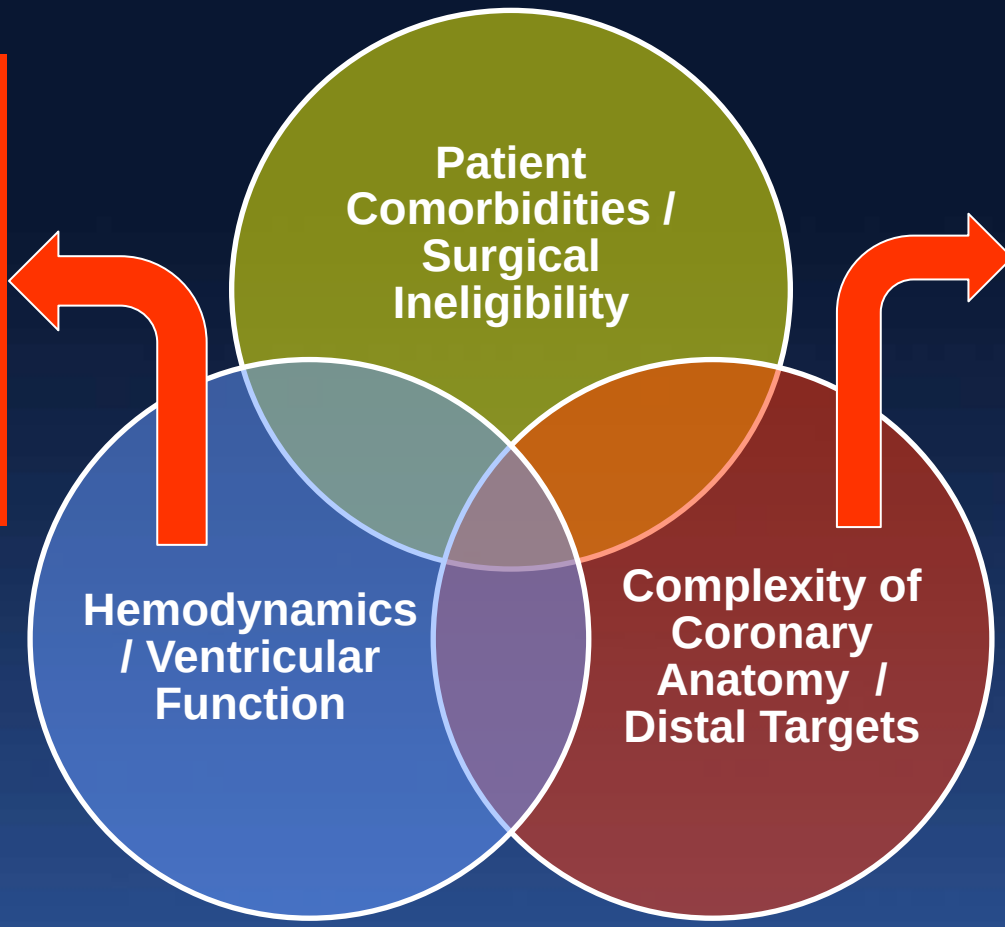
*Assuming medical treatment only.

