

Clinical Indications of CTO Recanalization

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BAPTIST HOSPITAL OF MIAMI

Disclosure Statement of Financial Interest

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

Company

Grant/Research Support

None

Consulting Fees/Honoraria

Abbott, Cordis, St. Jude,
W.L. Gore, Boston Scientific Corp.
Terumo

Major Stock Shareholder/Equity

None

Royalty Income

None

Ownership/Founder

None

Intellectual Property Rights

None

Other Financial Benefit

None

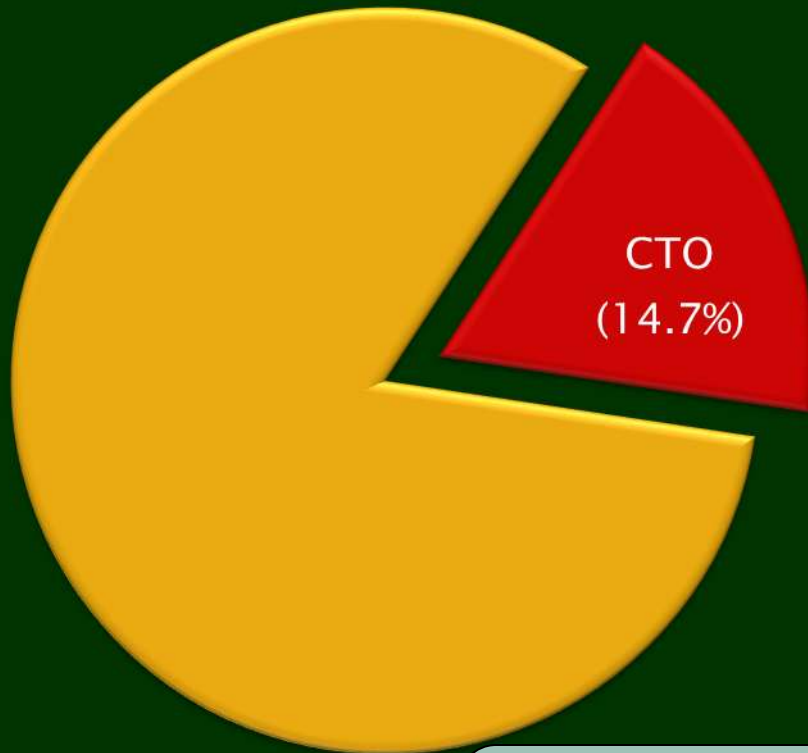
CTO-PCI: The Final Frontier

- Dispel misconceptions
- Safe and suitable treatment option
- Reproducible and teachable

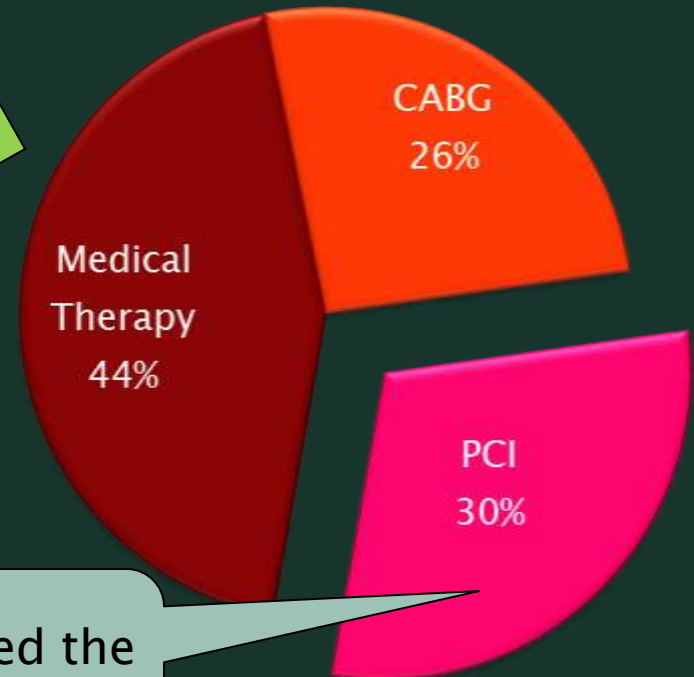
CTO Prevalence and Treatment

Coronary Angiograms

N = 14,439



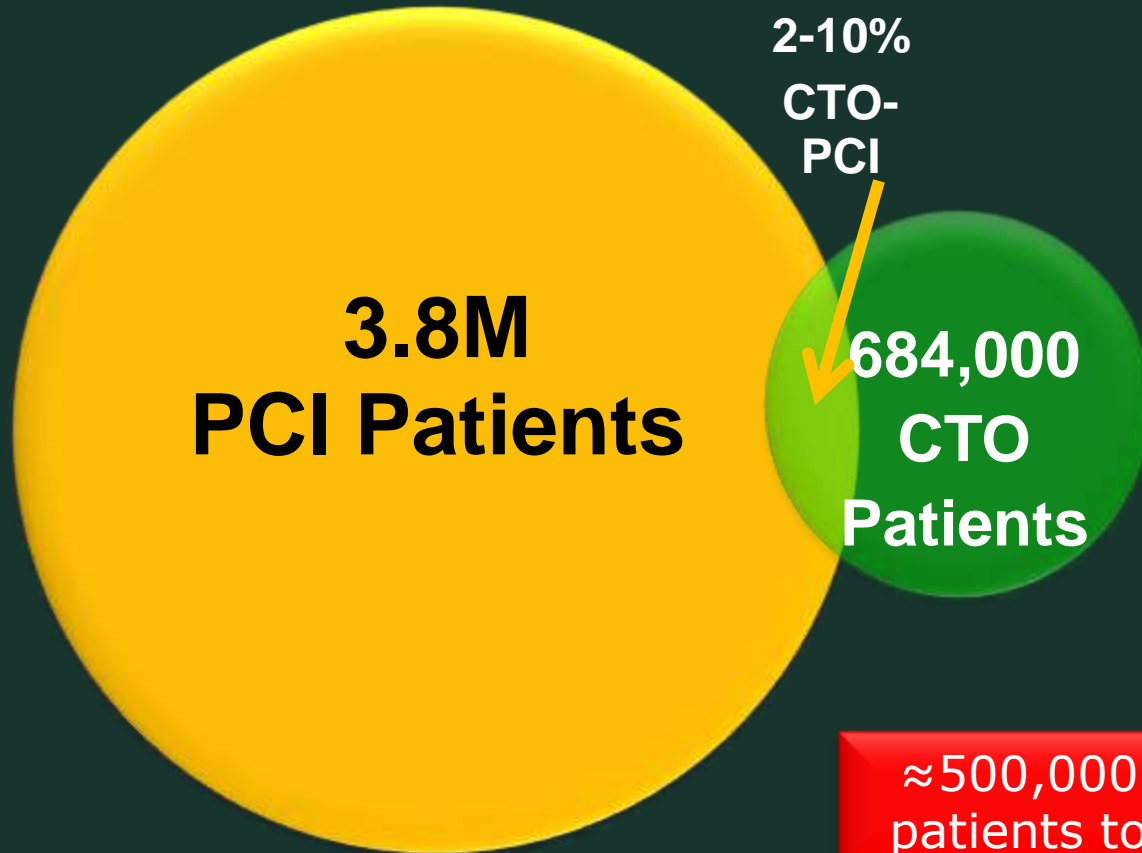
Treatment of CTOs



Only 10% of PCI involved the CTO, with 70% success rate!

CTO Prevalence and Treatment

Translating the results of the Canadian Registry

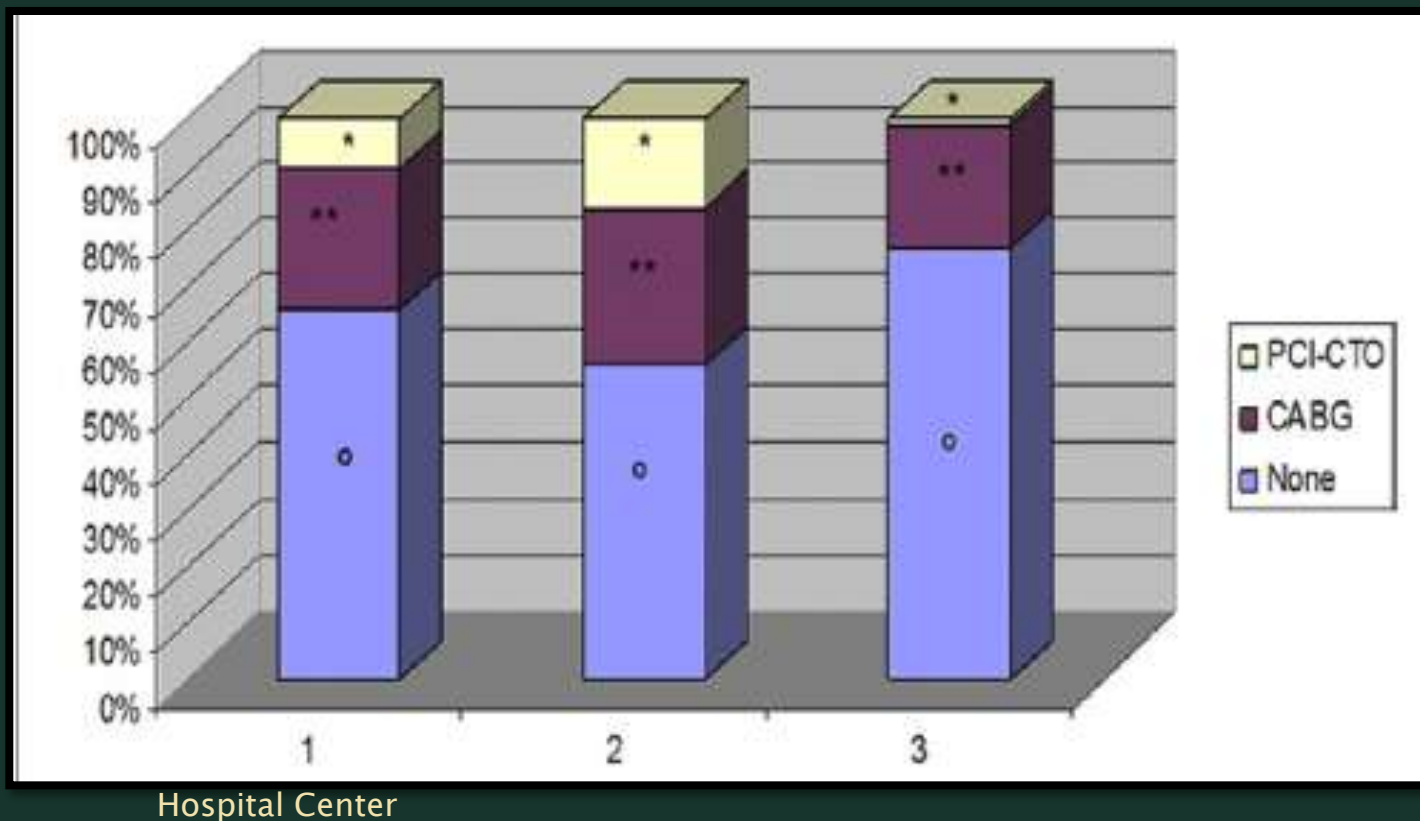


≈500,000 clinically eligible patients to receive CTO-PCI

Brilakis ES, et.al., *JACC Cardiovasc Interv* 2012. Fefer et. al.. *JACC* 2012. ARRIVE 1, ARRIVE 2, SCAR, eCypher real-world registries. Japan PCI CTO report.

Variability in Current Treatment *CTO treatment strategies in 3 Canadian centers*

- CTO identified in 18.4% of 1,697 pts
- CTO-PCI attempt rate varied among hospitals from 1% to 16%

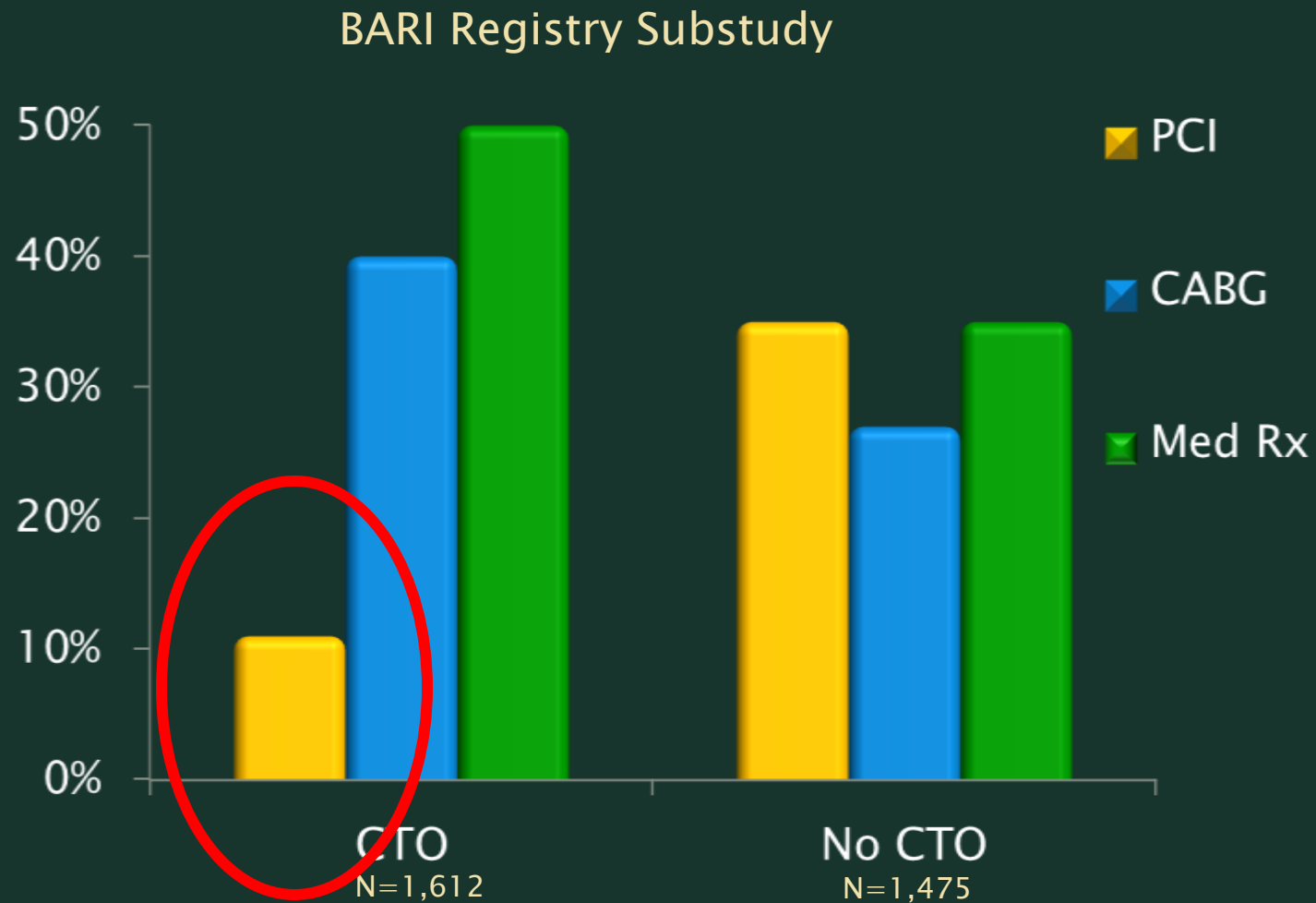


*p < 0.001; **p = NS; °p < 0.001.

Fefer et al. JACC 2012.

CAD Treatment Strategies

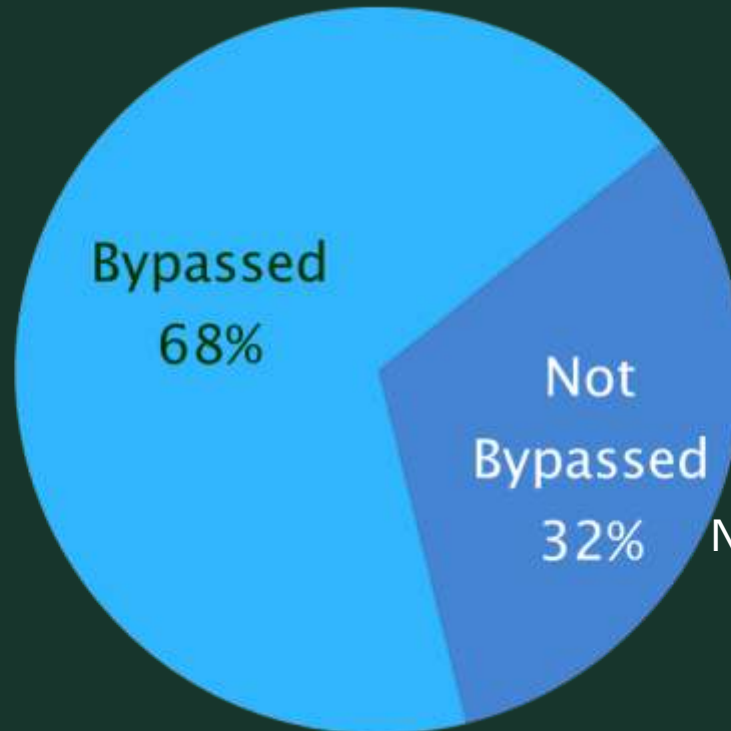
CTO-PCI disproportionately low



CABG is Not Always an Option

SYNTAX CTO substudy

266 CTO patients
randomized to receive CABG










Reason not bypassed:

- Not intended to treat (n=12)
- Diseased (n=11)
- Inadequate conduit (n=2)
- Too small (n=19)
- Unable to find (n=1)
- Other (n=36)

Why are CTO-PCI Attempt Rates So Low?

Common misconceptions

-  There is no clinical justification
-  CTOs are stable and benign
-  The procedure is too complex
-  Success rates are low
-  We don't have time for long procedures
-  Results are not reproducible or teachable
-  CTO-PCI is cost-prohibitive

“If you really want to do something, you’ll find a way. If you don’t, you’ll find an excuse.”

–Jim Rohn

There is No ~~Critical~~ Justification

Clinical Indications

Why open a chronically occluded coronary artery?



SYMPTOM CONTROL¹
and INCREASED
QUALITY OF LIFE²



IMPROVED LV
FUNCTION³



IMPROVED
SURVIVAL⁴

¹ Grantham JA et al., Circulation: Cardiovascular Quality and Outcomes 2009.

