Growing Evidence to Support Aggressive CTO-PCI

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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	Boston Scientific, Asahi Intecc, Vascular Solutions
Consulting Fees/Honoraria	Boston Scientific, Abbott Vascular, Asahi Intecc
Major Stock Shareholder/Equity	None
Royalty Income	None
Ownership/Founder	US patent#14/575,977
Intellectual Property Rights	None
Other Financial Benefit	

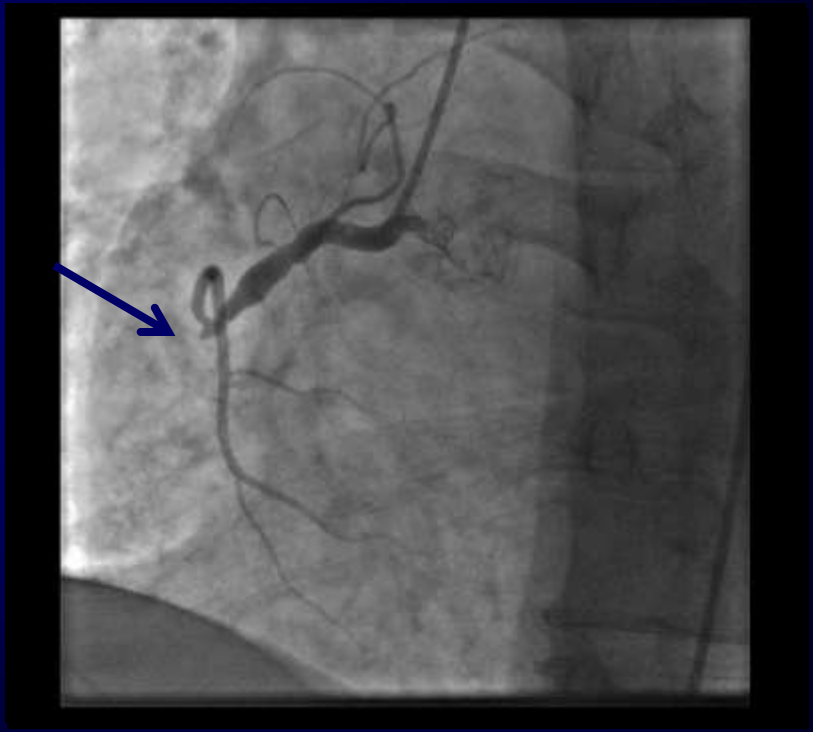
Benefits of CV Care

Quality of Life

Quantity of Life

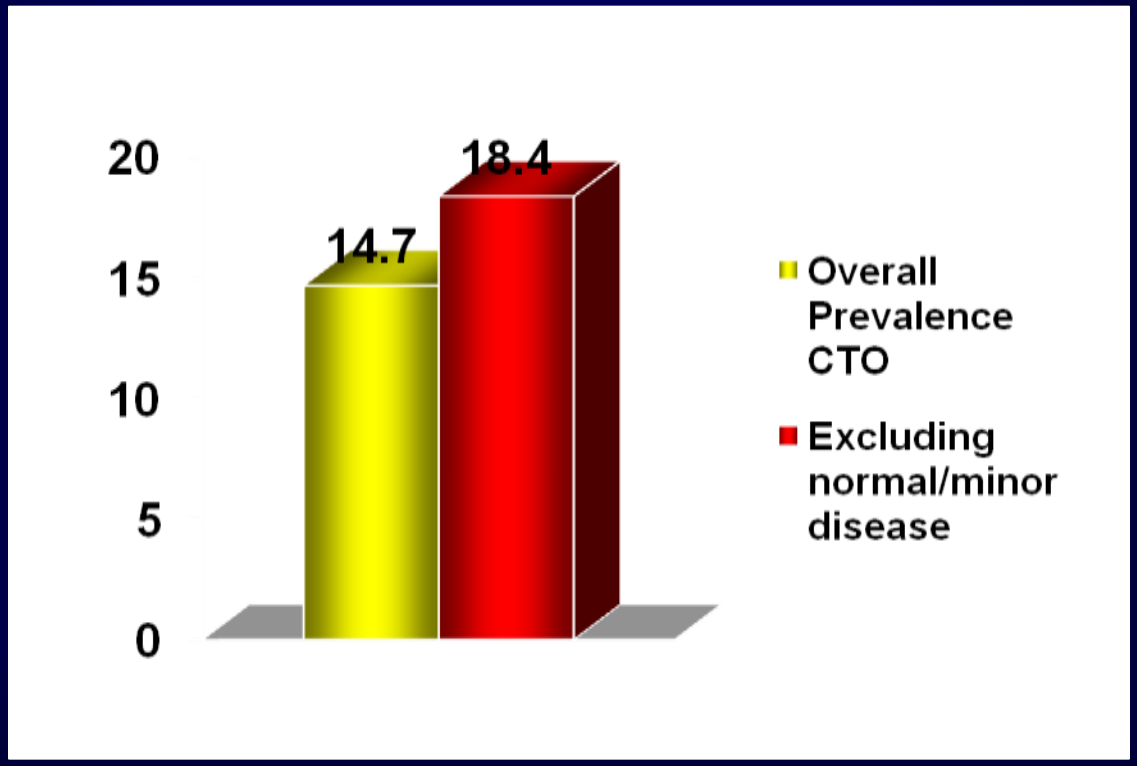
Outline

- CTOs are common
- Treatment varies
- Barriers to PCI
  - Myths
    - Can't get worse
    - Well collateralized
    - Too Risky/too difficult
  - New data



CTOs are common

7559 Patients with Coronary Angiography April 2008-July 2009 at 3 centers in Canada



74% had CCS class II or more angina

Fefer et al J Am Coll Cardiol 2012;59:991–7

CTOs are common

- **CCS estimates 1,000,000 Americans with Refractory angina** McGillion et al. Can J Cardiol 2012;28:S20-41
- **A persistent, painful condition characterized by the presence of angina caused by coronary insufficiency in the presence of coronary artery disease which cannot be controlled by a combination of medical therapy, angioplasty, and CABG.**

TABLE III. Reasons Precluding Revascularization in Group 6

Reason for no revascularization[a]	Number	% ($n = 33$)
Chronic total occlusion	23	69.7%
Diffuse disease	15	45.5%
Collateral dependent perfusion	14	42.2%
Comorbidities	4	12.1%
Multiple restenoses	2	6.1%
Poor distal targets	1	3.0%

[a]Patients could have more than one reason precluding revascularization.