All-cause Mortality



Definition of the CHIP Population: Complex Higher-Risk (and Indicated) Patients

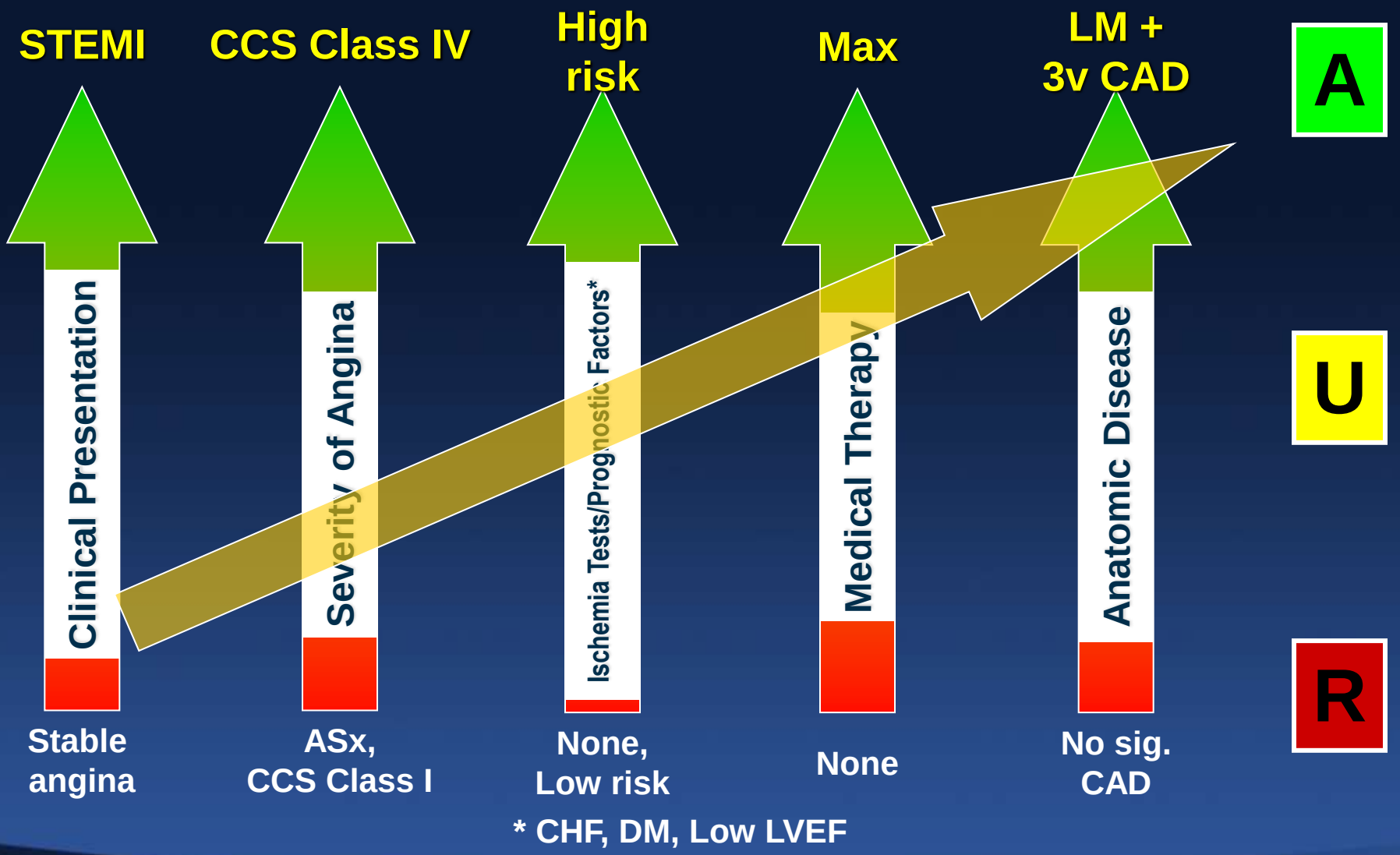
Understand:
- Echo Parameters
- Valvular Dz
- RHC
- Support Devices



- CTO
- LMCA
- Bifurcations
- Calcium
- SVGs
- Tortuosity
- (Thrombus)

These patients are being undertreated!

Revasc Appropriateness Criteria: Key Inputs



Rule #2 for Success

Make sure you are properly trained

Adequate training is crucial…the knowledge and catheter skills learned will be invaluable in the future