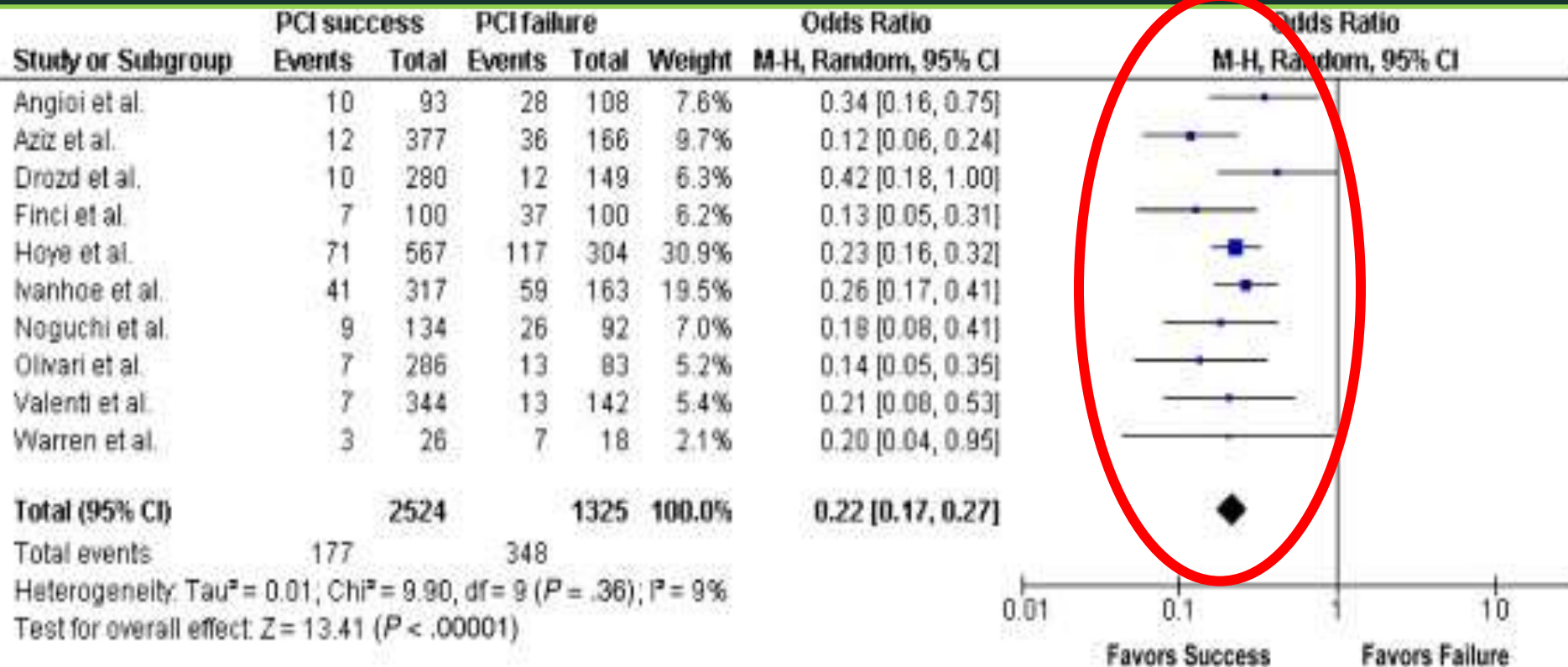
¹⁻² Safley D, Grantham JA, Jones P, and Spertus JA, ACC 2012

³ Kirschbaum SW et al. American Journal of Cardiology 2008

⁴ Hachamovitch et al Circulation. 2003; 107:2900-2907

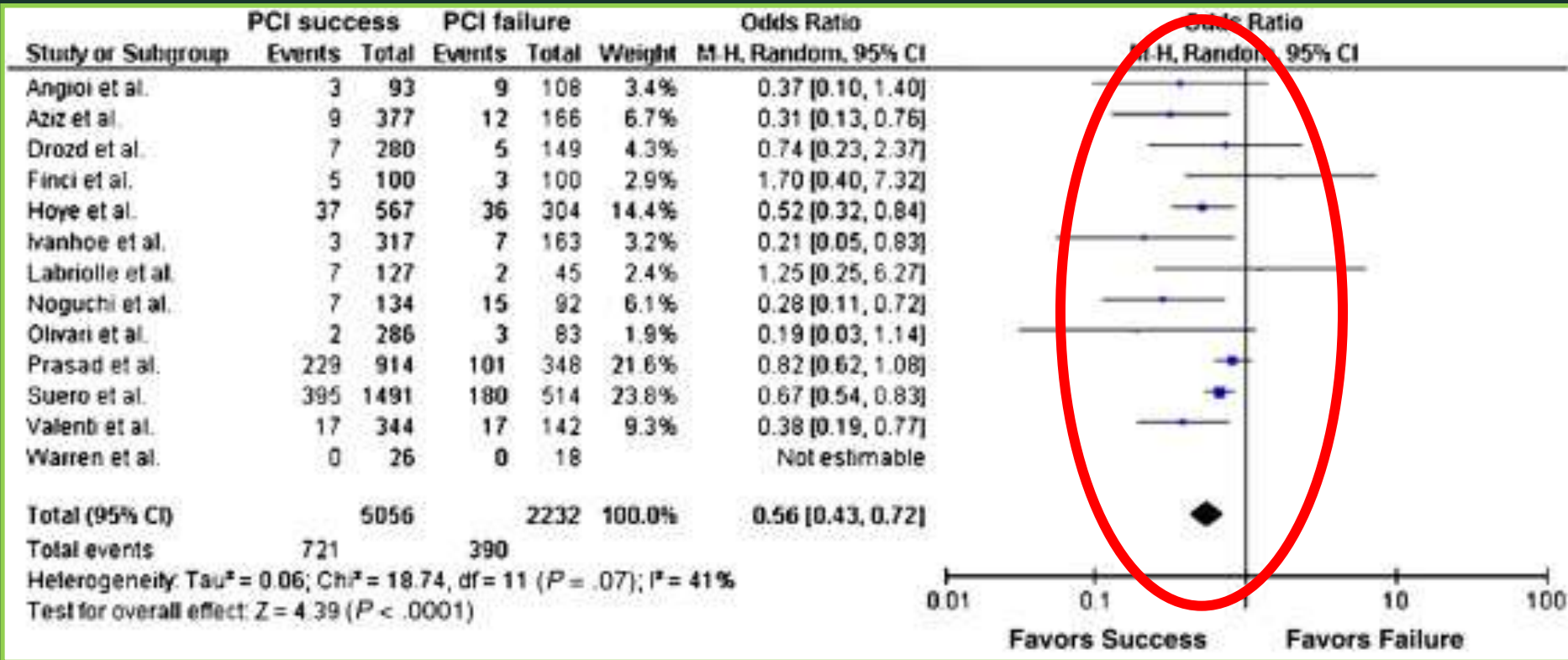
Impact of Successful CTO-PCI: Angina

Long-term angina benefit favors CTO-PCI success

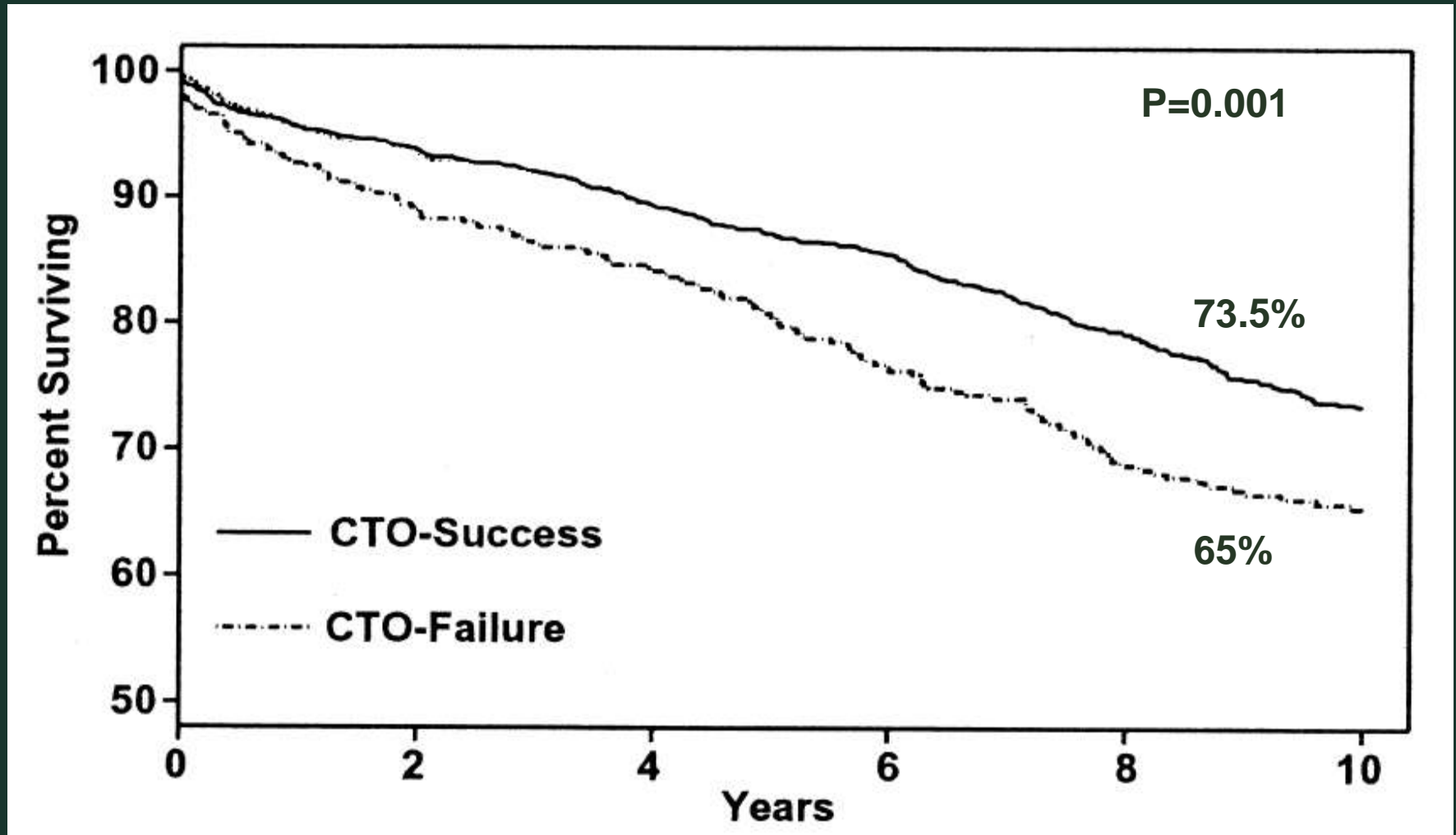


Impact of Successful CTO-PCI: Mortality

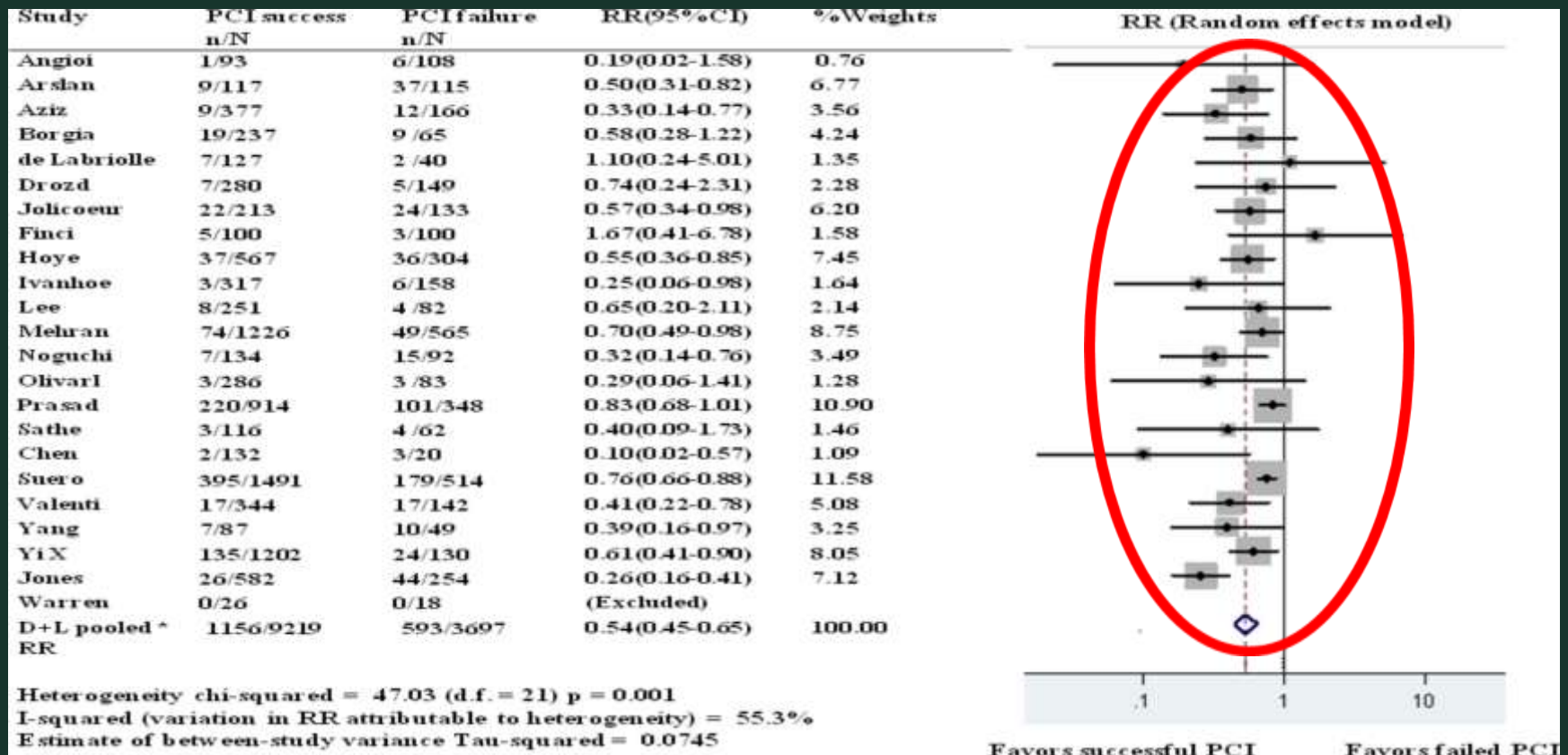
Long-term survival benefit favors CTO-PCI success



Re-opening of CTO: 20 years Experience

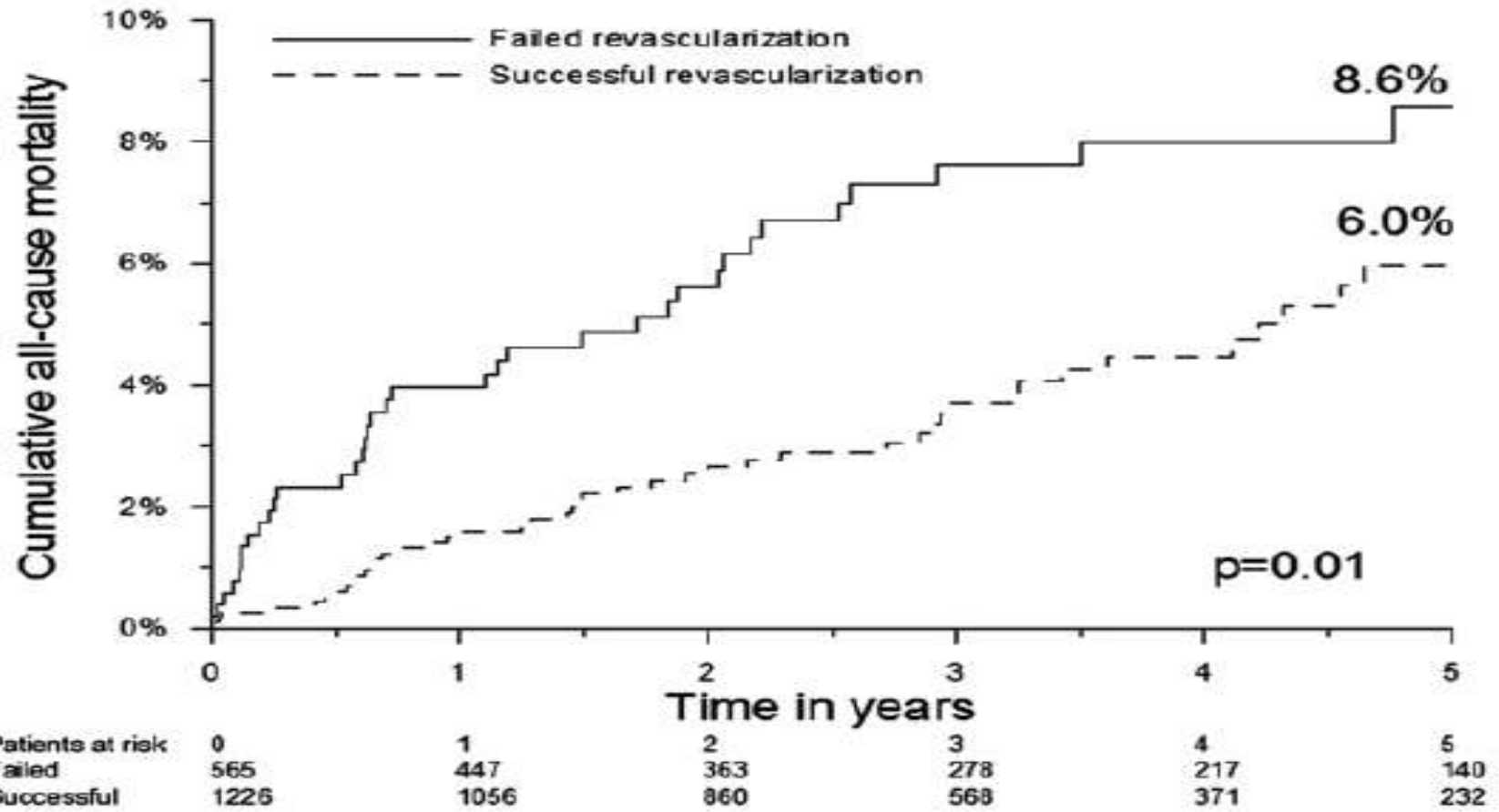


Impact of Successful CTO-PCI on All Cause Mortality



Clinical Event Rates

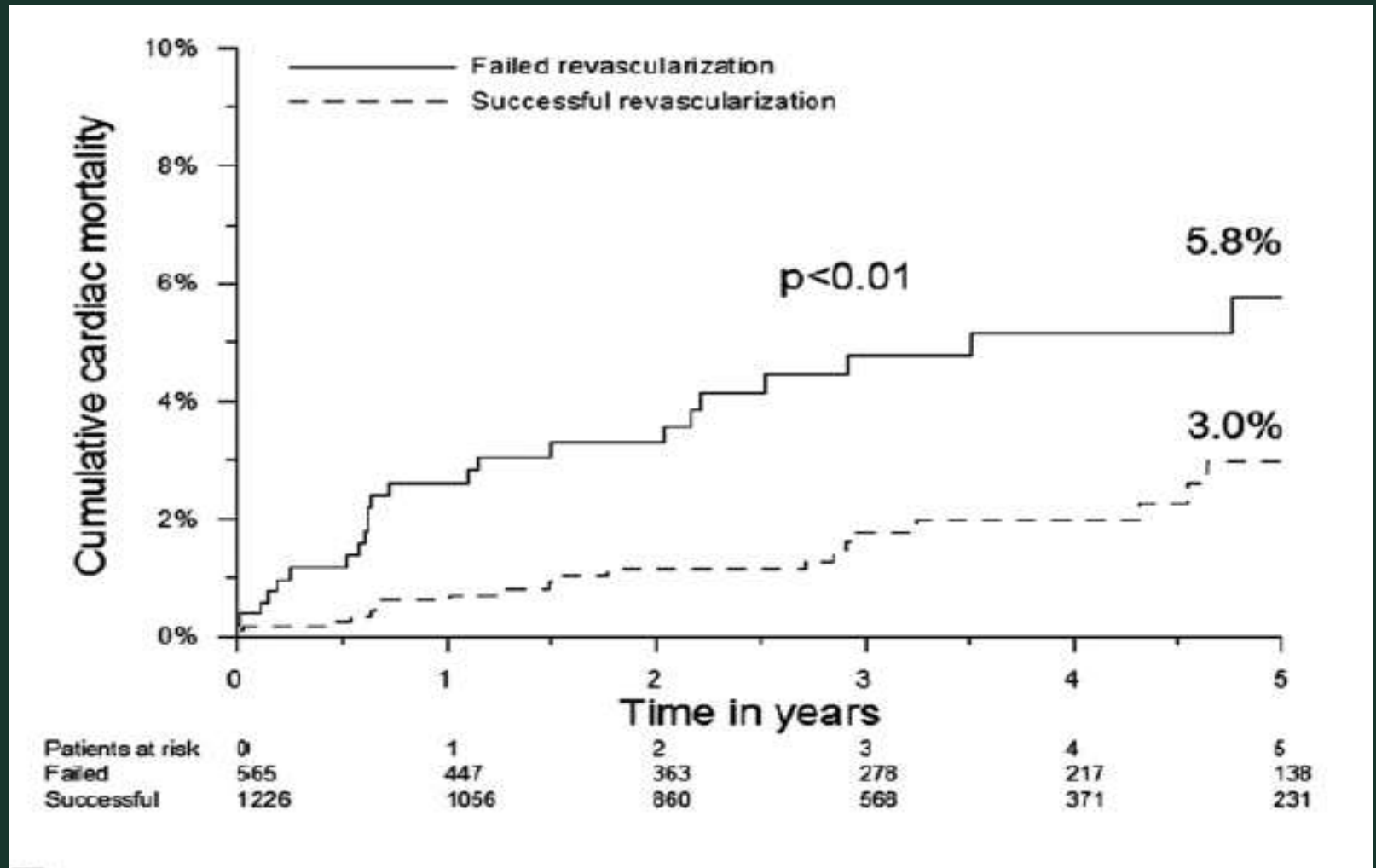
All-cause Mortality for Successful versus Failed PCI of a CTO



Mehran, et al. *J Am Coll Cardiol Interv.* 2011;4(9):952-961.