Williams et al. Catheter and Cardiovsc Int 2010

CTO Treatment Varies:
Operator Bias

>34,000 patients in NCDR with CTO, 13.7% attempted

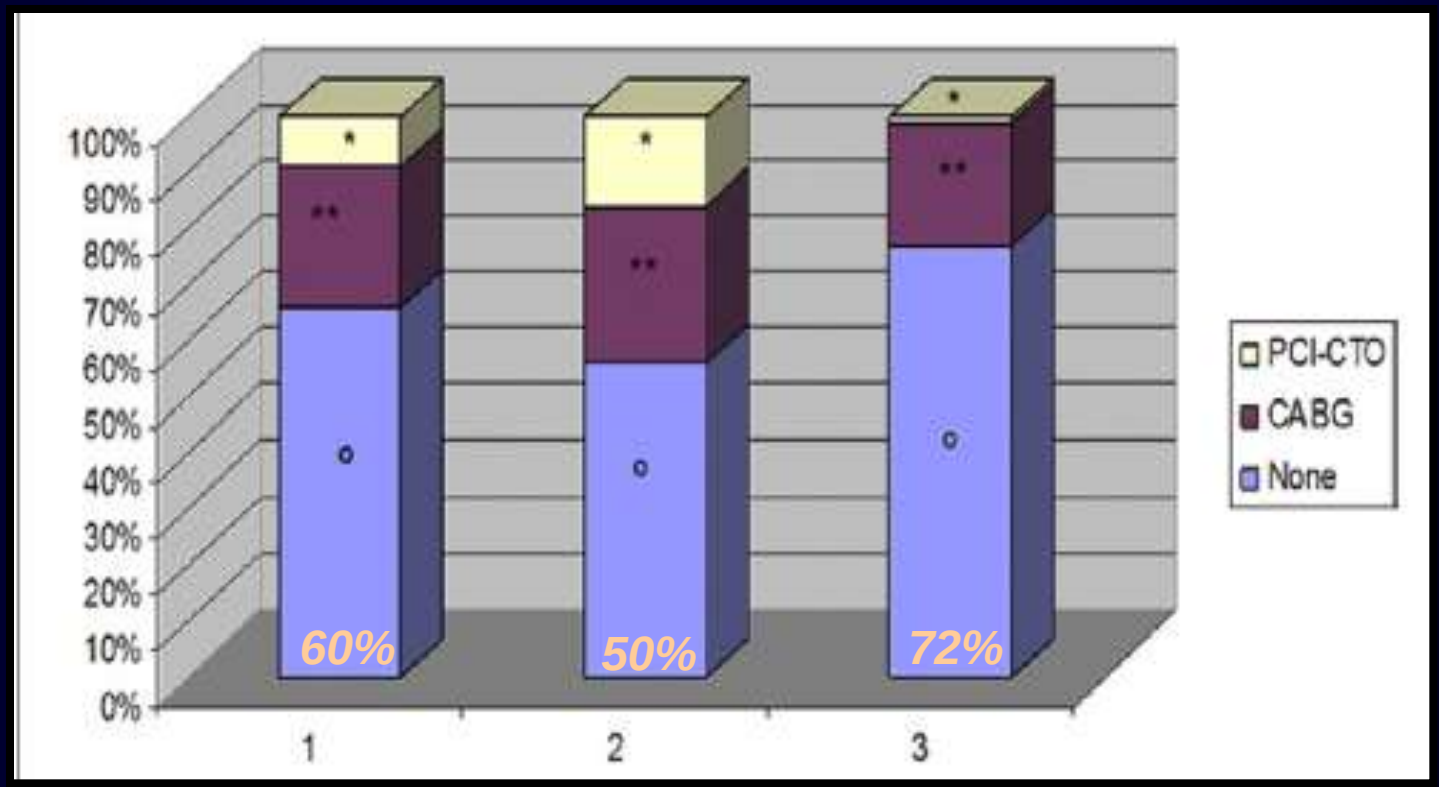
	Point Estimate	95% CI
No Diabetes	1.25	1.17-1.34
No Prior AMI	1.48	1.38-1.59
Creatinine < 2.0	1.93	1.57-2.38
Stress Test Positive vs Negative	1.18	1.07-1.31
Angina vs asymptomatic	1.78	1.63-1.96
LVEF > 40%	1.26	1.15-1.38
SVD vs MVD	3.07	2.87-3.28
Low vs Intermediate Operator	0.59	0.54-0.65
Low vs High Volume Operator	0.50	0.46-0.55