Fundamentals of the CHIP Mindset

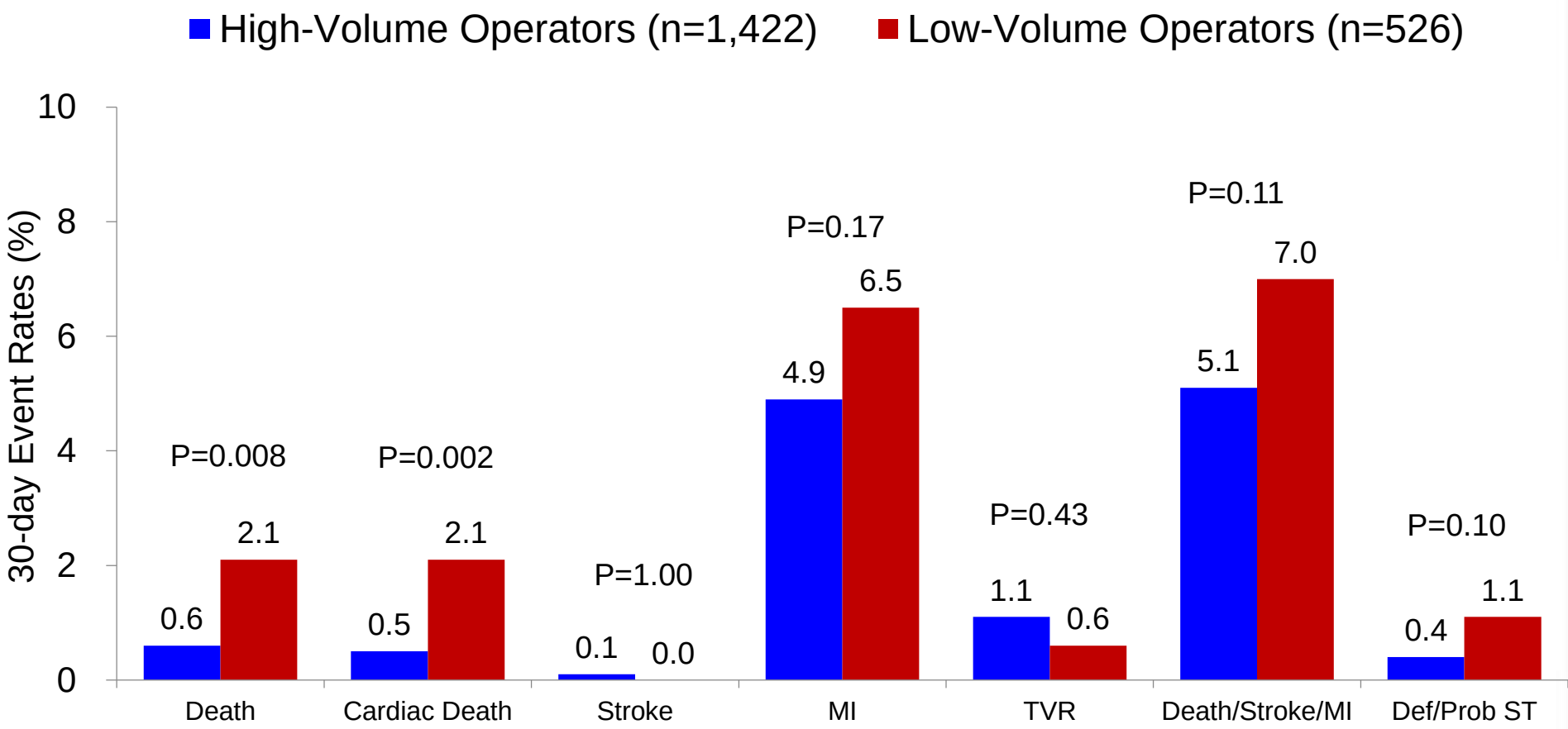
The indications for the case do not change just because the lesion is "harder to treat"!