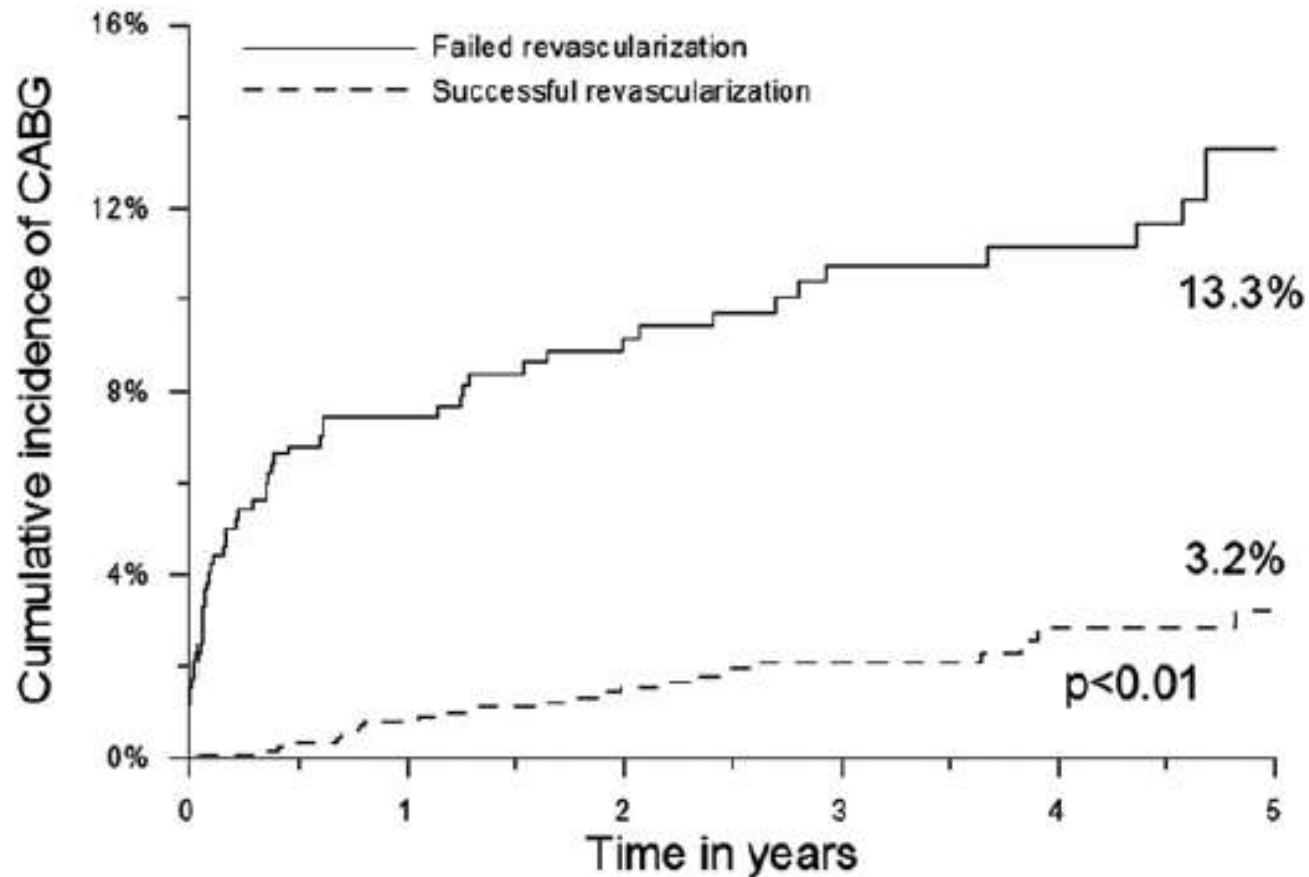
Clinical Event Rates

Cumulative Cardiac Mortality for Successful versus Failed PCI of a CTO



Clinical Event Rates

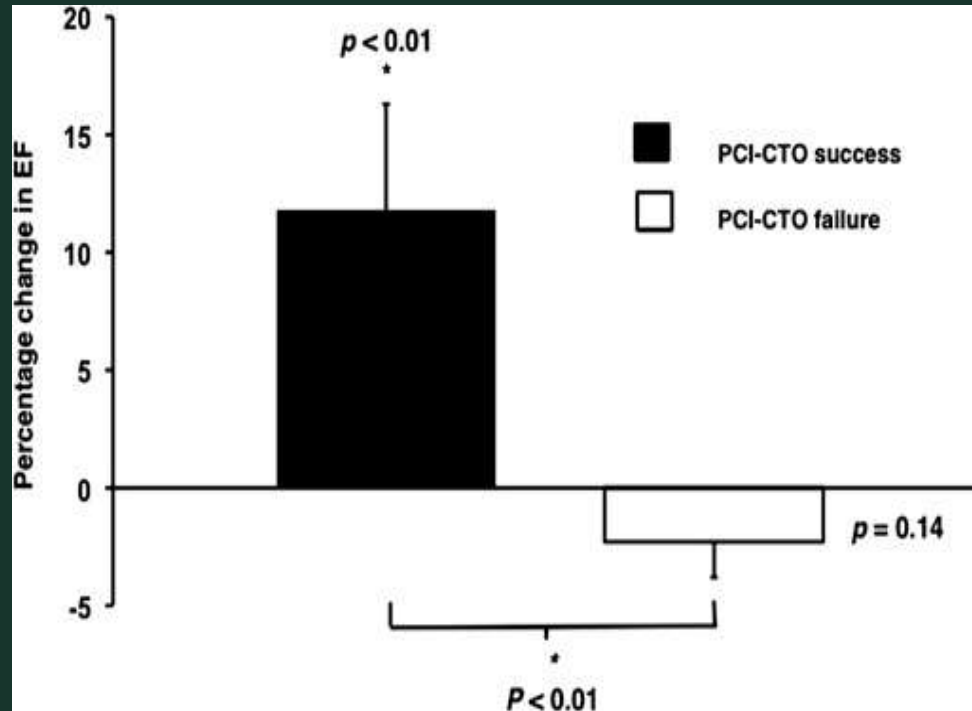
Cumulative Incidence of CABG for Successful versus Failed PCI of a CTO



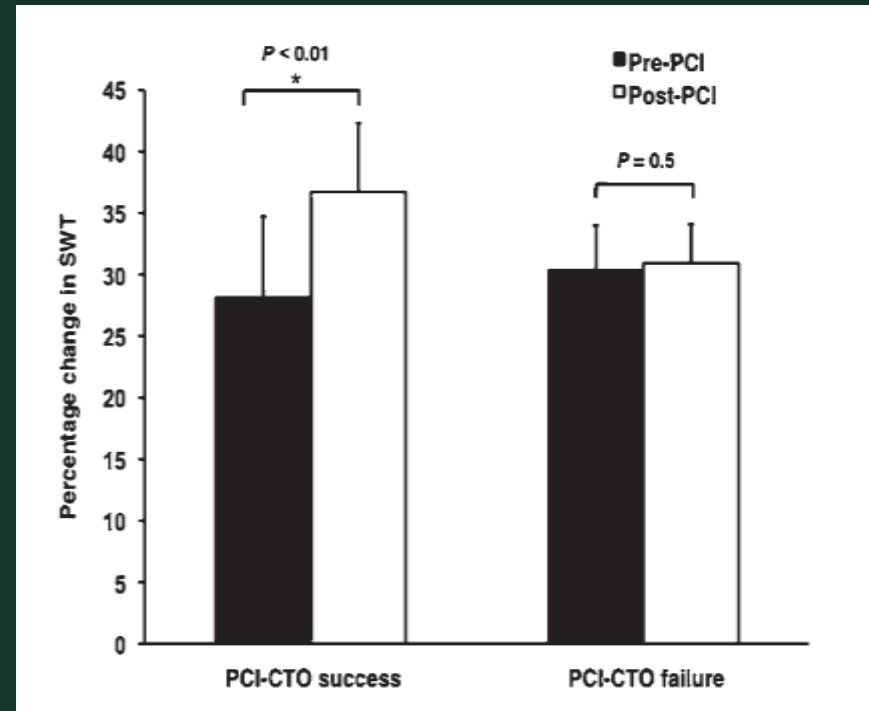
Patients at risk	0	1	2	3	4	5
Failed	565	420	336	253	198	124
Successful	1226	1049	848	557	359	222

Improvement of LV function with CTO-PCI

Ejection Fraction (EF)



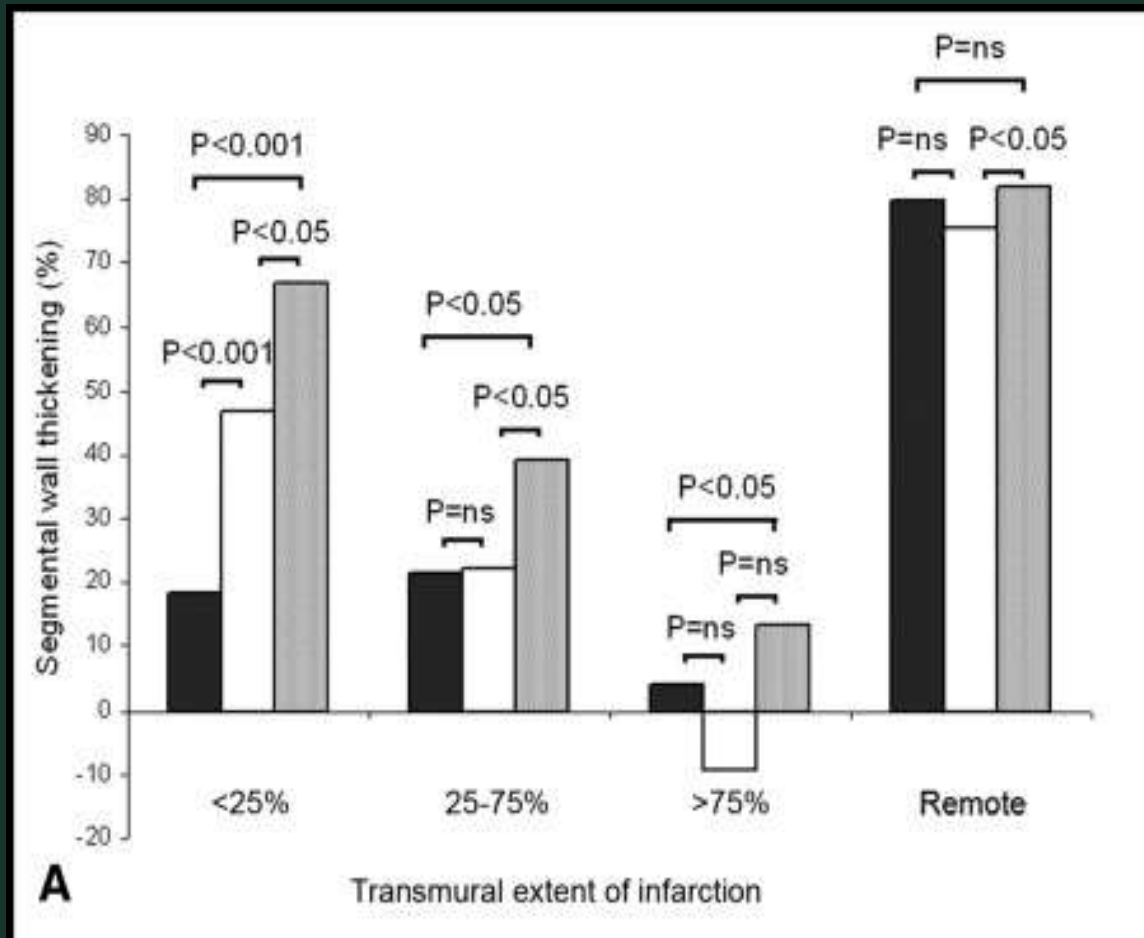
Segmental Wall Thickening (SWT)



MRI assessment at baseline and at 6 months shows an improvement in EF and SWT in patients who had successful CTO-PCI

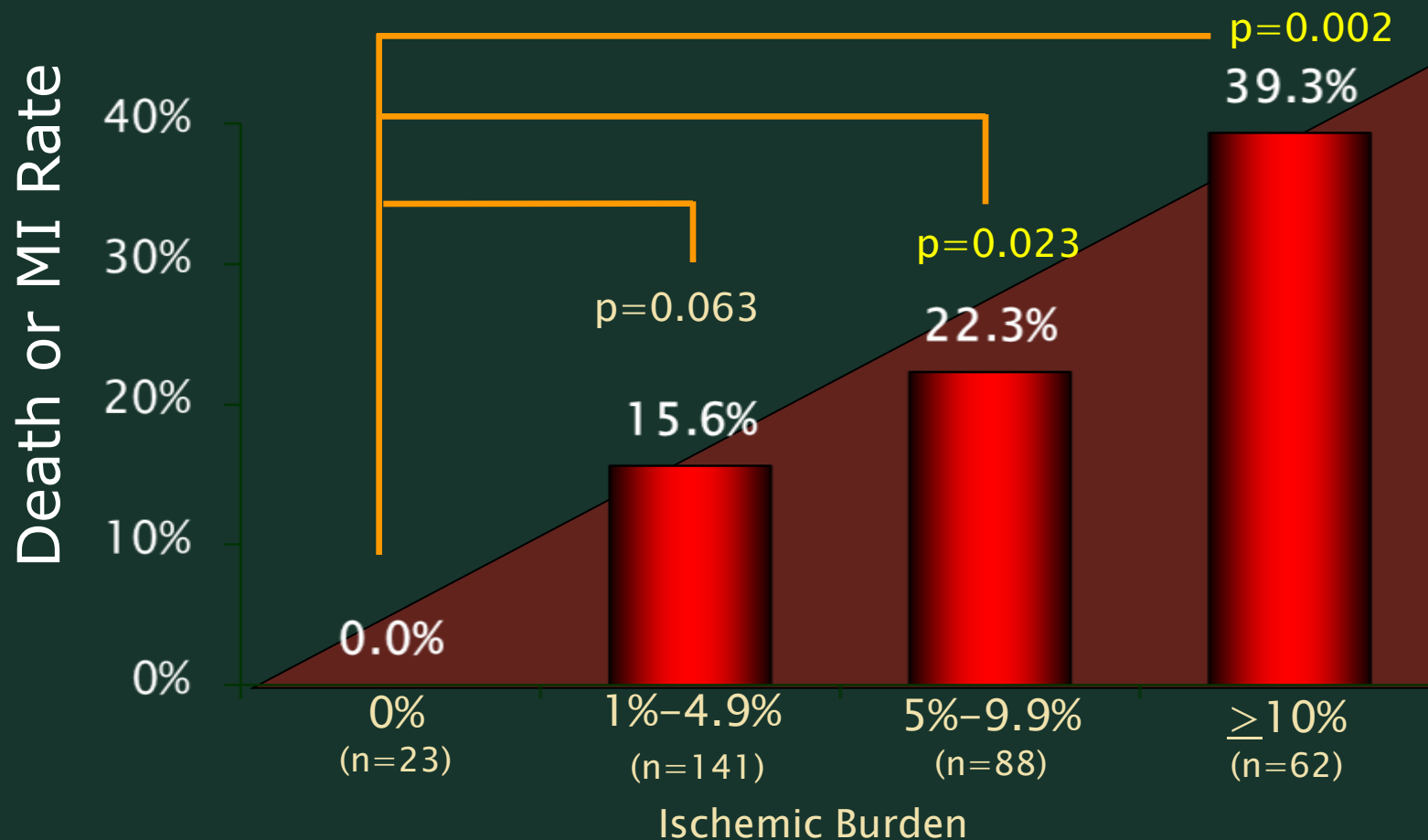
Long Term LV Function Improvement with CTO-PCI

<25% infarcted has most significant improvement



- Improvements in LV volume maintained at 3 years
- Degree of transmuralty of scar by MRI

Medical Therapy may not be enough!
Higher ischemic burden correlated to mortality



When is CTO-PCI Appropriate?

Single vessel CTO

		Angina →		
		Class 0	Class I/II	Class III/IV
↑ Risk	High Risk Max Rx	U	A	A
	Int Risk Max Rx	U	U	A
	Low Risk Max Rx	U	U	A

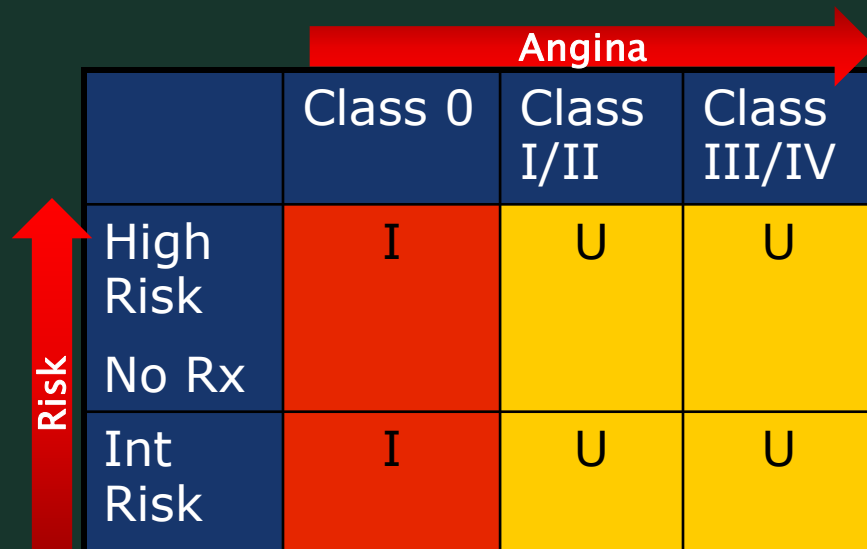
1 or 2 vessel disease (No proximal LAD)

		Angina →		
		Class 0	Class I/II	Class III/IV
↑ Risk	High Risk Max Rx	A	A	A
	Int Risk Max Rx	U	A	A
	Low Risk Max Rx	U	A	A

CTO-PCI appropriateness is based on patient risk and angina, assuming maximum medical therapy

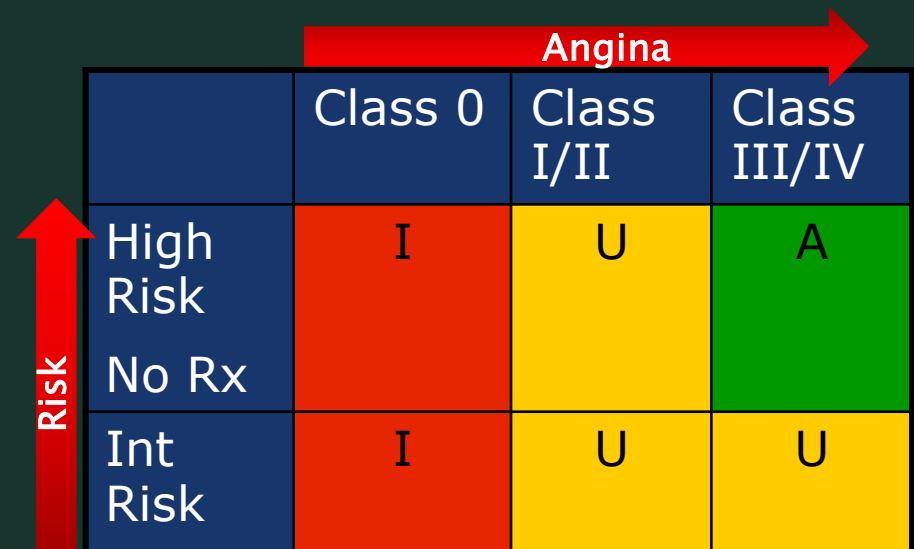
But not all CTOs are appropriate

Single vessel CTO



	Angina		
	Class 0	Class I/II	Class III/IV
High Risk No Rx	I	U	U
Int Risk No Rx	I	U	U
Low Risk No Rx	I	I	I

1 or 2 vessel disease (No proximal LAD)



	Angina		
	Class 0	Class I/II	Class III/IV
High Risk No Rx	I	U	A
Int Risk No Rx	I	U	U
Low Risk No Rx	I	I	U

If maximum medical therapy is absent, CTO-PCI
may not be appropriate

2011 ACC CTO-PCI Guidelines

Chronic Total Occlusions



PCI of a CTO in patients with appropriate clinical indications and suitable anatomy is reasonable when performed by operators with appropriate expertise.

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*Helping Cardiovascular Professionals
Learn, Advance, Heal.*



American
Heart
Association.