- *Likelihood of attempted PCI independently associated with operator volume*

Grantham, JA et al JACC: CI 2009; 2:479-486

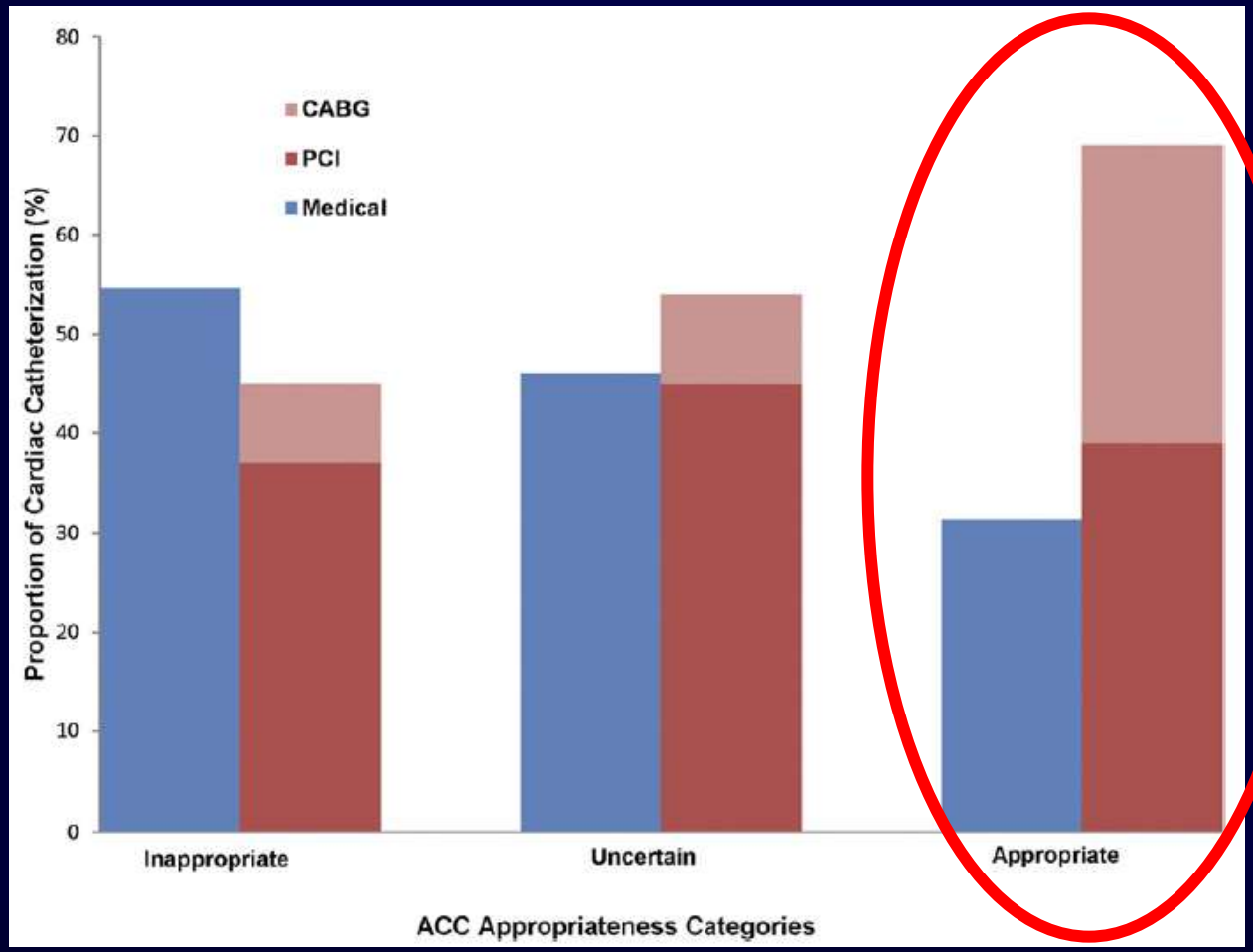
CTO Treatment Varies:
Institutional Bias

Overall 10% of patients with a CTO were treated with PCI



Fefer et al. JACC 2012

Underuse of Revascularization



Adjusted hazard for death or ACS with revasc vs medical therapy among "A" group (0.61; 95% confidence interval [CI]: 0.42 to 0.88)

Ko et al JACC 2012;60:1876-84

Variability can represent underuse

- ***Interventional risk treatment paradox***

Baseline SYNTAX score	7.5 ± 5.6	9.3 ± 6.1	12.6 ± 6.9	21.7 ± 8.6	<.001
Residual SYNTAX score	0	1.5 ± 0.5	5.2 ± 1.6	15.8 ± 6.5	<.001
Delta† SYNTAX score	7.3 ± 5.4	7.5 ± 6.1	6.9 ± 6.3	5.7 ± 6.4	.15