The risk/benefit equation can be modified with training, the correct technical advances and training, and the appropriate devices/equipment

Technical Skills and Training/Infrastructure Requirements (for Physicians, Staff, and Institutions) for the Care and Revascularization of Patients with Higher-Risk, Severe CAD

Patient/Lesion Subsets	Techniques/Devices	Patient/Lesion Subsets	Techniques/Devices
Chronic total occlusions	Dual access and injections Antegrade and retrograde techniques, including dissection/ re-entry devices Specialty wires, microcatheters, devices for increasing guide/catheter support, externalization techniques	**Poor hemodynamic status/ventricular function coexisting with complex anatomy**	Left/right ventricular percutaneously implanted support devices Intra-aortic balloon counterpulsation Extracorporeal membrane oxygenation Large-vessel access/closure Transradial expertise (when both femoral arteries are used) Alternative access considerations (axillary, transcaval)
Left main stenosis/ bifurcations	Single- and 2-stent strategies (both primary and for provisional/bailout use) Intravascular imaging	**Stent underexpansion/ restenosis**	Intravascular imaging Aggressive noncompliant and plaquemodification balloons Atherectomy (laser, rotational) Vascular brachytherapy
Calcific disease	Rotational/orbital atherectomy Intravascular imaging		
Multivessel disease	Coronary physiological studies (e.g., fractional flow reserve) Intravascular imaging	**Complication management**	Echocardiography-guided pericardiocentesis Covered stents, coils, beads Snares/snaring techniques Dual guide techniques Dissection/re-entry to salvage distal flow Endovascular rescue

Impact of Operator Volume on Outcomes of LMCA PCI at a Single High-Volume Center (Fu Wai Hospital)