The Society for Cardiovascular
Angiography and Interventions

Controlled, randomized trial needed

OPEN CTO Registry Coming

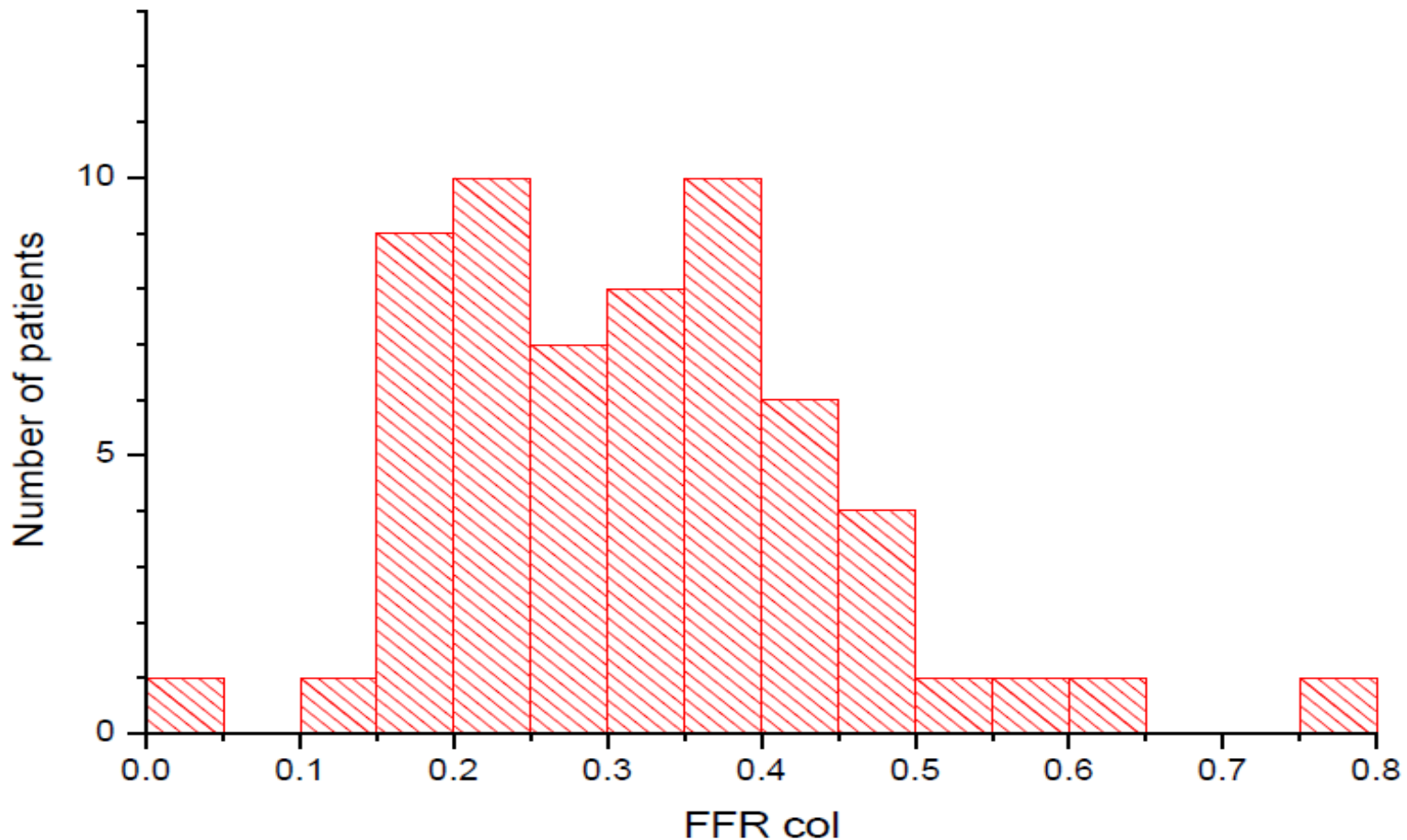


Primary Investigators	<ul style="list-style-type: none">• J. Aaron Grantham (PI)• William L. Lombardi (Co-PI)
Overview	<ul style="list-style-type: none">• 10 US sites• 1000 patients• Multi-center, prospective, single arm observational registry
Aims	<ul style="list-style-type: none">• Safety, success, efficiency of hybrid approach• Health status effects of CTO-PCI• Indications and appropriateness of CTO-PCI• Economic analysis
Status	<ul style="list-style-type: none">• Enrolling 2014
Sponsorship	<ul style="list-style-type: none">• Saint Luke's Mid-America Heart Institute• Investigator Sponsored Research trial made possible by a grant from Boston Scientific

CTOs are ~~Stupid~~ and Benign

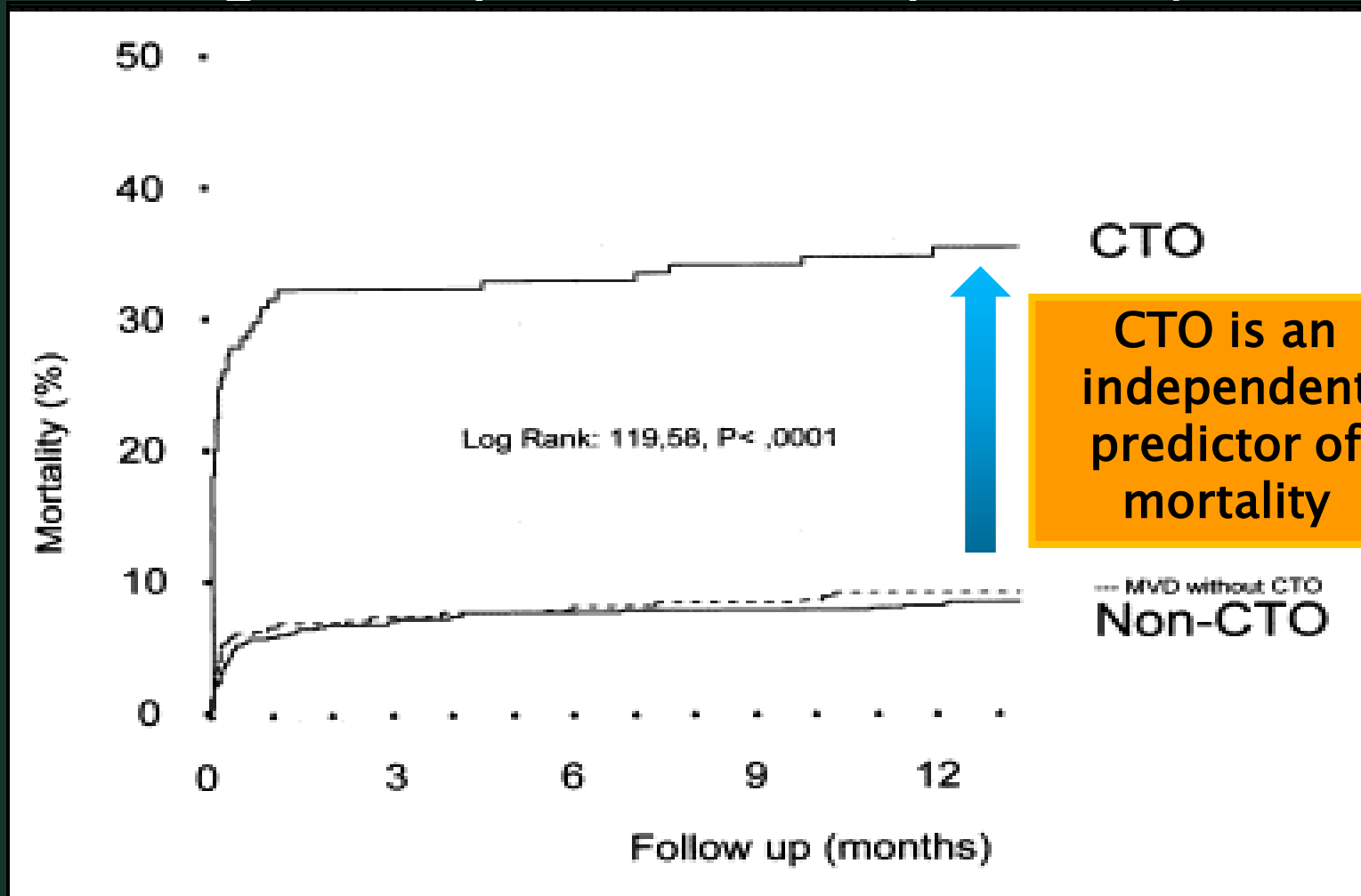
Ischemia in “Adequately Collateralized” CTOs

*No CTOs are adequately collateralized
FFR in 59 pts after successful wire crossing of a CTO*



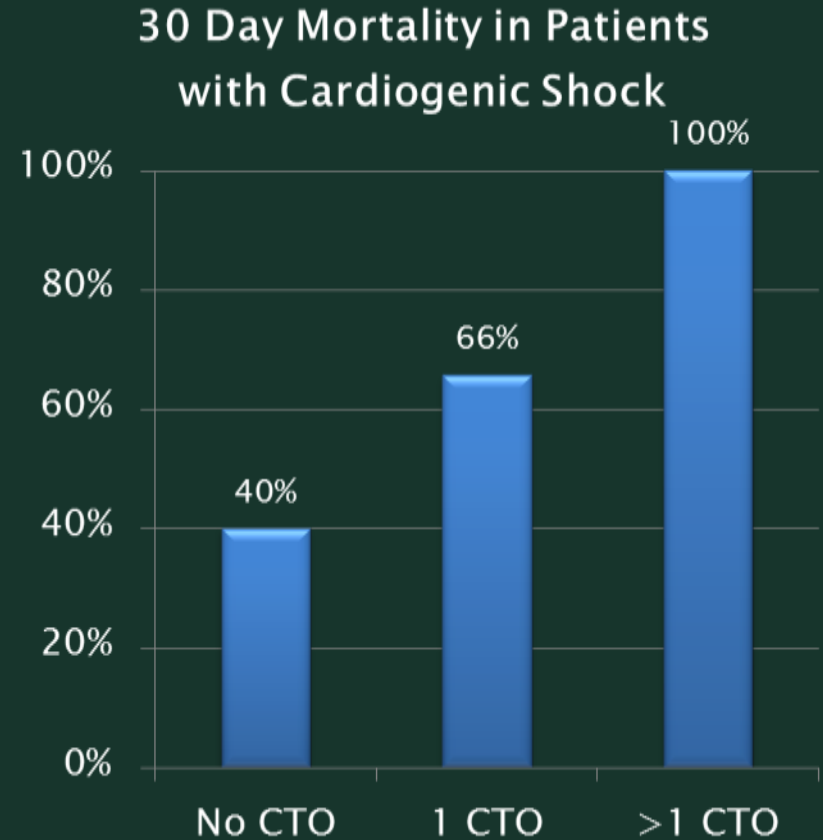
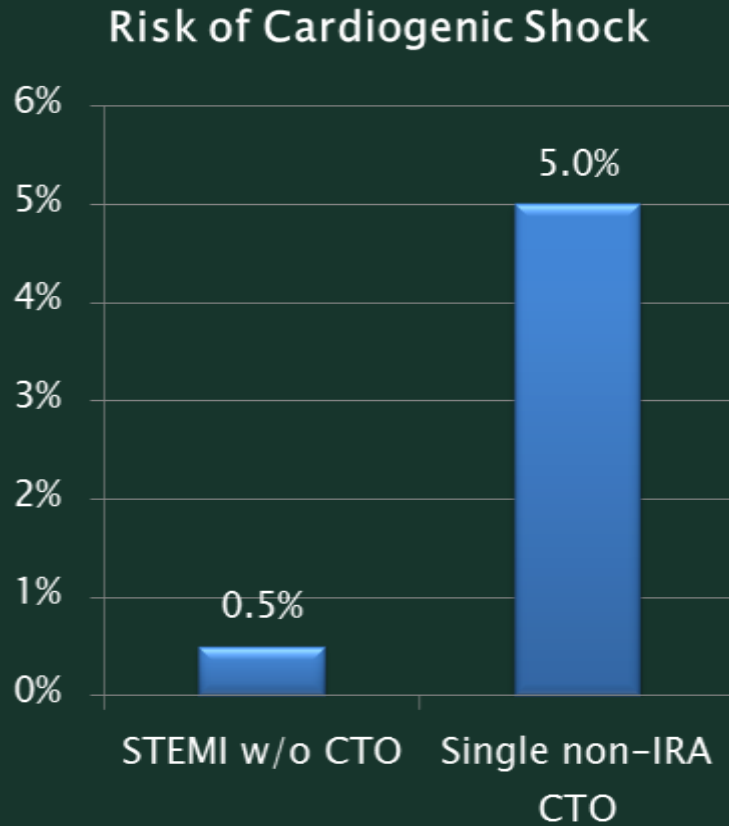
CTO Impact on Non-CTO vessel AMI Mortality

Higher 1-year mortality rate w/ CTO



CTO and Cardiogenic Shock

CTO is independent predictor of mortality



The Procedure  Too Complex

Evolution of CTO-PCI

Increasing success rates related to technique evolution

2004

- Antegrade Wires and IVUS

2007

- Rudimentary Retrograde

2010

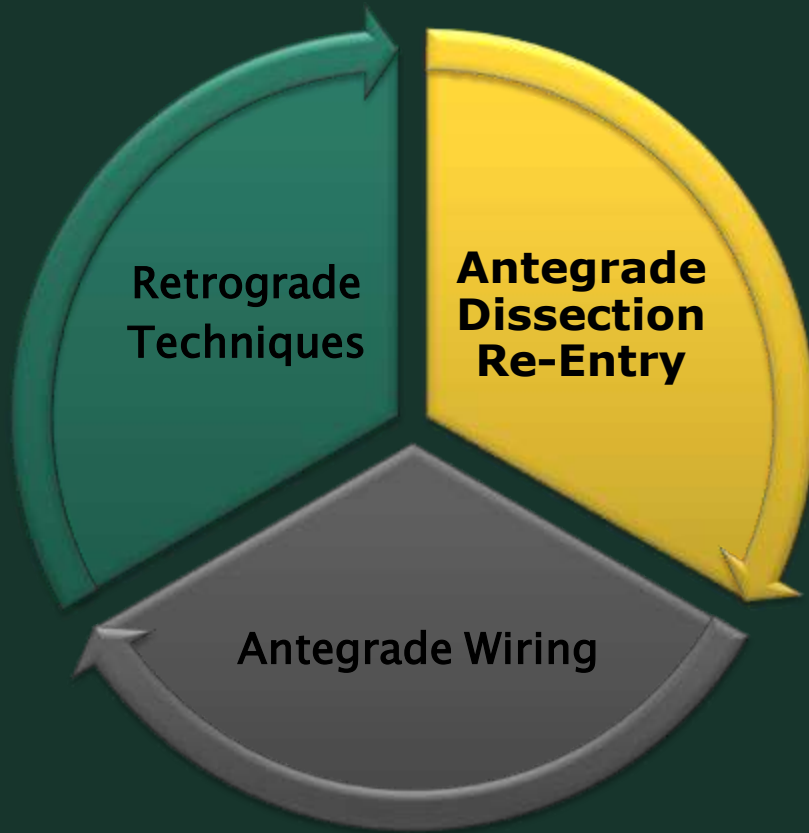
- Early Antegrade Dissection Re-Entry

2012

- Hybrid

New Approach to Treat CTOs

The Hybrid Strategy



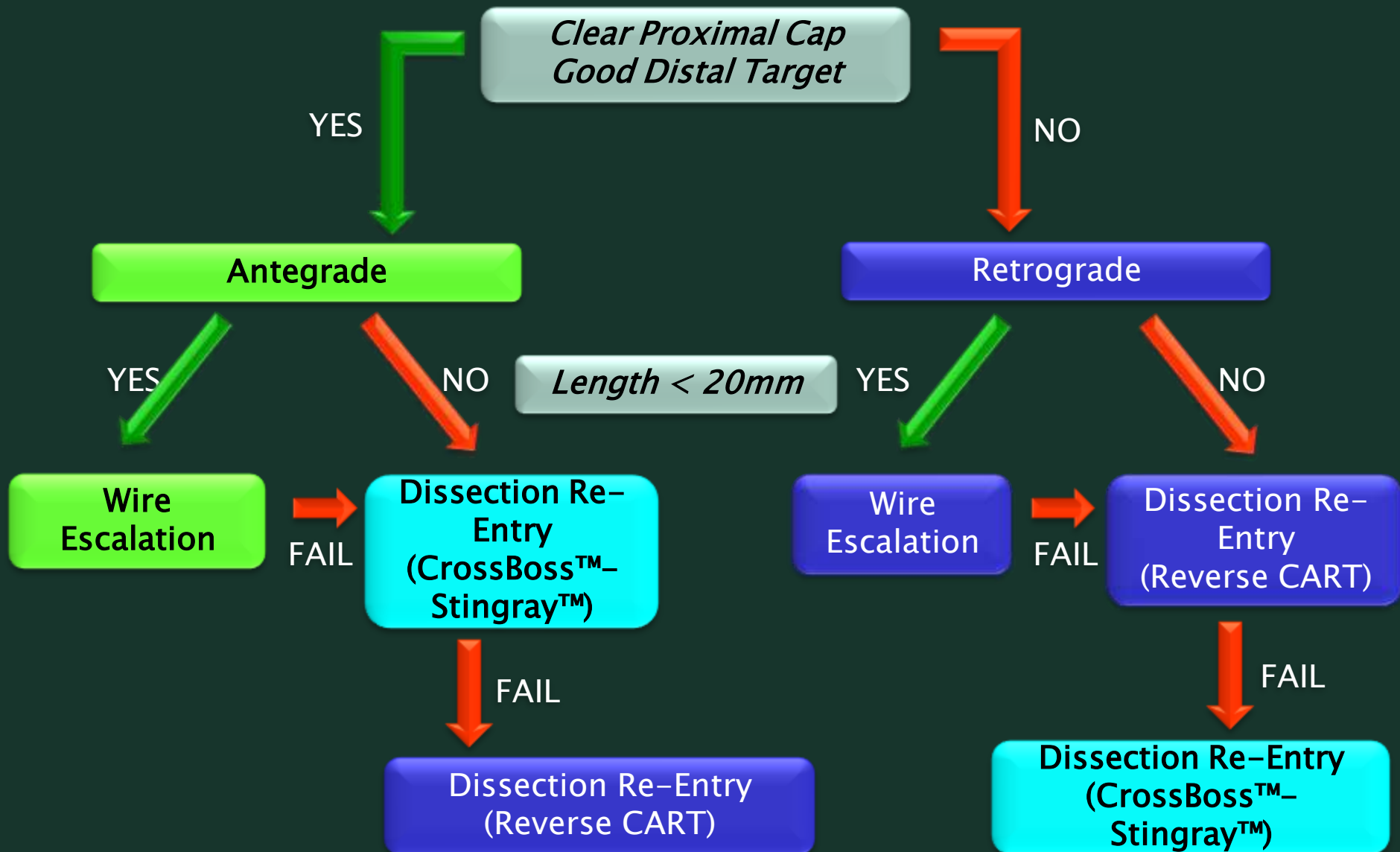
FOUR ANGIOGRAPHIC CHARACTERISTICS DICTATE STRATEGY

- Proximal cap ambiguity
- Lesion length
- Quality of distal target
- Suitability of “interventional” collaterals

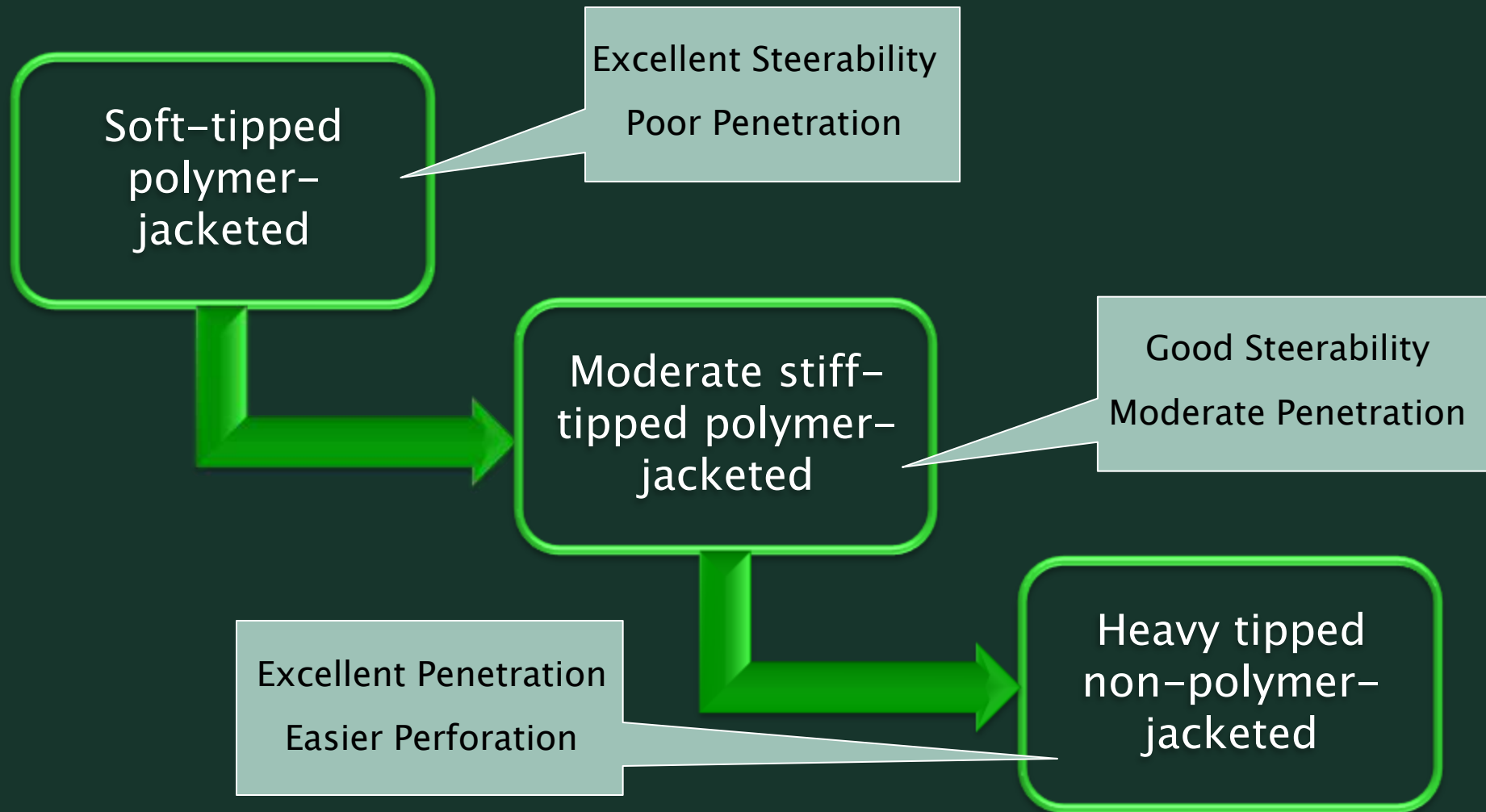
HYBRID STRATEGY PRINCIPLES

- ◆ Consistent evaluation approach
- ◆ Emphasizes procedural safety, success, and efficiency
- ◆ Minimizes radiation and contrast
- ◆ Quick transition to alternate plans when failure mode occurs