- ***Untreated lesions***

	rSS >0–2 (n = 523)	rSS >2–8 (n = 578)	rSS >8 (n = 501)	p Value All Groups
Severe calcification	0 (0%)	10 (1.7%)	59 (11.8%)	<0.001
Chronic total occlusion	1 (0.2%)	58 (10.0%)	216 (43.1%)	<0.001
Bifurcation/trifurcation	0 (0%)	179 (30.9%)	287 (57.3%)	<0.001
Aorto-ostial lesion	1 (0.2%)	4 (0.7%)	14 (0.3%)	<0.001
Lesion length >20 mm	3 (0.6%)	143 (24.7%)	351 (70.1%)	<0.001
Small vessel/diffuse disease*	409 (78.2%)	303 (52.4%)	264 (52.7%)	<0.001

Généreux et al J Am Coll Cardiol 2012;59:2165–74

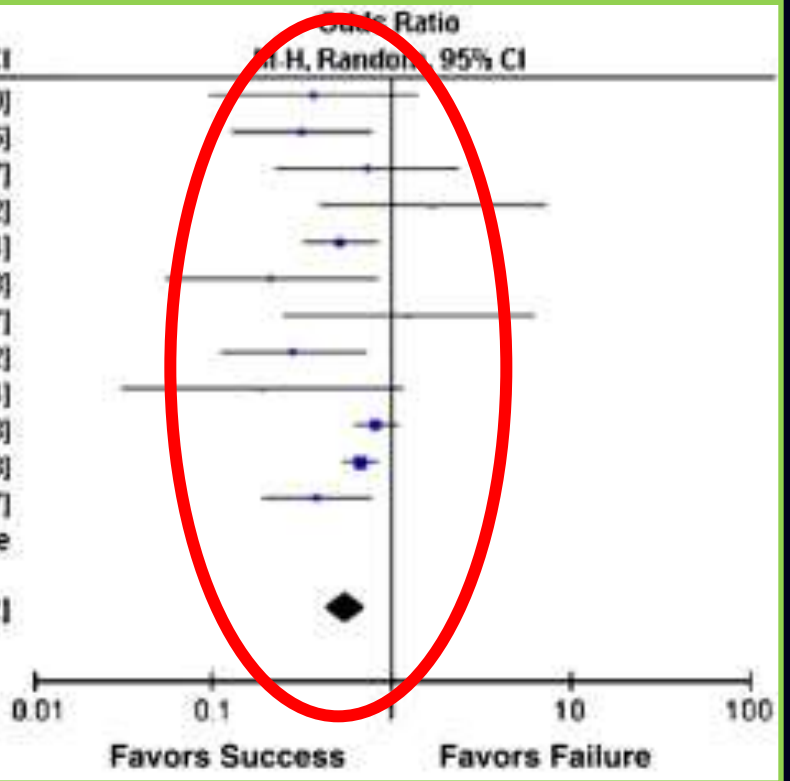
CTO Mythbusters

- "Can't get any worse"
- "Well collateralized"
- "Too risky"