Bo X et al, JACC CV Intv 2016

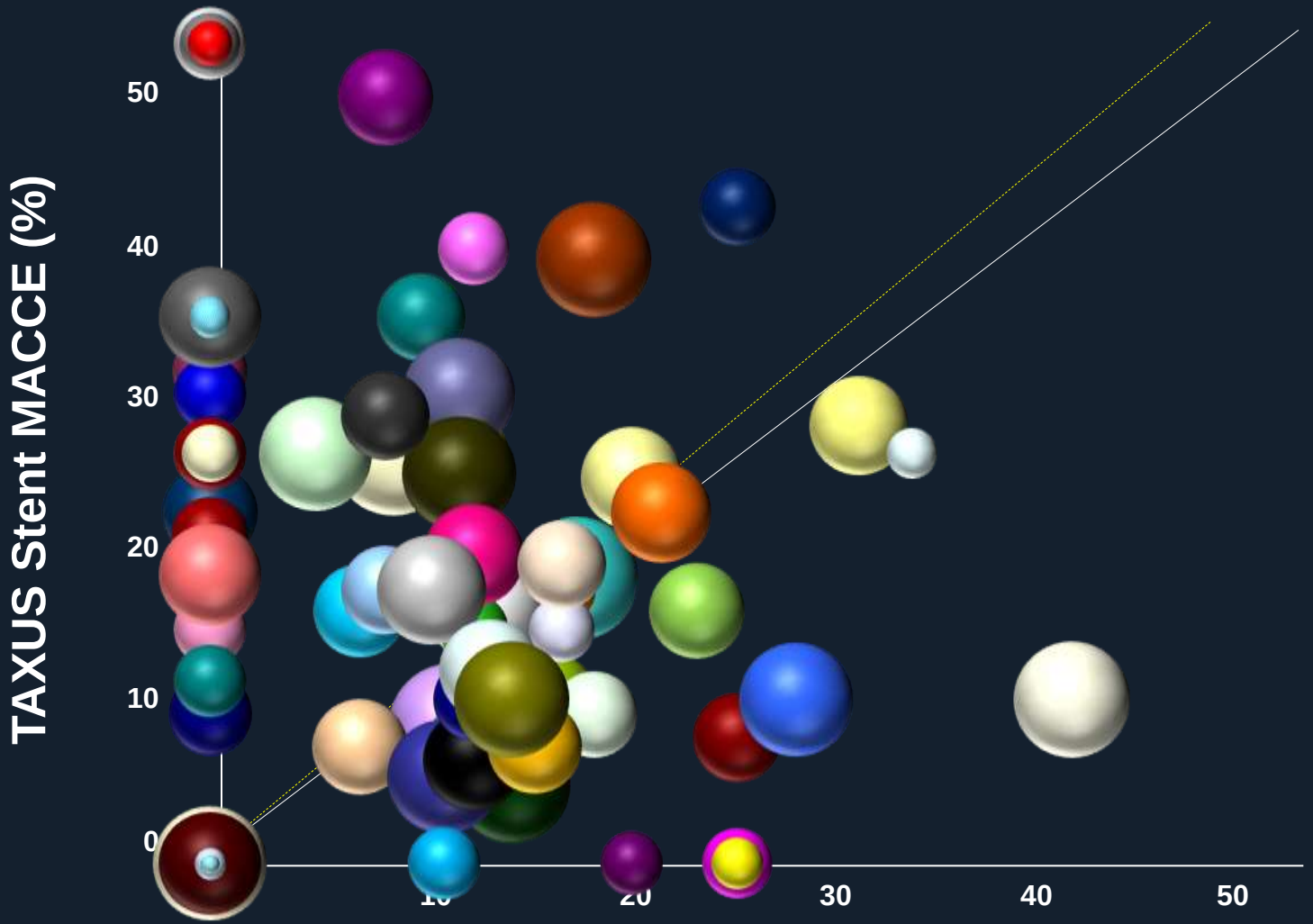
New York State Database: CTO PCI

7/2009 – 6/2012: 4030 (3.1%) CTO PCI procedures with 61.3% success

	Estimate	Standard Error	Adjusted Odds Ratio (95% CI)	*P* Value
Intercept	2.5109	0.3317		<0.0001
Age by 10	–0.1098	0.0307	0.90 (0.84, 0.95)	0.0003
Ejection fraction <20%	–0.9714	0.3051	0.38 (0.21, 0.69)	0.0015
Previous PCIs	–0.2606	0.0712	0.77 (0.67, 0.89)	0.0003
Previous CABG surgery	–0.4488	0.0920	0.64 (0.53, 0.76)	<0.0001
Carotid/cerebrovascular disease	–0.2987	0.1215	0.74 (0.58, 0.94)	0.0140
CTO lesion location				
Right coronary artery	–0.4057	0.0814	0.67 (0.57, 0.78)	<0.0001
Left circumflex artery	–0.3480	0.0924	0.71 (0.59, 0.85)	0.0002
LAD artery and others*	…	…	Reference	…
CTO PCIs only	–0.5192	0.0707	0.59 (0.52, 0.68)	<0.0001
Operator CTO PCI volume per year (quartiles)				
Q1: <4	–0.8875	0.2657	0.41 (0.24, 0.69)	0.0008
Q2: 4–8	–0.6958	0.2720	0.50 (0.29, 0.85)	0.0106
Q3: 9–47	–0.4204	0.2852	0.66 (0.38, 1.15)	0.1405
Q4: ≥48	…	…	Reference	…

Highest volume quartile operators (48+) had >2X higher success than lowest 2 quartiles