The Hybrid Algorithm



Antegrade Wire Escalation



Guidewire Selection

Procedure	Guide-wire	Commercial name
Antegrade micro-channel or soft tissue probing	A hydrophilic and/or polymer-jacket 0.014-inch guidewire, low gram-force, with tapered 0.009-I	Fielder XT wire (Asahi Intecc, Nagoya, Japan) & Runthrough taper wire (Terumo Corporation, Tokyo, Japan)
Knuckle techniques	A hydrophilic and/or polymer-jacket 0.014-inch guidewire, low gram-force, with tapered 0.009-inch tip - Moderately high- gram-force (4 to 6 g), polymerjacket, nontapered 0.014-inch	Fielder XT wire (Asahi Intecc, Nagoya, Japan)
		Fielder FC wire (Asahi Intecc)
Retrograde collateral channel crossing	Nontapered , polymer-jacket hydrophilic 0.014-inch guidewire	Fielder FC wire (Asahi Intecc) and Pilot 50 wire (Abbott Vascular, Santa Clara, California)
Complex lesion crossing	Moderately high-gram-force (4 to 6 g), polymerjacket, nontapered 0.014-inch High-gram-force 0.014-inch guidewire, with a tapered 0.009-inch nonjacketed tip	Pilot 200 guidewire (Abbott Vascular) (<i>for tortuous vessels</i>)
		Confianza Pro 12 wire (Asahi Intecc)- <i>straight vessels</i>
Long lesions	Moderately high-gram-force (4 to 6 g), polymerjacket, nontapered 0.014-inch	Pilot 200 guidewire (Abbott Vascular)
Dissection/re-entry	Moderately high-gram-force (4 to 6 g), polymerjacket, nontapered 0.014-inch High-gram-force 0.014-inch guidewire, with a tapered 0.009-inch nonjacketed tip	Pilot 200 guidewire (Abbott Vascular)
		Confianza Pro 12 wire (Asahi Intecc)
Penetration techniques	High-gram-force 0.014-inch guidewire, with a tapered 0.009-inch nonjacketed tip	Confianza Pro 12 wire (Asahi Intecc)
Cap puncture	High-gram-force 0.014-inch guidewire, with a tapered 0.009-inch nonjacketed tip	Confianza Pro 12 wire (Asahi Intecc)

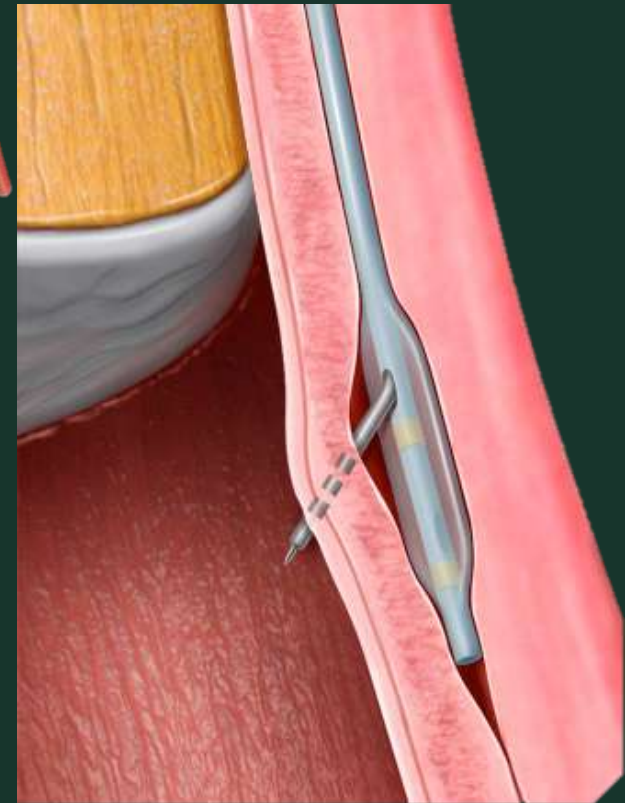
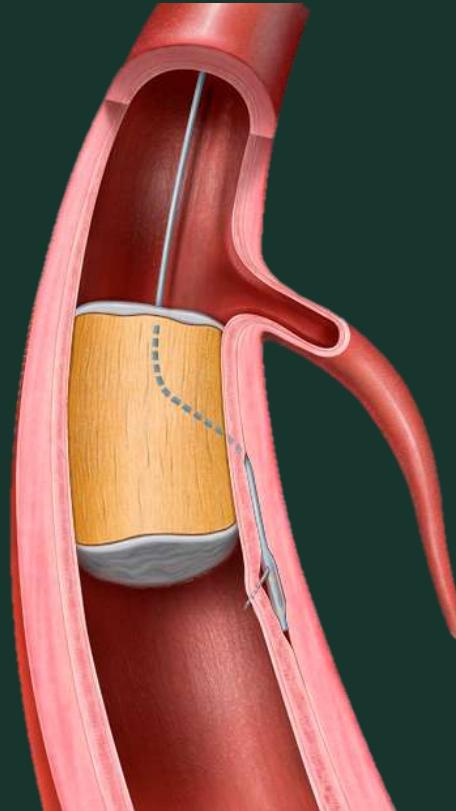
Micro-catheters

- ◆ Corsair microcatheter- 2.7 Fr
- ◆ Small outer diameter, over-the-wire (OTW) microcatheters- V and Quickcross, finecross-2.6 to 1.8Fr
- ◆ Small OTW balloons for wire support and exchange- 1.0 to 1.5 balloons
- ◆ Tornus microcatheter

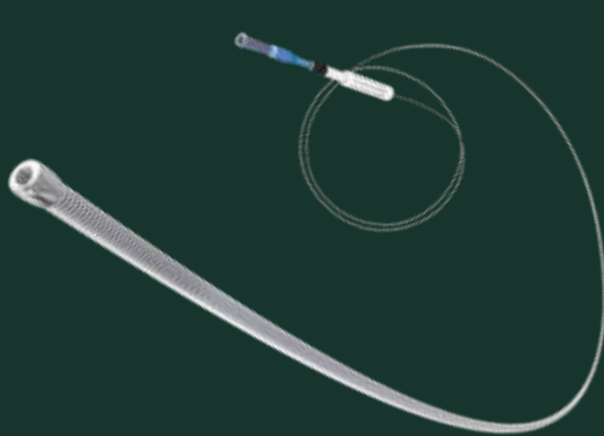
Antegrade Dissection Re-Entry



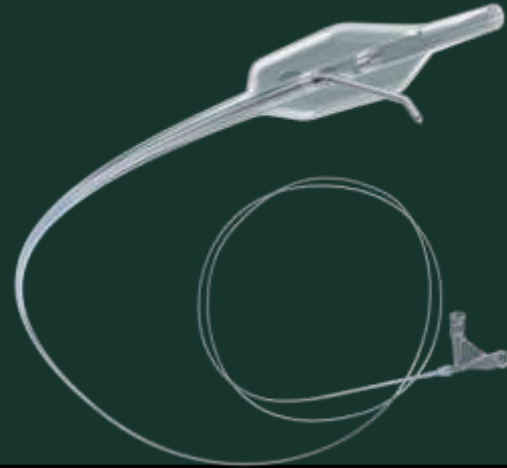
CTO crossing through the subintimal space, advancing across the occlusion, re-entering into the distal true lumen



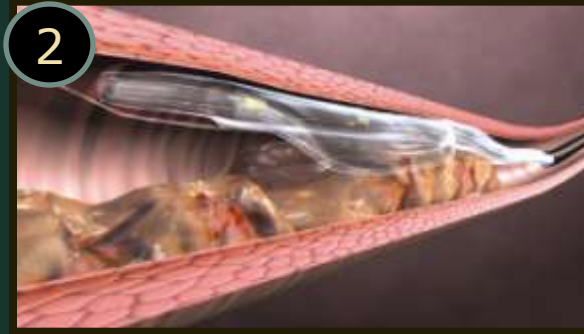
Coronary CTO Crossing and Re-entry System



CrossBoss™ Catheter
Designed to quickly and safely deliver a guidewire via true lumen or subintimal pathways

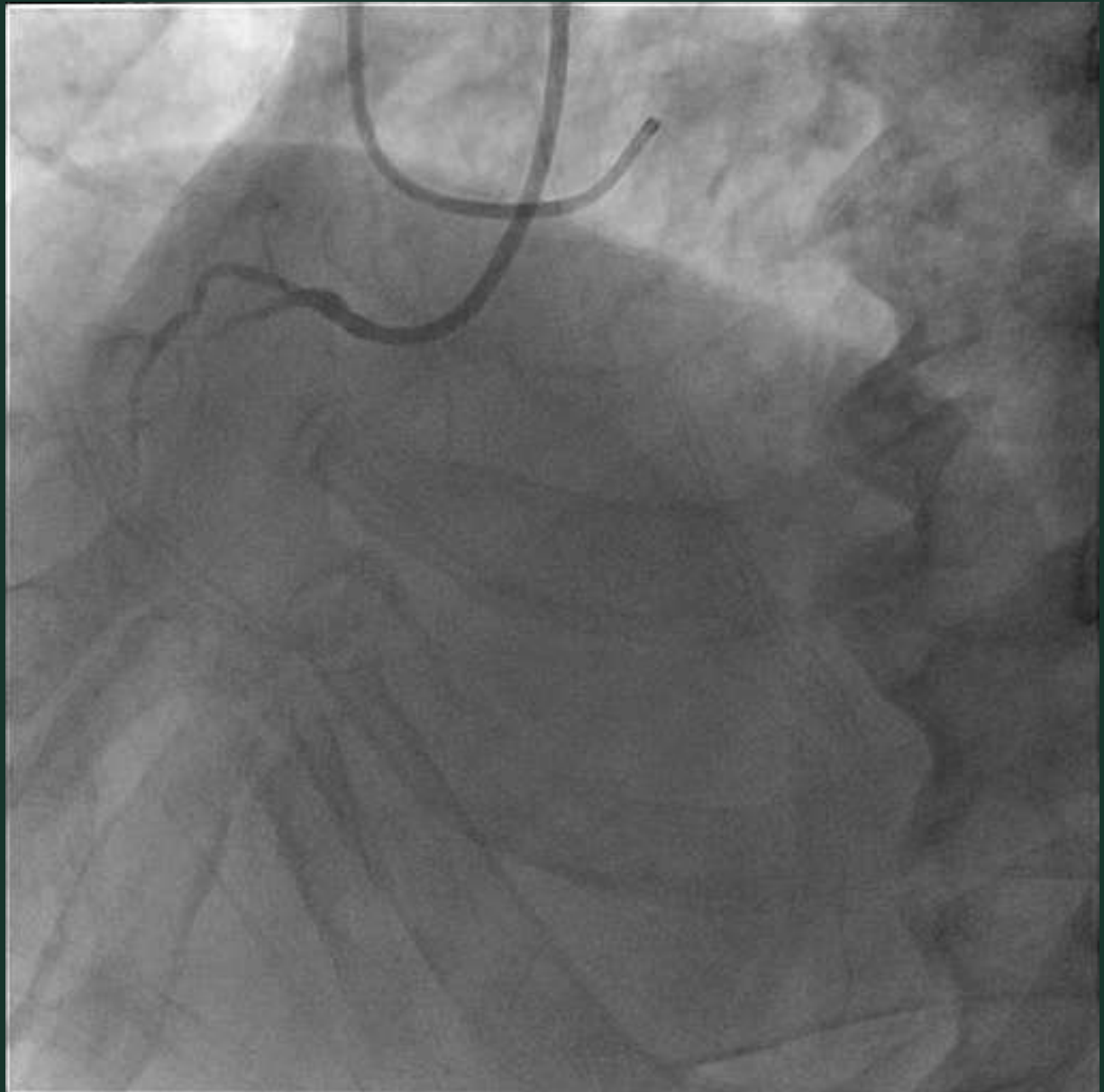


Stingray™ Catheter
Designed to accurately target and re-enter the true lumen from a subintimal position