Top 3 Myths:
Can't any worse

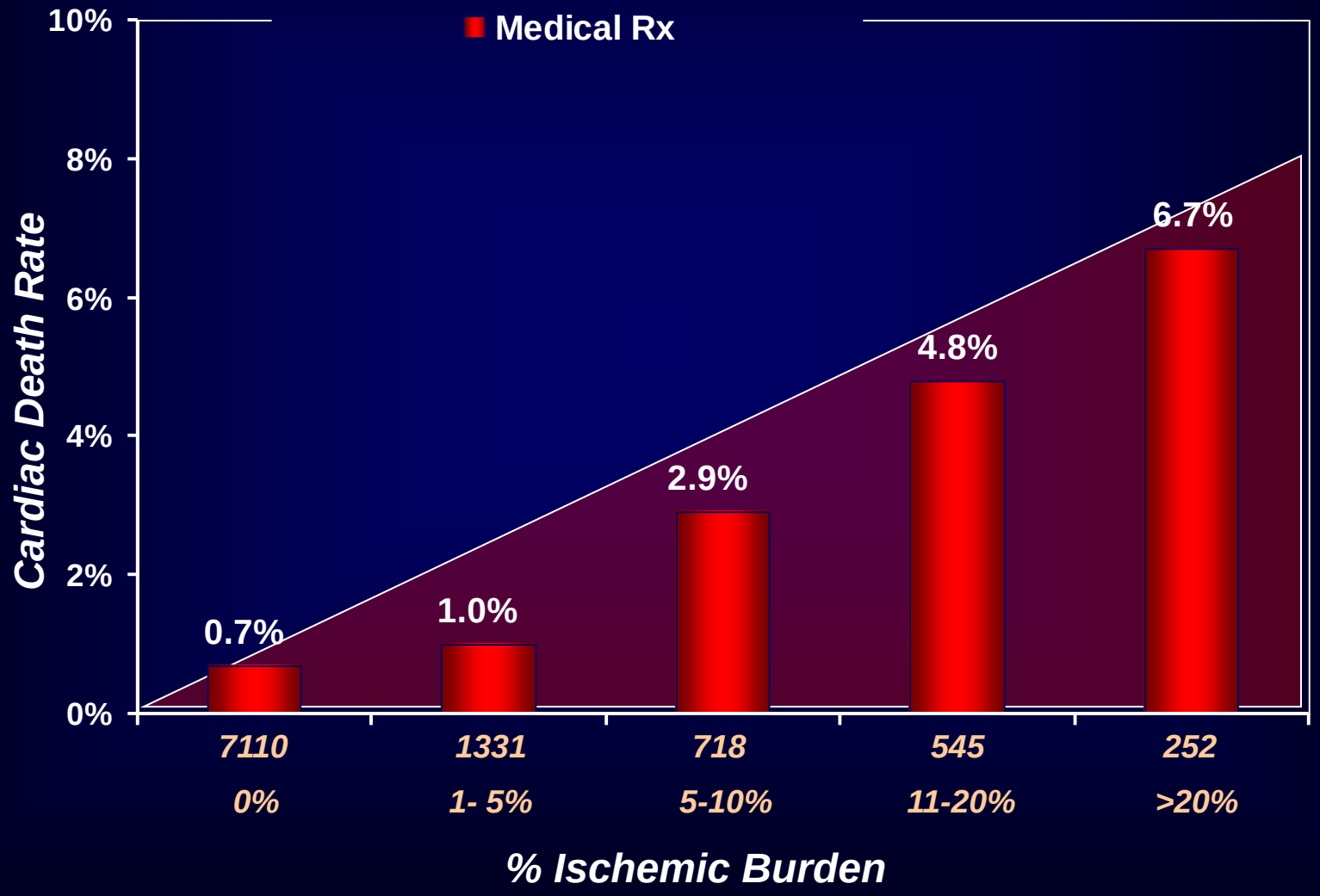
Study or Subgroup	PCI success Events	Total	PCI failure Events	Total	Weight	Odds Ratio M-H, Random, 95% CI
Angioi et al.	3	93	9	108	3.4%	0.37 [0.10, 1.40]
Aziz et al.	9	377	12	166	6.7%	0.31 [0.13, 0.76]
Drozd et al.	7	280	5	149	4.3%	0.74 [0.23, 2.37]
Finci et al.	5	100	3	100	2.9%	1.70 [0.40, 7.32]
Hoye et al.	37	567	36	304	14.4%	0.52 [0.32, 0.84]
Ivanhoe et al.	3	317	7	163	3.2%	0.21 [0.05, 0.83]
Labriolle et al.	7	127	2	45	2.4%	1.25 [0.25, 6.27]
Noguchi et al.	7	134	15	92	6.1%	0.28 [0.11, 0.72]
Olivari et al.	2	286	3	83	1.9%	0.19 [0.03, 1.14]
Prasad et al.	229	914	101	348	21.6%	0.82 [0.62, 1.08]
Suero et al.	395	1491	180	514	23.8%	0.67 [0.54, 0.83]
Valenti et al.	17	344	17	142	9.3%	0.38 [0.19, 0.77]
Warren et al.	0	26	0	18		Not estimable
Total (95% CI)		5056		2232	100.0%	0.56 [0.43, 0.72]
Total events	721		390			

Heterogeneity: Tau² = 0.06; Chi² = 18.74, df = 11 (P = .07); I² = 41%
Test for overall effect: Z = 4.39 (P < .0001)