Variability in Practice Should be Taken into Account: The SYNTAX Trial

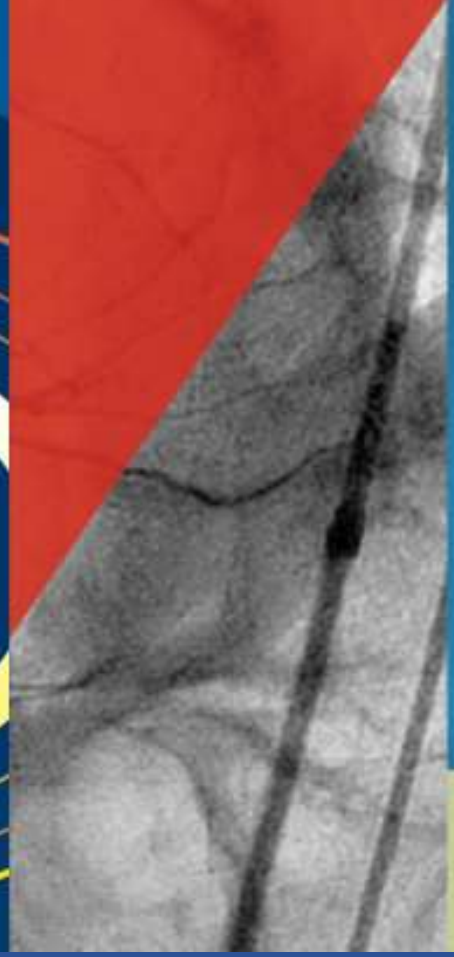


Advances in Hemodynamic and Left Ventricular Support

Advances in Hemodynamic Support

CTO

Chronic Total Occlusion Summit
A Live Case Demonstration Course



CHIP

Complex Higher-Risk (and Indicated) Patients

Training Initiatives

- CHIP fellowships encompassing HRPCI (including CTO), hemodynamic support:
  - NY
  - Seattle
  - Detroit
  - TBD…