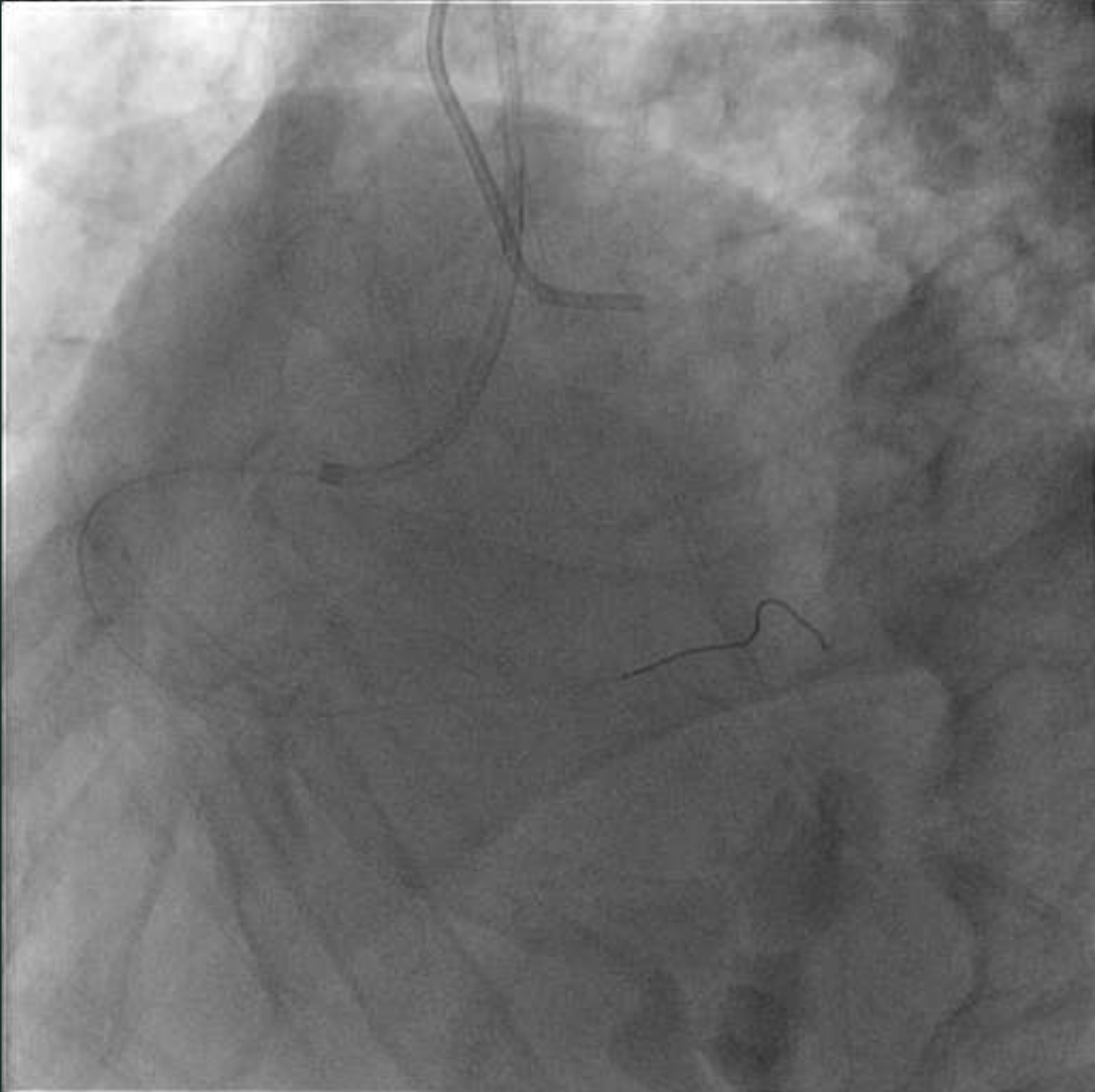


Bilateral Transradial Access

7 Fr JR Guide
RTRA
6 Fr Jackie LTRA



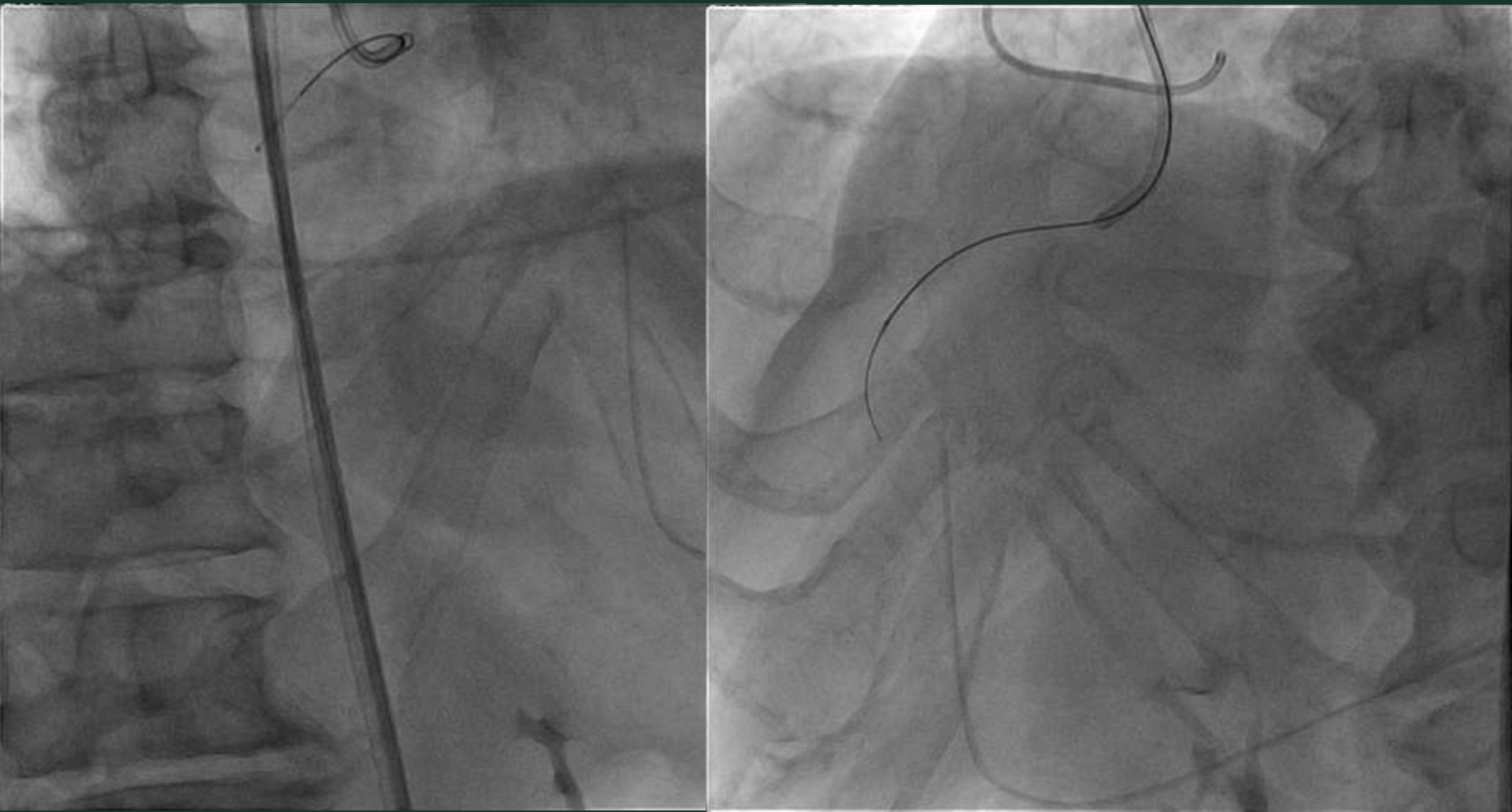
Post
balloon
angioplasty



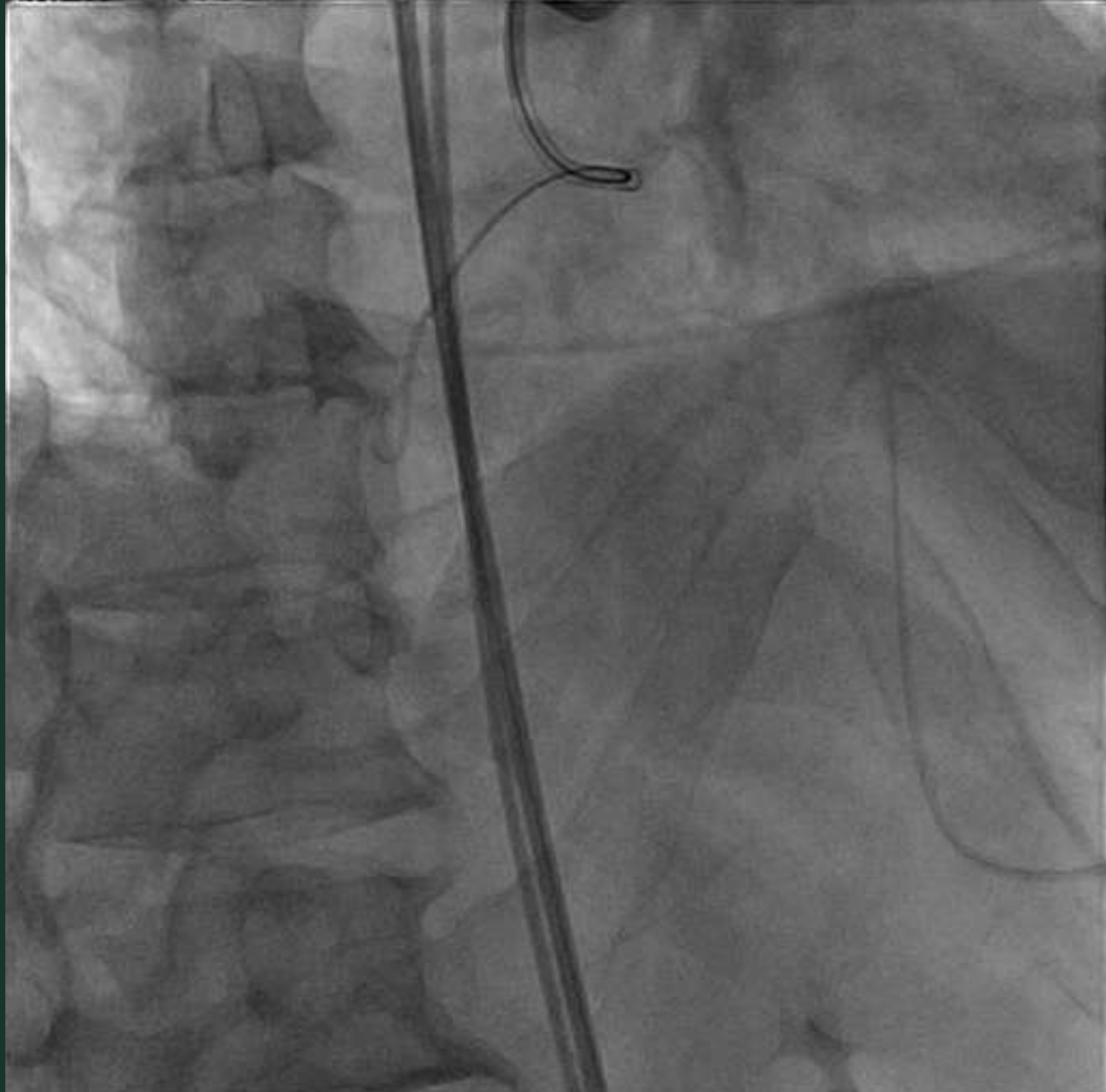
Final Angio
Patient sent
home to return
in 6-8 weeks



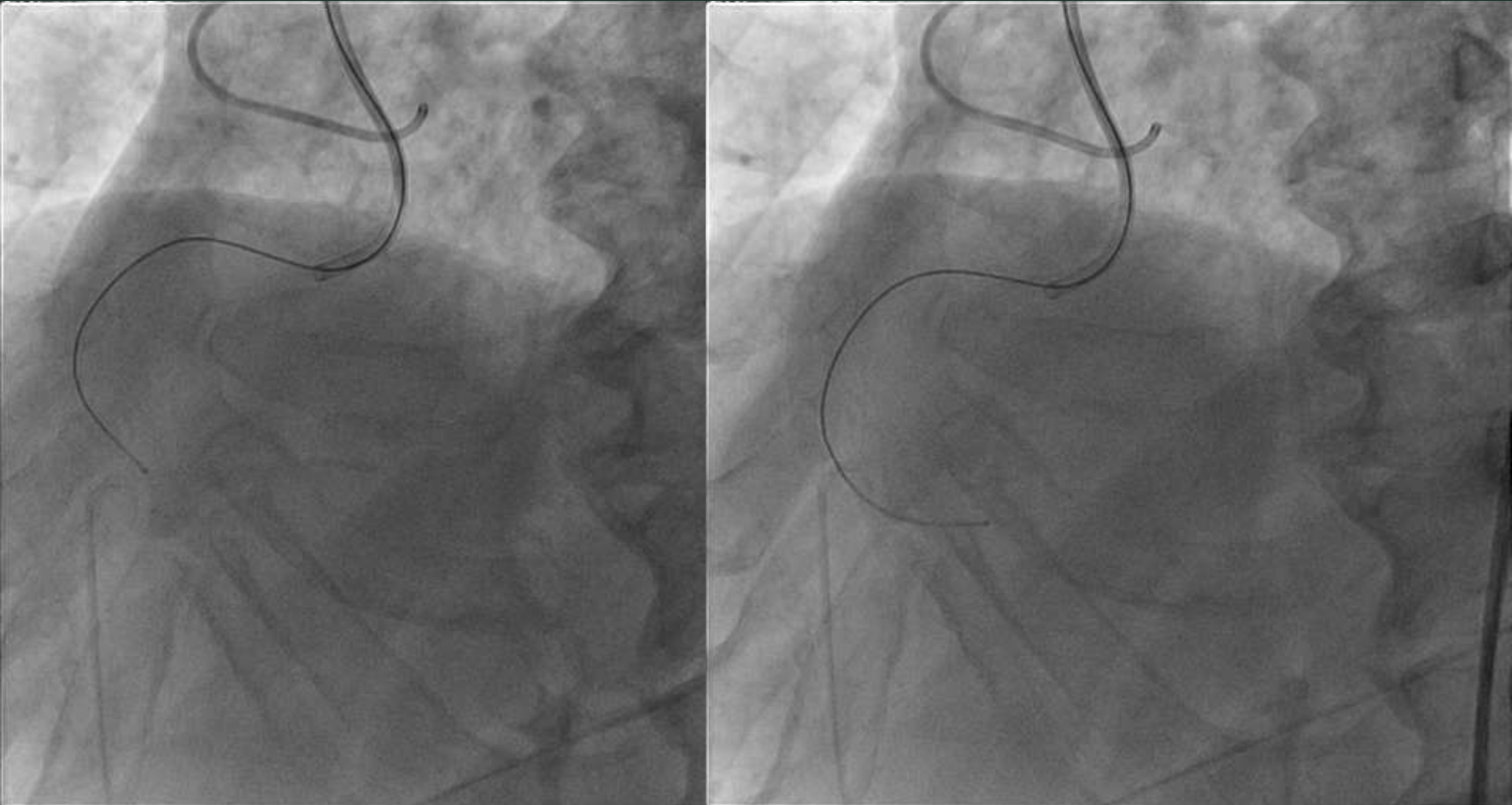
RCA Crossbow with a Fielder XT Wire



Crossbow
redirect with a
“knuckle” wire
technique



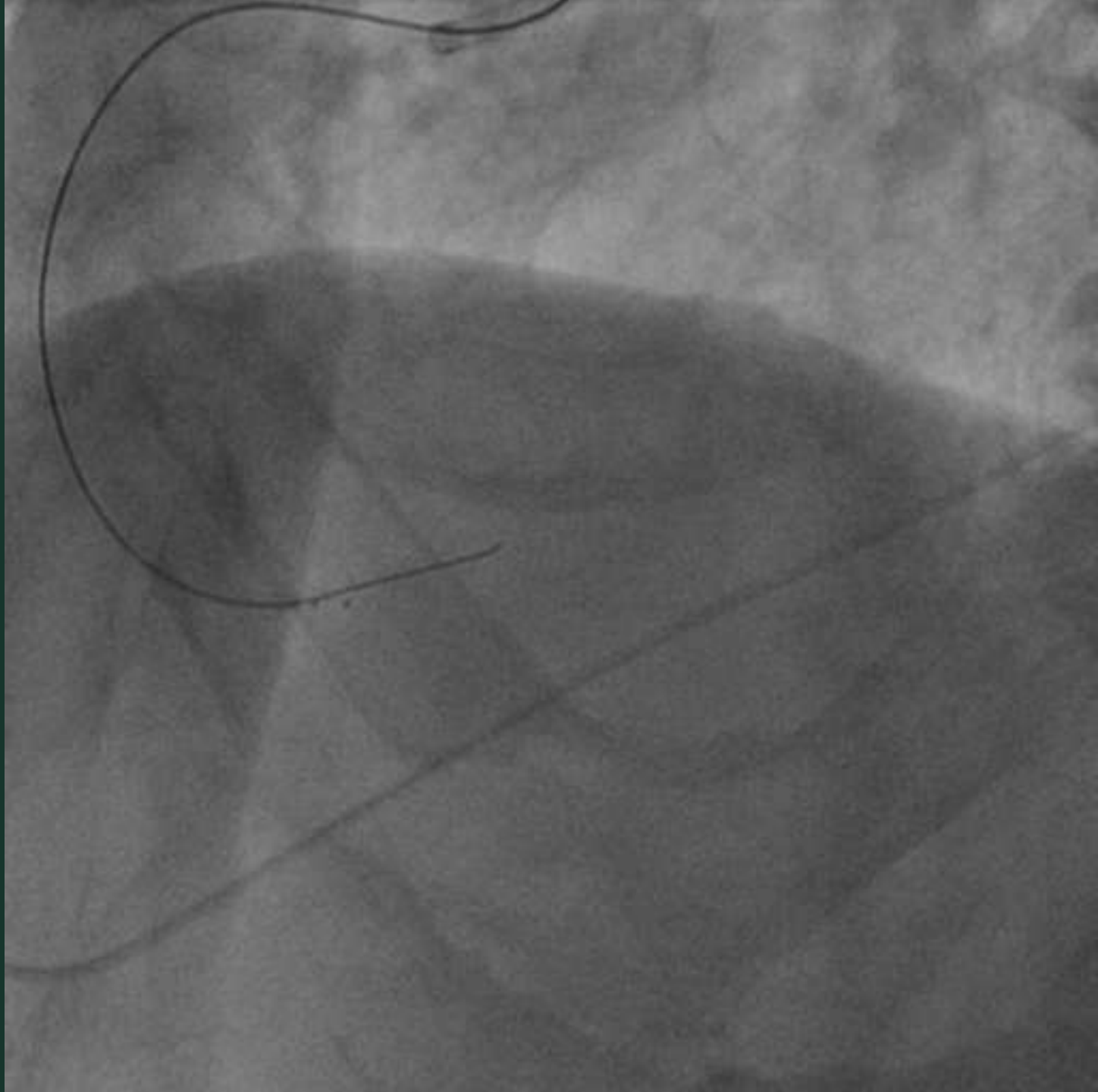
Mini-loop Subintimal



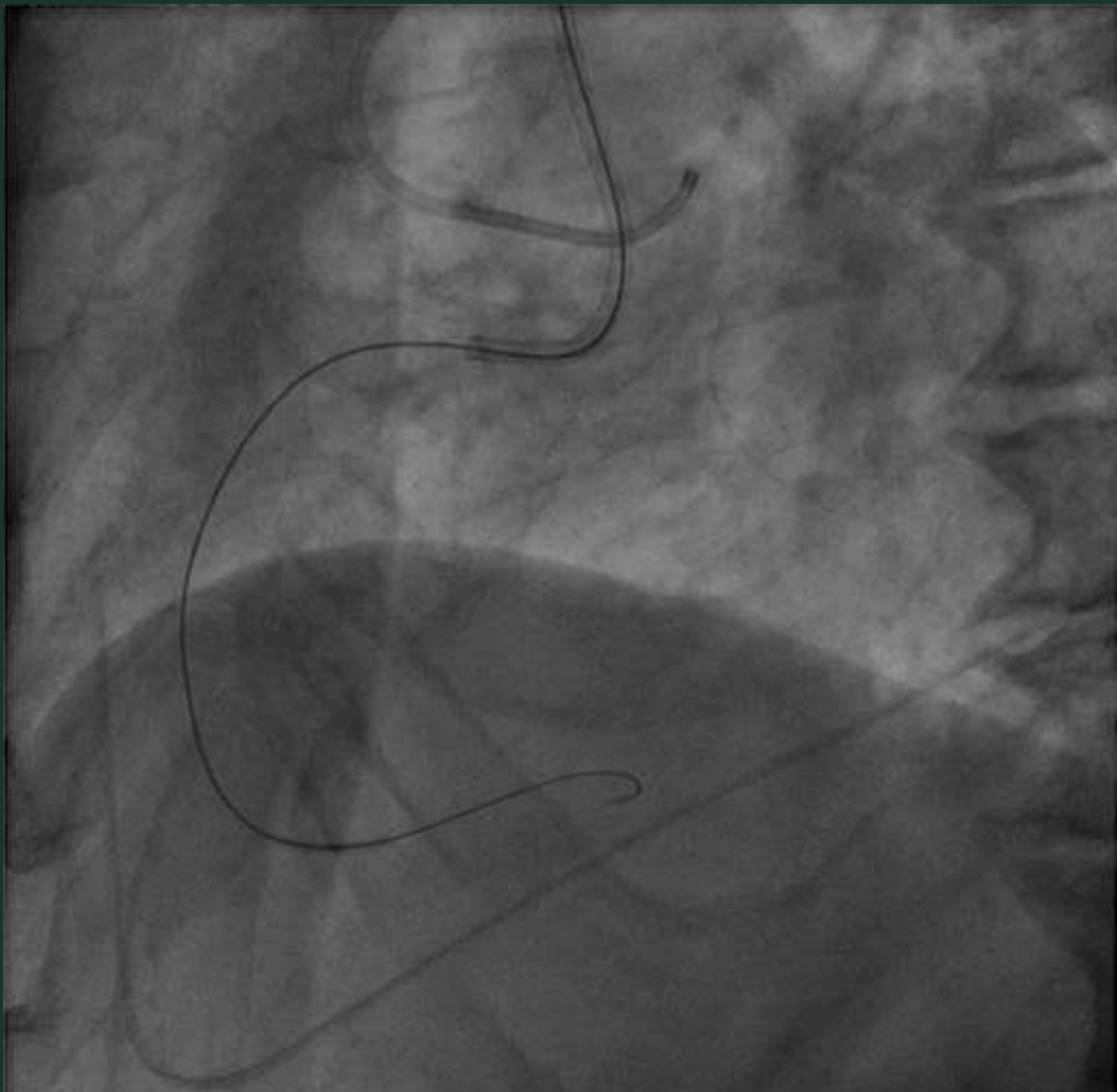
Verify the
placement
of Stingray
catheter
subintimally