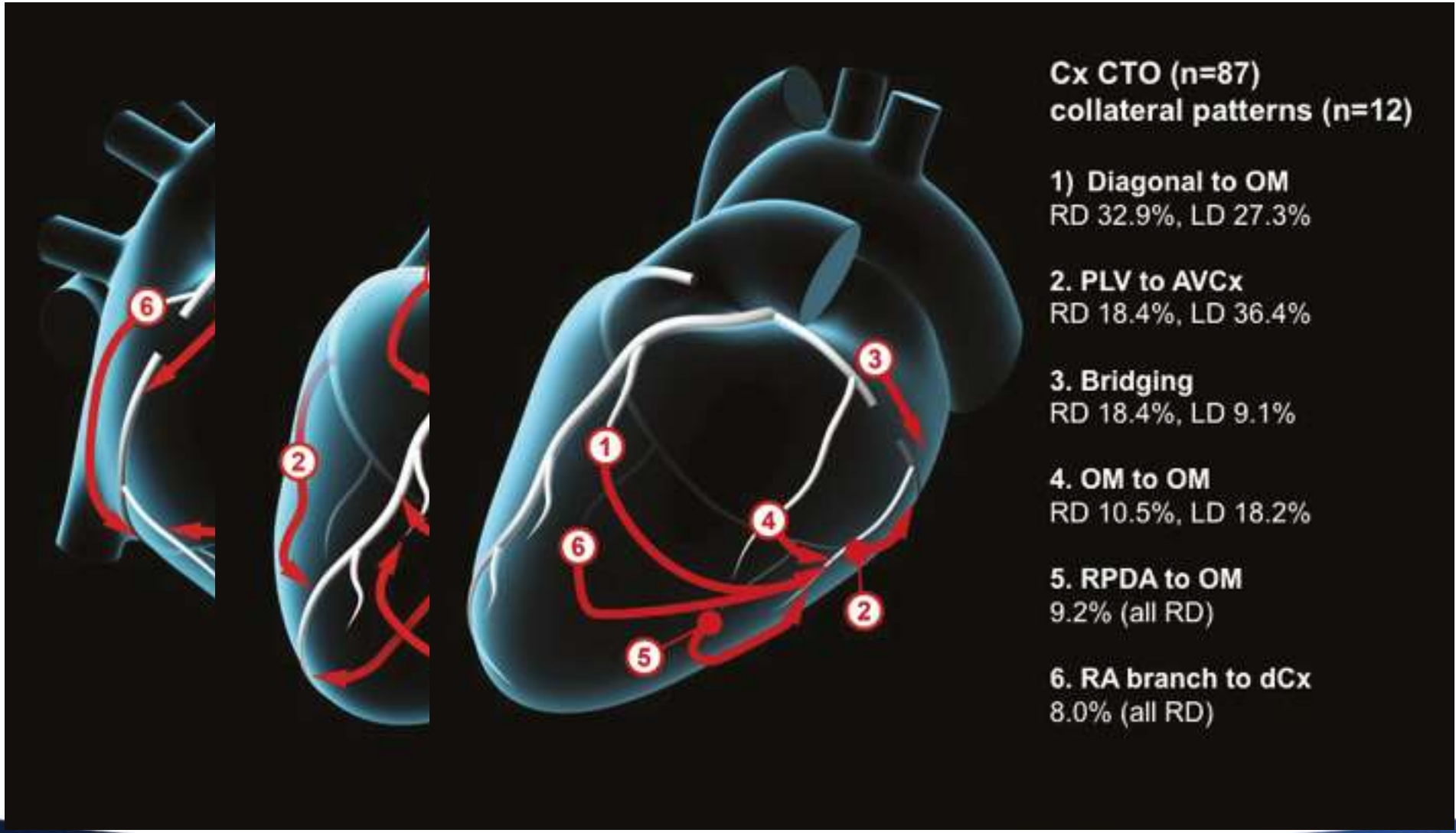
Columbia CHIP Fellows

Research Priorities in the Higher-Risk CAD Population Potentially Eligible for PCI

Research Priority/Question	Study Design/Cohort
What is the prevalence of severe (and nonrevascularized) CAD?	Disease-based (as opposed to solely procedure-based) registries
What are the outcomes of PCI in higher-risk CAD patients (e.g., nonsurgical patients), and are there specific operator/institution volumes that are required to achieve the best procedural outcomes?	Procedural registries
What are the costs associated with revascularization in higher-risk CAD patients?	Dedicated cost-effectiveness studies within procedure- and disease-based registries
What are the outcomes with PCI, surgical revascularization, and medical therapy among higher-risk patients with an indication for revascularization?	Disease-based registries with embedded procedural data Potential randomized trials
What is the variability in care patterns for patients meriting consideration of revascularization?	Disease-based registries with embedded procedural data
To what extent are contemporary interventionalists trained and skilled to perform complete revascularization across complex lesion subsets?	Procedure- and disease-based registries
To what extent can PCI achieve surgery-like outcomes in higher-risk CAD patients?	Randomized trials, possible comparative-effectiveness assessments

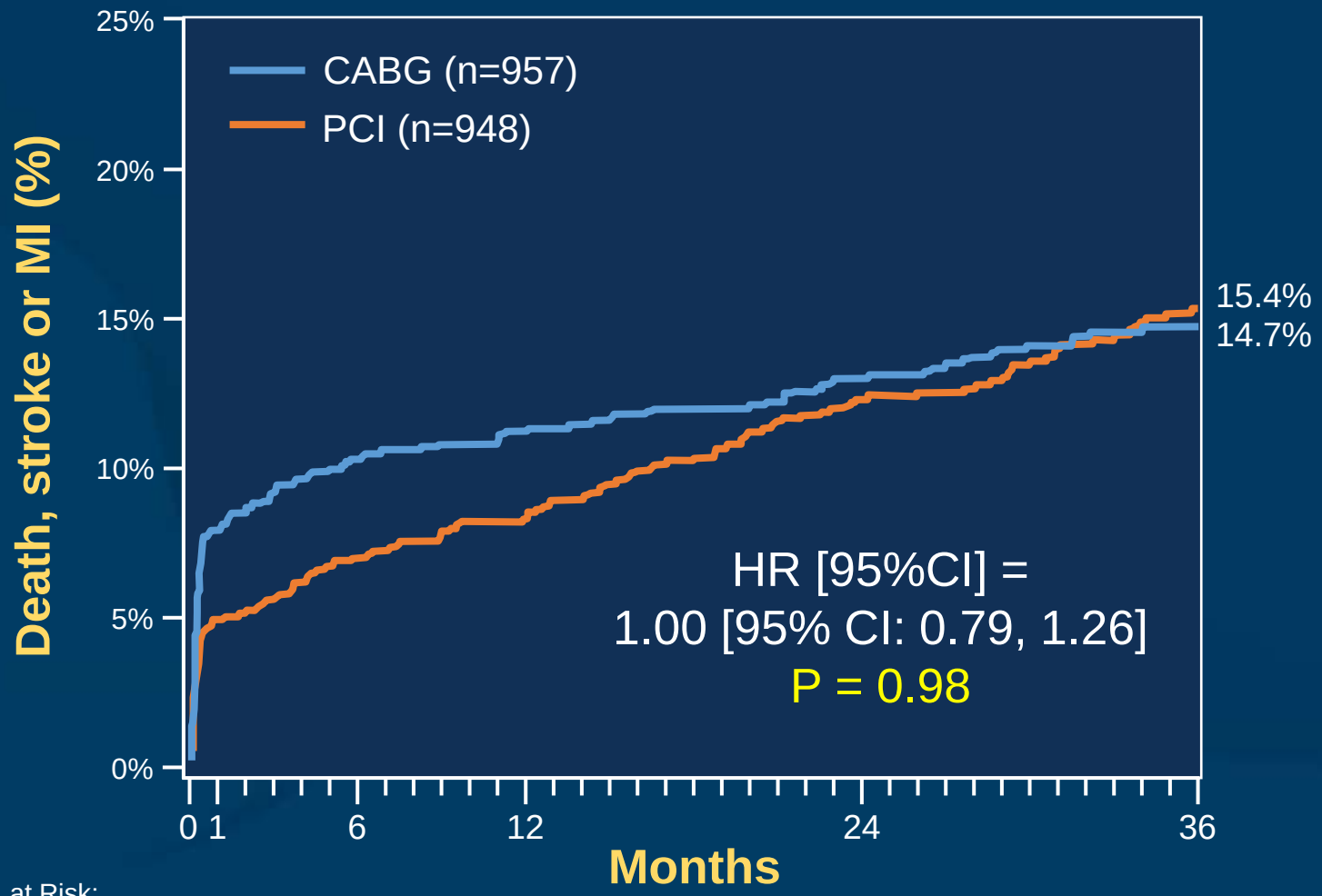
Characterization of Collateral Circulation of CTOs