Stingray Wire Crossing 2



Dilating Site of Re-entry

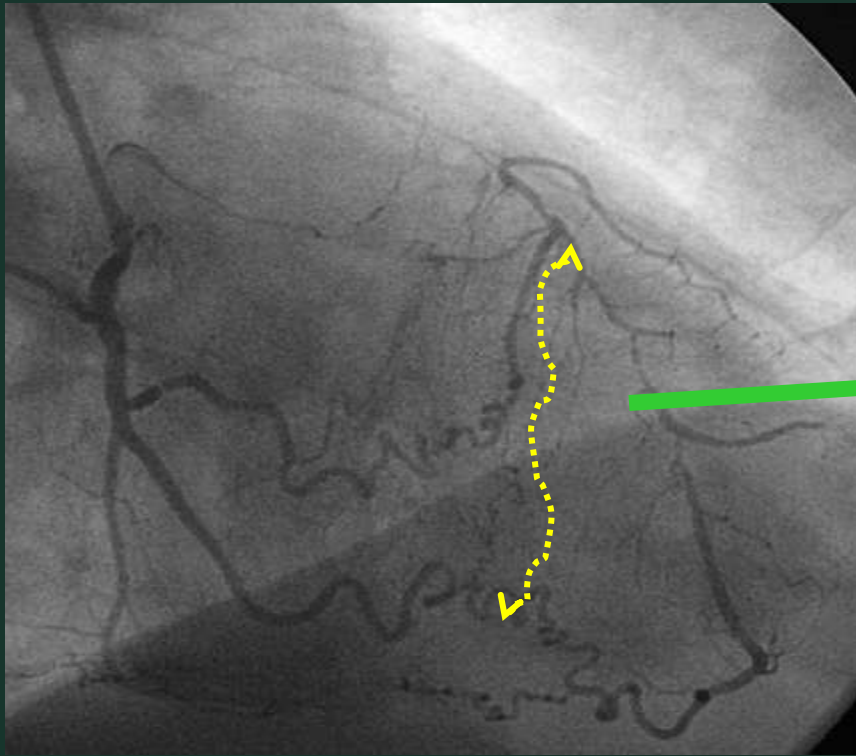


Final Result



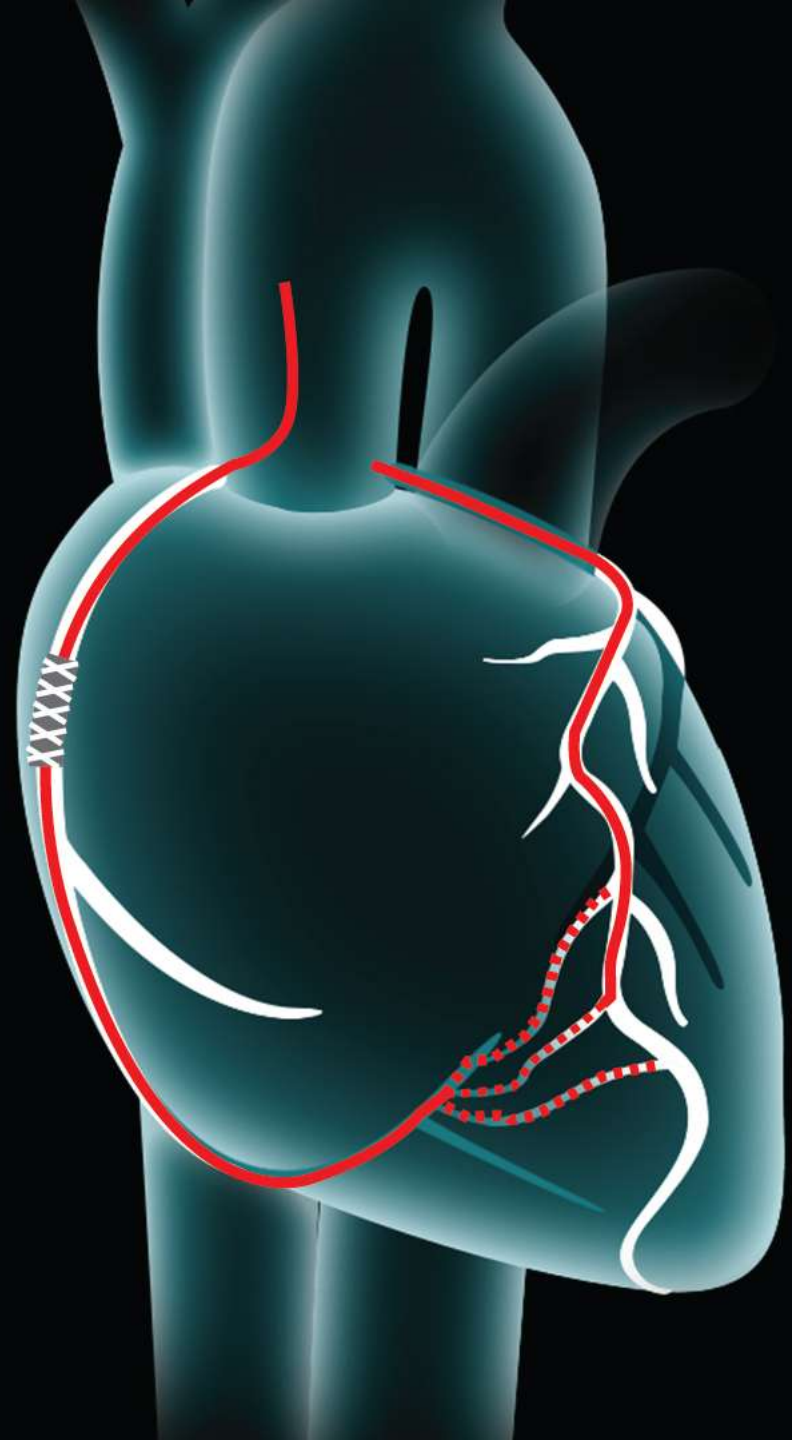
Retrograde Techniques

Retrograde collateral wiring



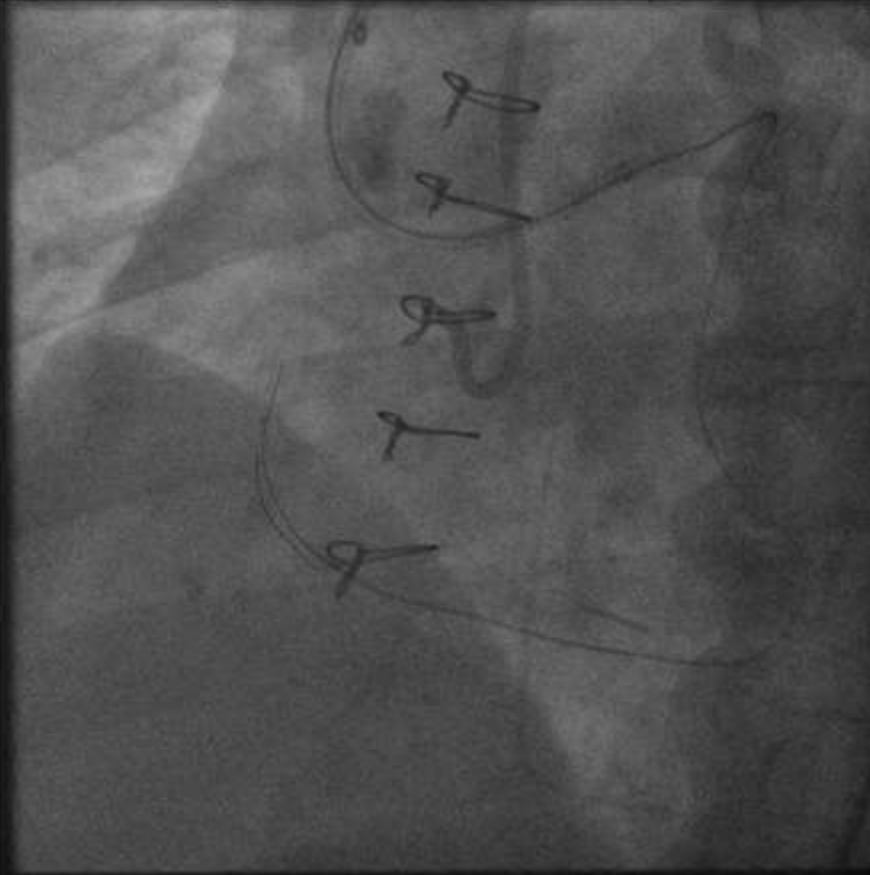
Essential tools for retrograde

1. Microcatheters
2. Wires



Retrograde Techniques

Lossy Compression - not intended for diagnosis



Once septal collaterals
allow access to distal
cap...



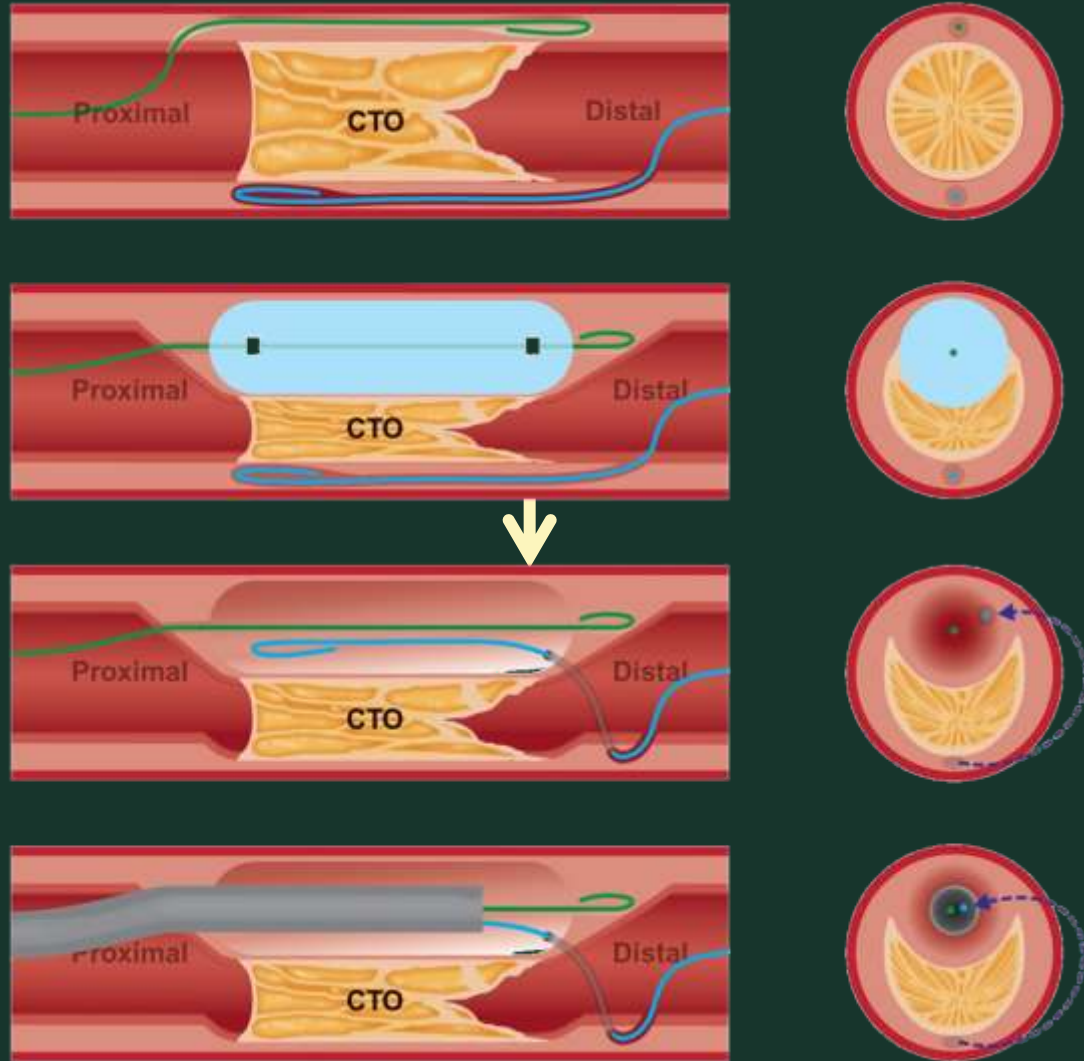
the distal cap should
then be tackled like
proximal cap.



Follow the Hybrid
approach.

Retrograde Techniques

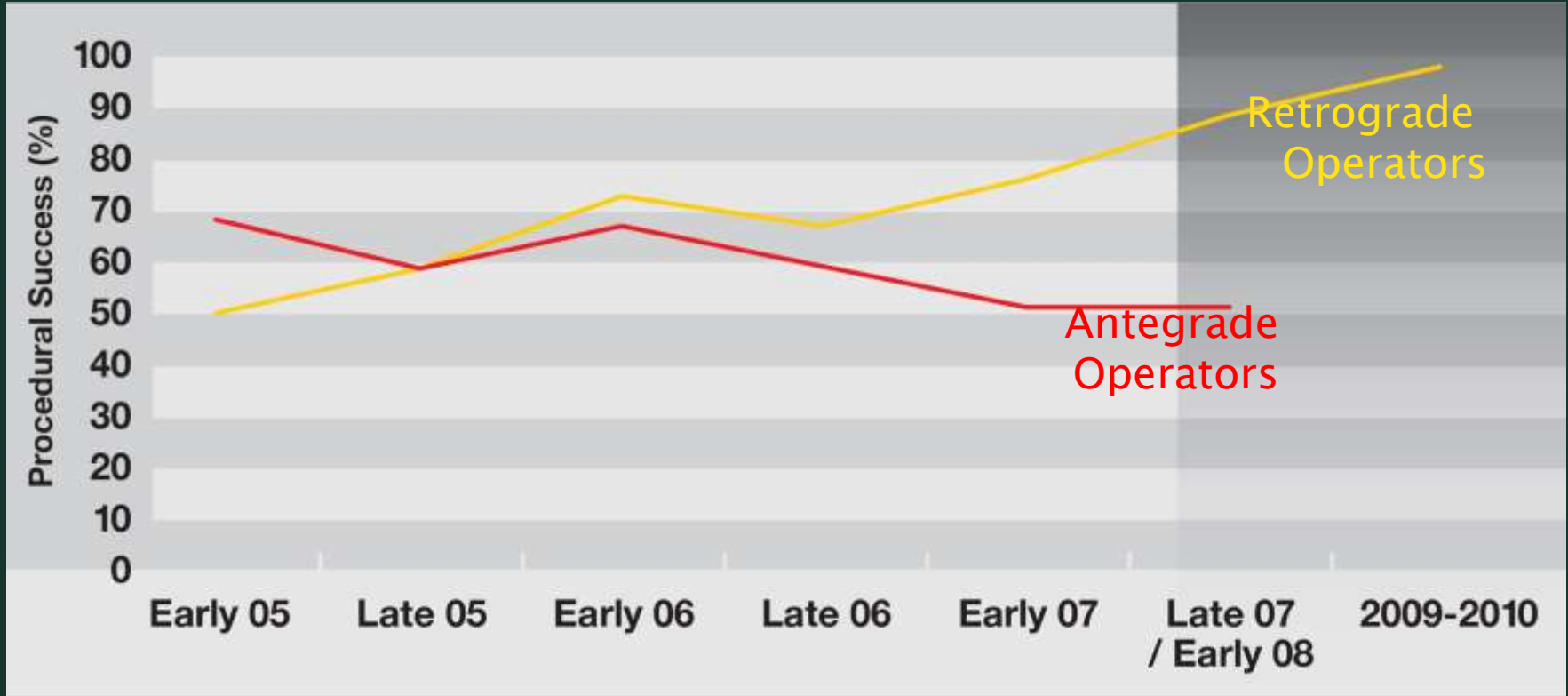
Dissection Re-Entry Techniques: Reverse CART



Success Rates are Low

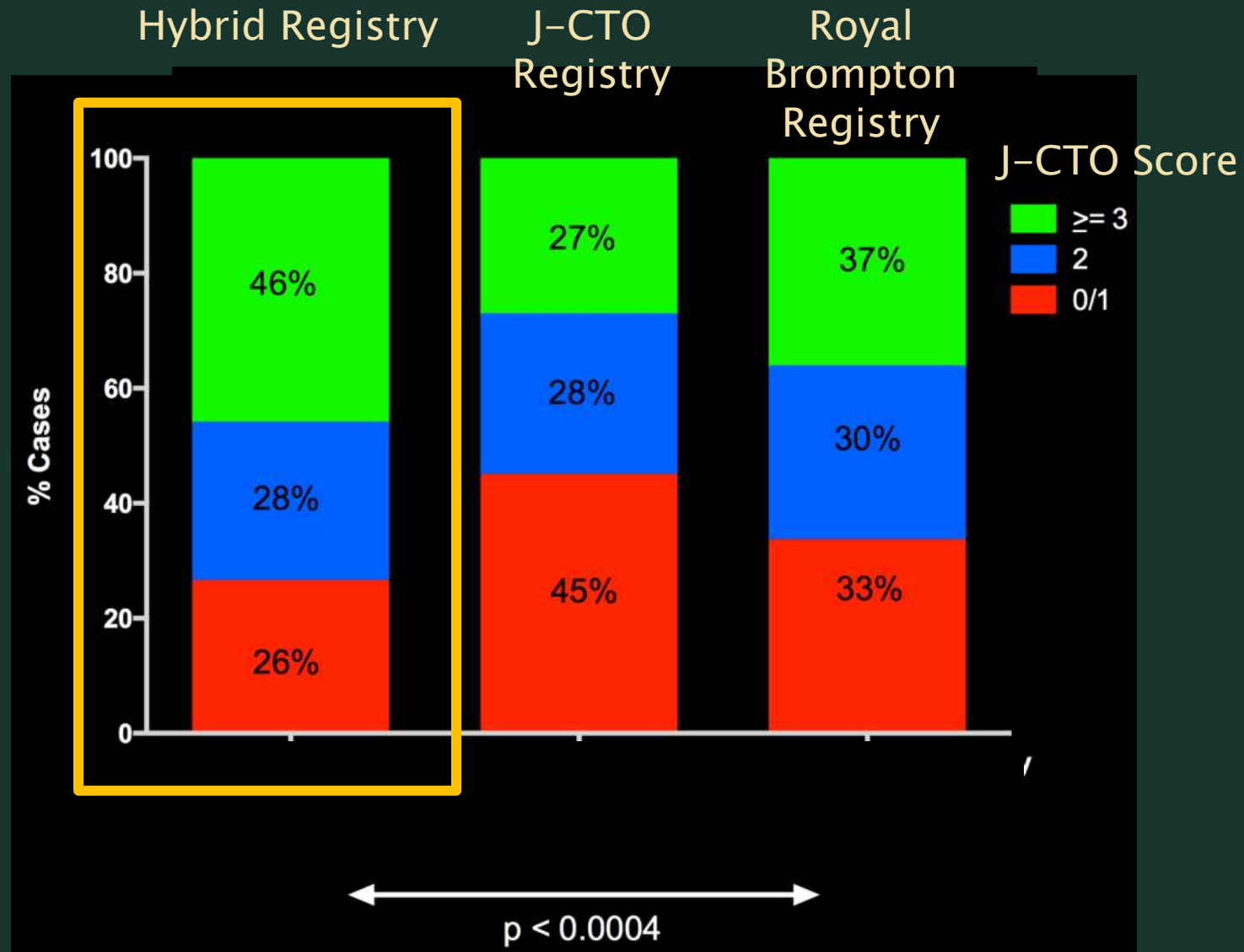
Procedural Success Rates Over Time

Operators with retrograde skills >90% success

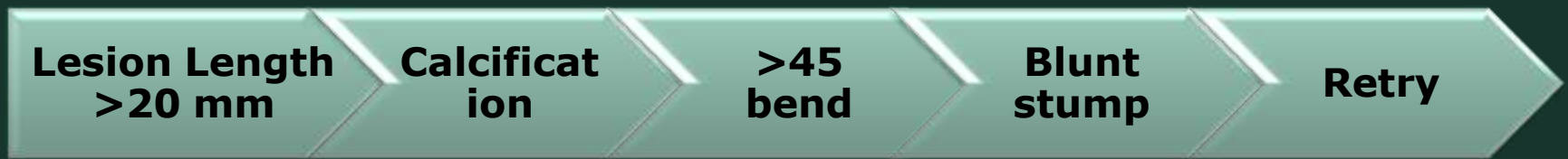


Hybrid CTO Registry Results

More Complex Lesions Overall by J-CTO Score



J-CTO Score

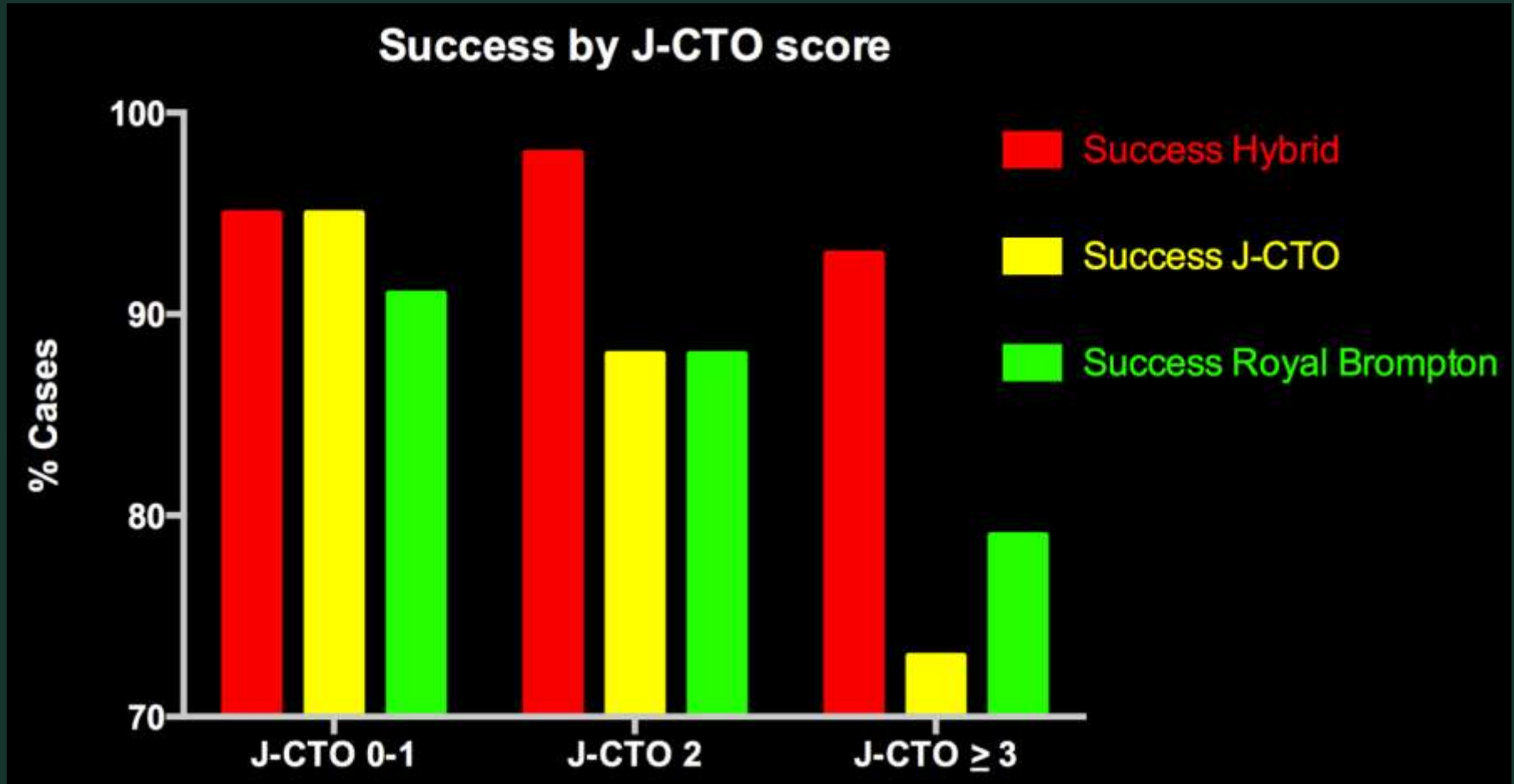


- Developed from the J-CTO registry
- Derivation and Validation
- Predictor of wiring time < 30 minutes
- Procedural success

Morino et al. JACC CI 2011;4:213-21

Hybrid CTO Registry Results

Most successful strategy for complex lesions

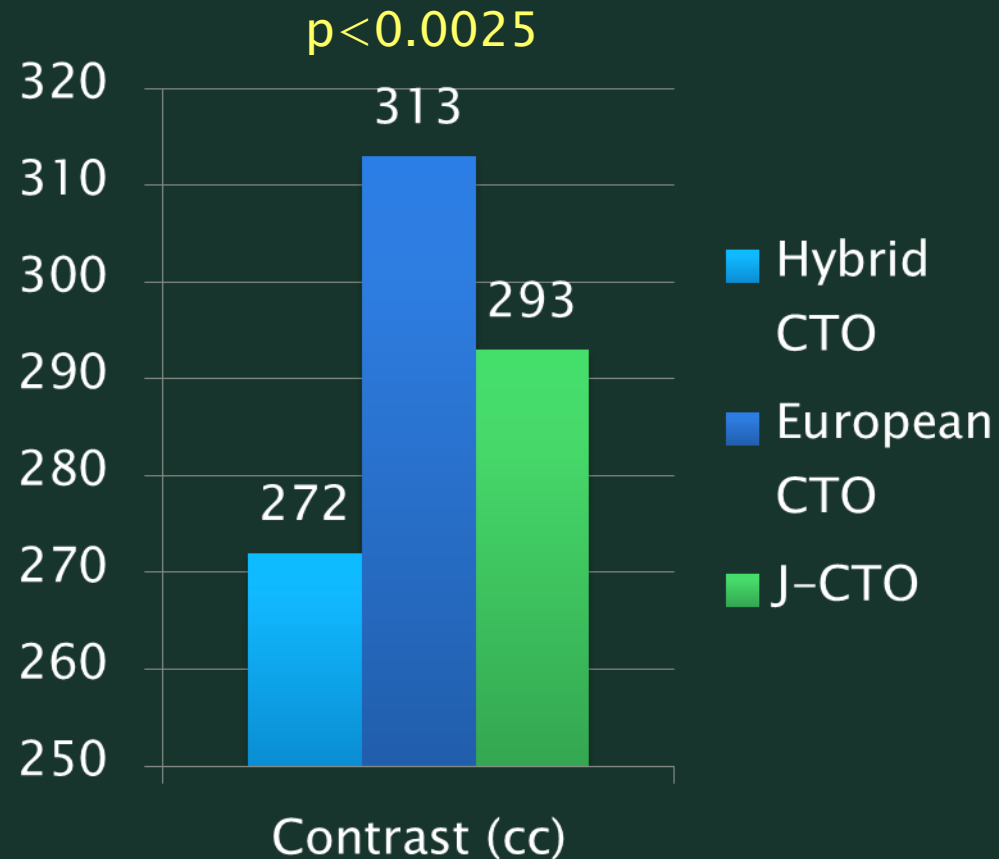
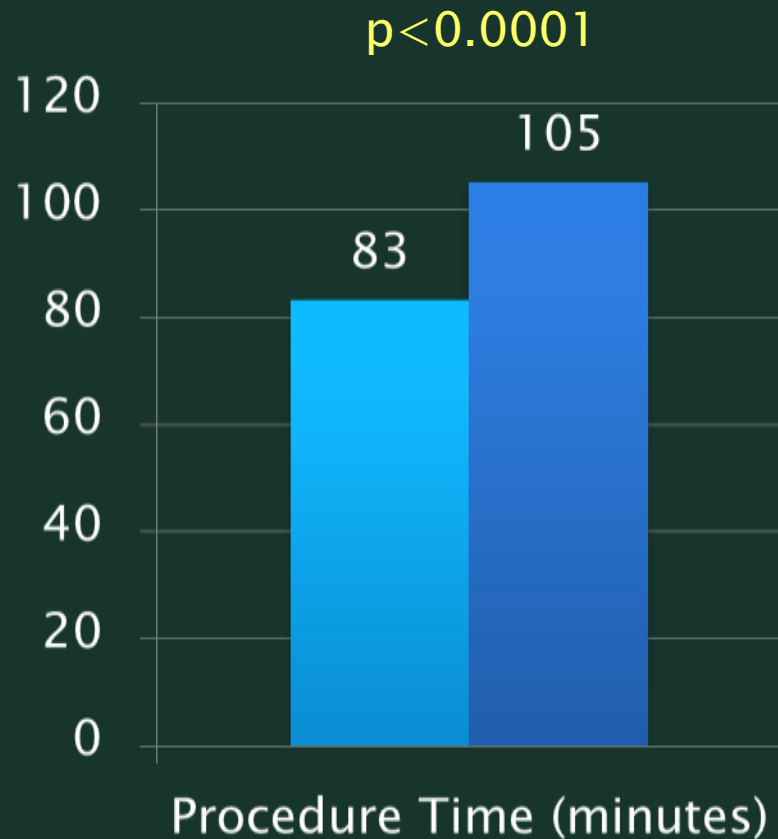


More Complex Lesions

CTO-PCI take  too much time

Procedural Efficiency

Hybrid showed lowest procedure time and contrast used



Data on procedure time from J-CTO was not published.

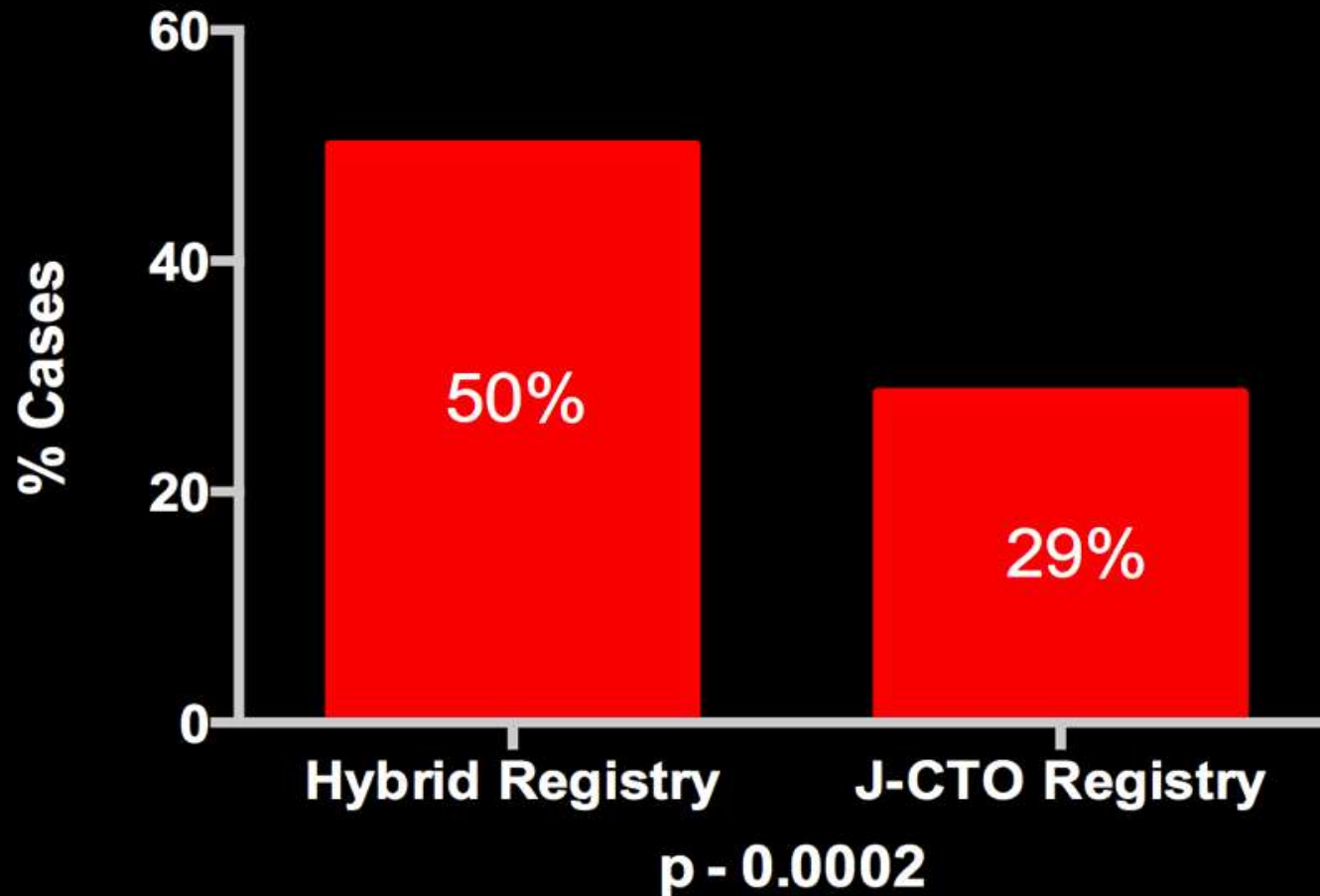
Presented by Daniels, D at TCT 2013

Gallasi et al. Eurointervention 2011;7:472-49

Hybrid CTO Registry Results

Complex Lesions Crossed Quickly in More Cases

J CTO ≥ 2 - Lesions Crossed in Less than 30 Minutes



The procedure is not
reproducible or teachable

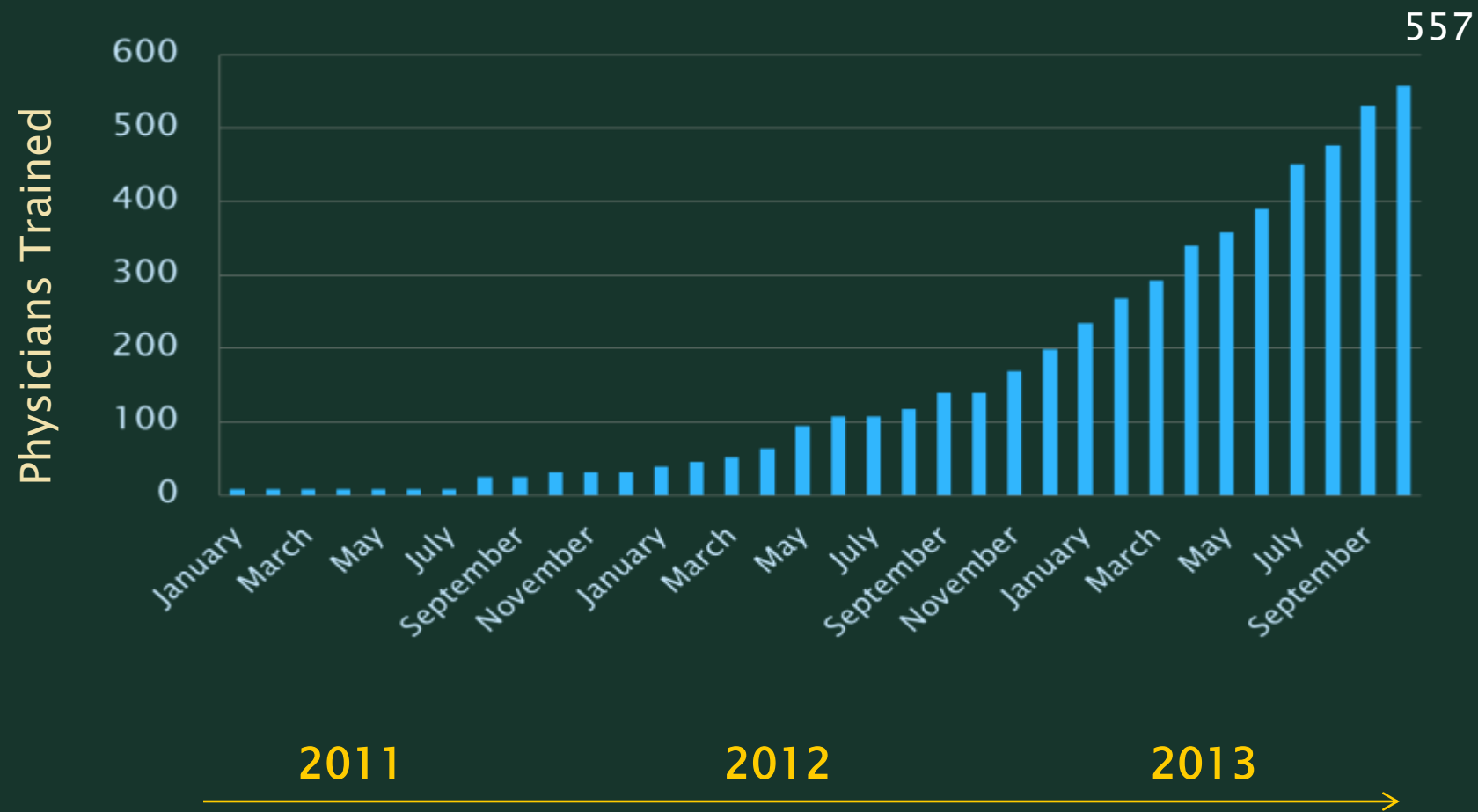


Training & Education



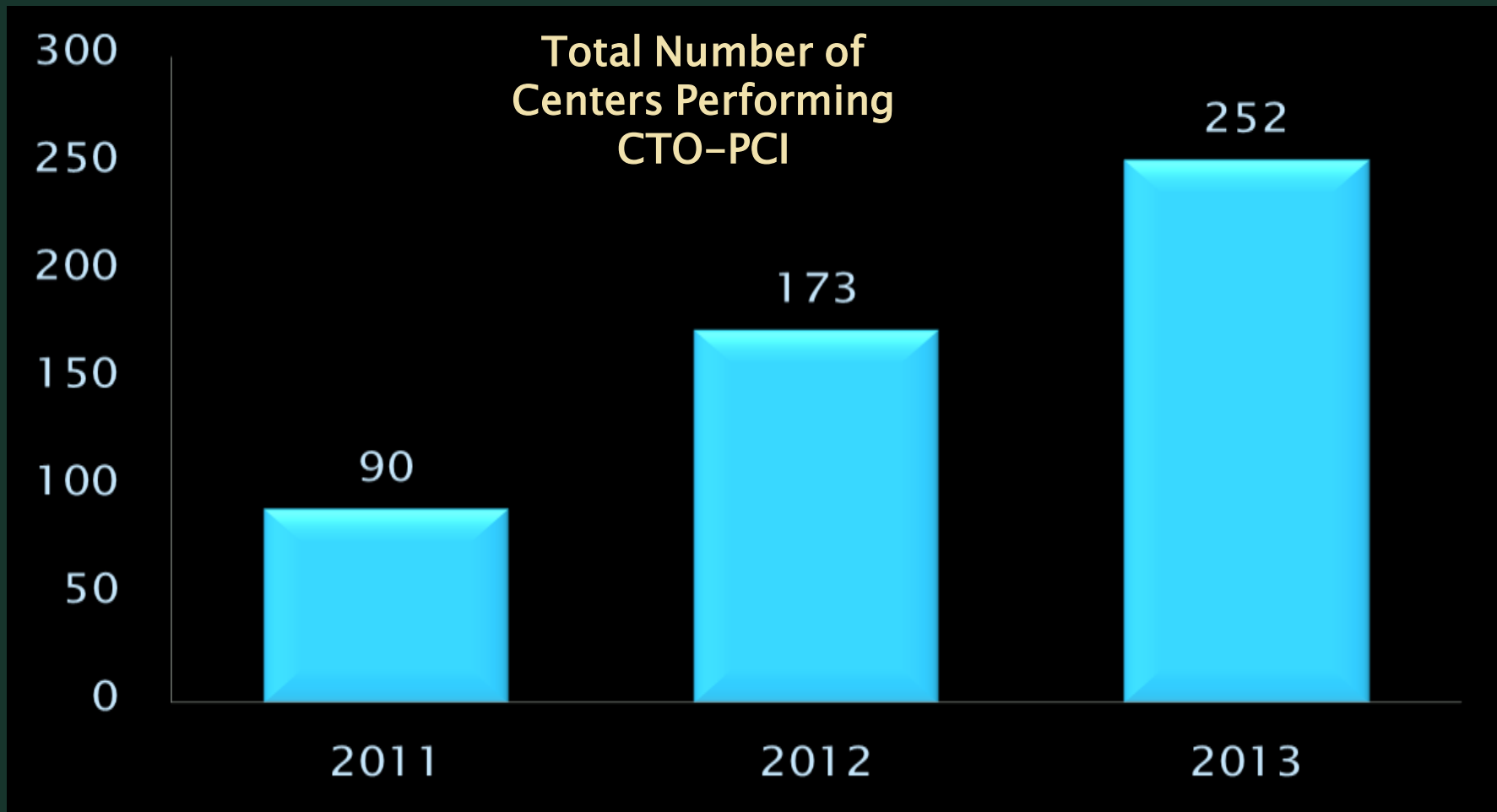
Training	2012	2013
Training Sites	5	11
Physician Attendees	167	359
Proctors	13	18
Training Events	14	18

North America Training Course Participation



*Data does not include international training numbers

CTO-PCI Adoption Curve



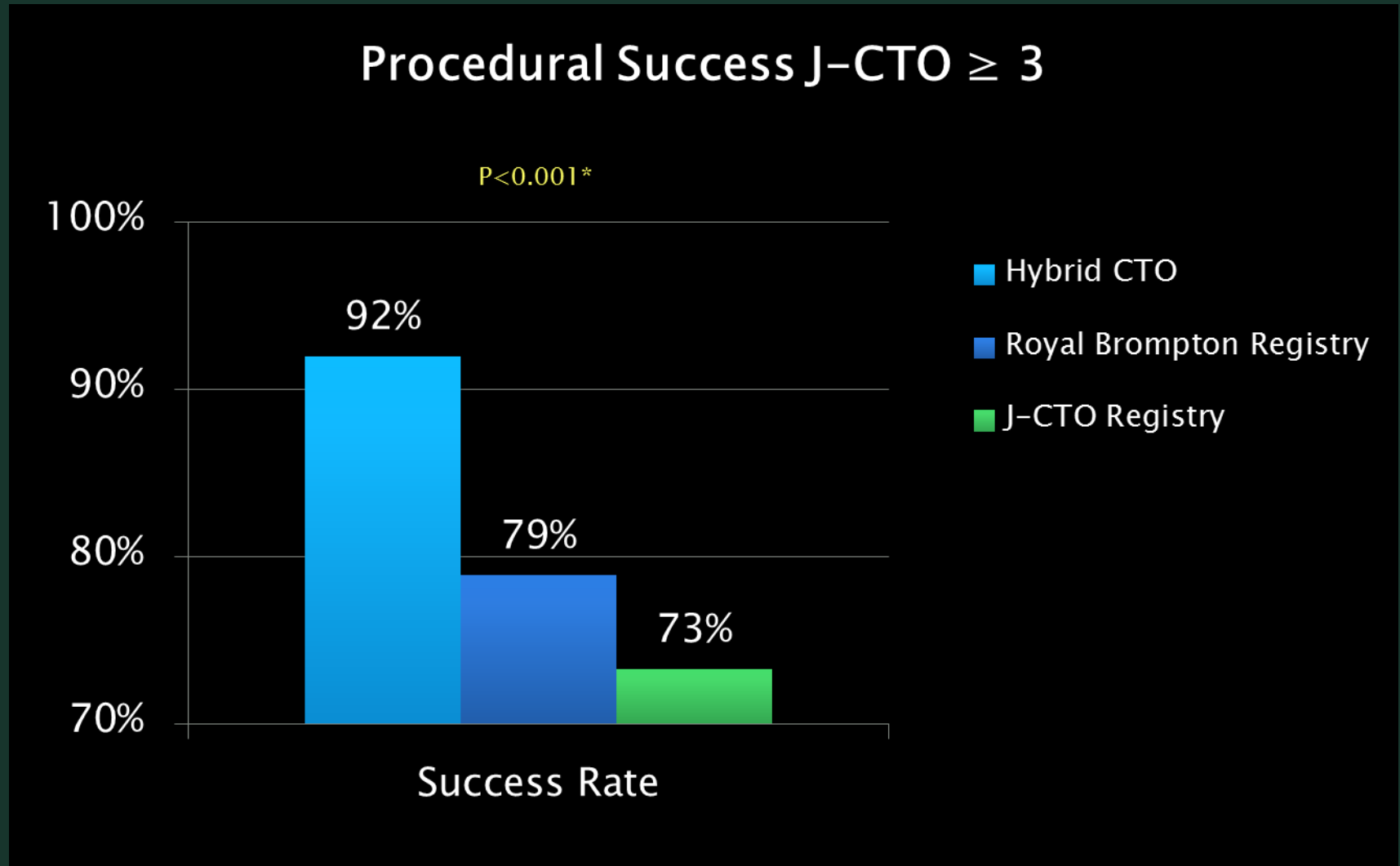
Proctoring Success



*Hands-off proctoring

Hybrid CTO Registry Results

Complex Lesions Crossed Quickly in More Cases



Presented by Daniels, D at TCT 2013

* Hybrid vs. RBR and Hybrid vs. J-CTO

The procedure is cost-
prohibitive



CTO Health Economics & Reimbursement

Physician Payment	
Basic PTCA/Stenting Procedure	\$604
CTO	\$677
AMI	\$677
SVG	\$604
Atherectomy	\$676

The Piedmont Study on Economic Outcomes of CTOs showed that both charges and payments were higher in the CTO group, and overall hospital contribution margins were similar¹

	CTO	Non CTO
Reimbursement	\$16,013	\$13,166
Procedure Cost (non device related)	\$4,640	\$4,376
Device Cost	\$6,230	\$3,060
Contribution Margin	\$5,173	\$5,730

¹ Piedmont Study: CTO, n=154; non CTO, n=1847

CTO Revascularization: Economic Outcomes



Why are CTO-PCI Attempt Rates So Low?

Common misconceptions



There is no clinical justification

- CTOs are stable and benign
- The procedure is too complex
- Success rates are low
- We don't have time for long procedures
- Results are not reproducible or teachable
- CTO-PCI is cost-prohibitive

- Quality of life benefit is indisputable
- Mortality benefit is a reasonable hypothesis being tested
- Underutilization exists and should be addressed
- Controlled, randomized trials are coming

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- CTO is an independent predictor of mortality

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- Hybrid approach helps direct decision-making

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- Historical CTO success rates are low
 - Expert CTO operators have >90% success rates
 - Hybrid algorithm is most successful strategy for complex lesions

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- Hybrid algorithm vs other CTO algorithm

- >20% less time to treat CTOs

- More complex lesions treated in under 30 minutes

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- CTO-PCI training programs rapidly expanding pool of operators
- With dedicated training and proctoring on the Hybrid Approach, trainee success rates are >80%

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- Contribution margin between CTO-PCI and standard PCI is not significant

Thank You!