519 CTOs at 6 centers in the UK



Primary Endpoint

Death, Stroke or MI at 3 Years



No. at Risk:

PCI	948	896	875	850	784	445
CABG	957	868	836	817	763	458

OPTIMUM

Outcomes of **P**ercutaneous revascularizaTI**I**on for **M**anagement of s**U**rgically inelgible patients with **M**ultivessel or left main coronary artery disease: *A Prospective Registry*

National Co-PIs: Adam Salisbury, MD, MSc, David Kandzari, MD, J. Aaron Grantham, MD,

Steering Committee: Ajay Kirtane, MD, SM, William Lombardi, MD, William O'Neil, MD, Joseph Sabik, MD, Robert Yeh, MD, MBA

Angiographic Core Lab: Philippe Généreux, MD

Health Economics: David Cohen, MD, MSc

ECLIPSE

*E*valuation of Treatment Strategies for Severe *C*a*L*cif*I*c Coronary Arteries: Orbital Atherectomy vs. Conventional Angioplasty *P*rior to Implantation of Drug Eluting *S*t*E*nts

~2000 pts with severely calcified lesions; ~60 US sites

Randomize 1:1

Orbital Atherectomy Strategy

(1.25 mm Crown followed by non-compliant balloon optimization)

2nd generation DES implantation and optimization

Conventional Angioplasty Strategy

(conventional and/or specialty balloons per operator discretion)

2nd generation DES implantation and optimization

1° endpoints: 1) Post-PCI in-stent MSA (N~400 in imaging study)
2) 1-year TVF (all patients)

2° endpoint: Procedural Success (stent deployed w/RS<20% & no maj complications)

Principal investigators: Ajay J. Kirtane, Philippe Généreux; **Study chairman:** Gregg W. Stone
Sponsor: Cardiovascular Systems Inc.

The Basic CHIP Premise

- **There is a large underserved patient population that can benefit from revascularization**
  - Rather than focusing on low-risk patients who may be “easy to treat”, we need to focus upon higher-risk patients who have the *most to gain*
  - These patients will be more commonly seen as our field / the healthcare system evolves
  - The development of comprehensive specialists trained with advanced technical and cognitive skills to assess and treat these patients is clearly needed

Good Start…More to Go!