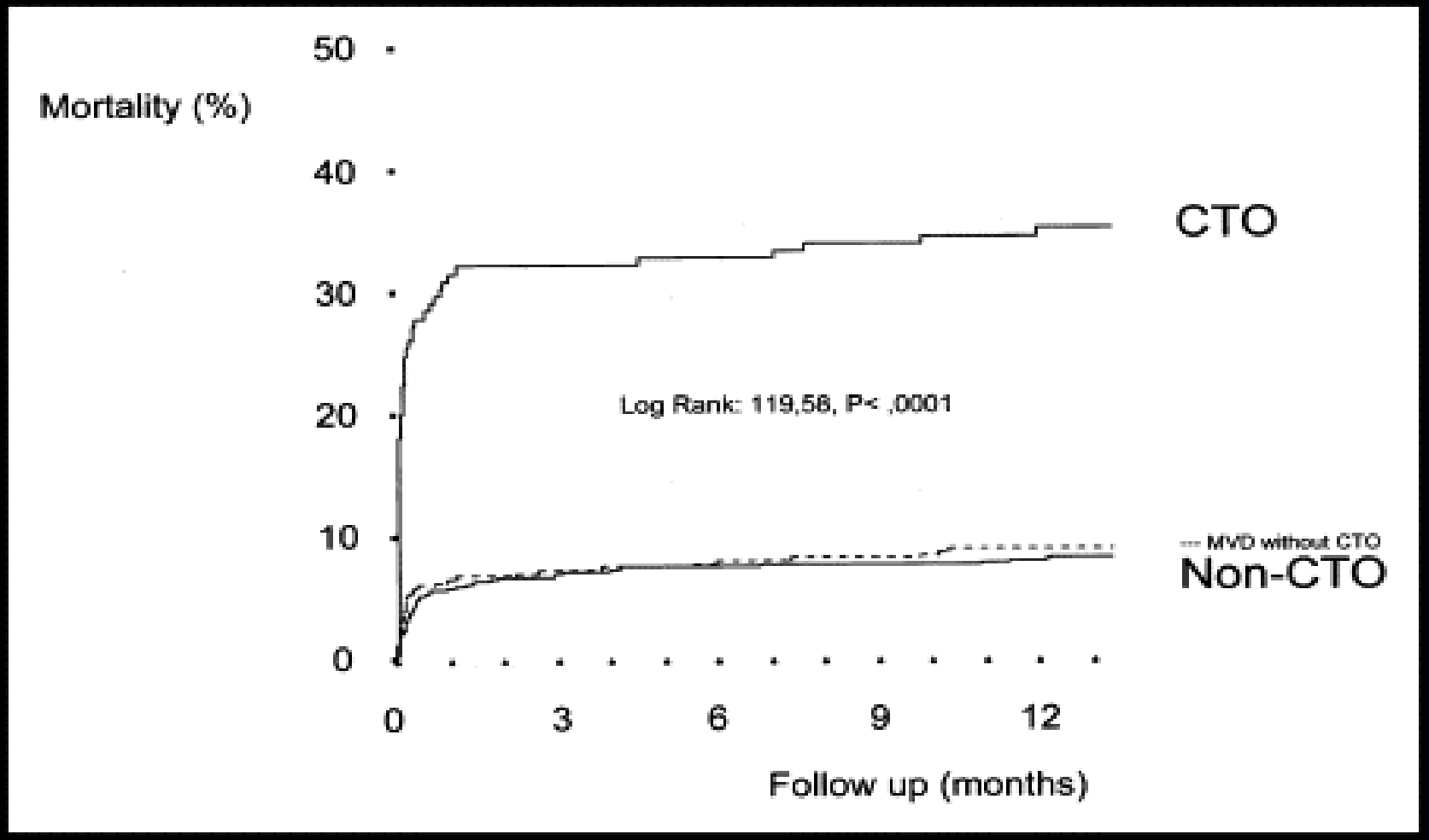
Joyal D, Afilalo J, Rinfret S. Am Heart J, 2010

Can't get any worse



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

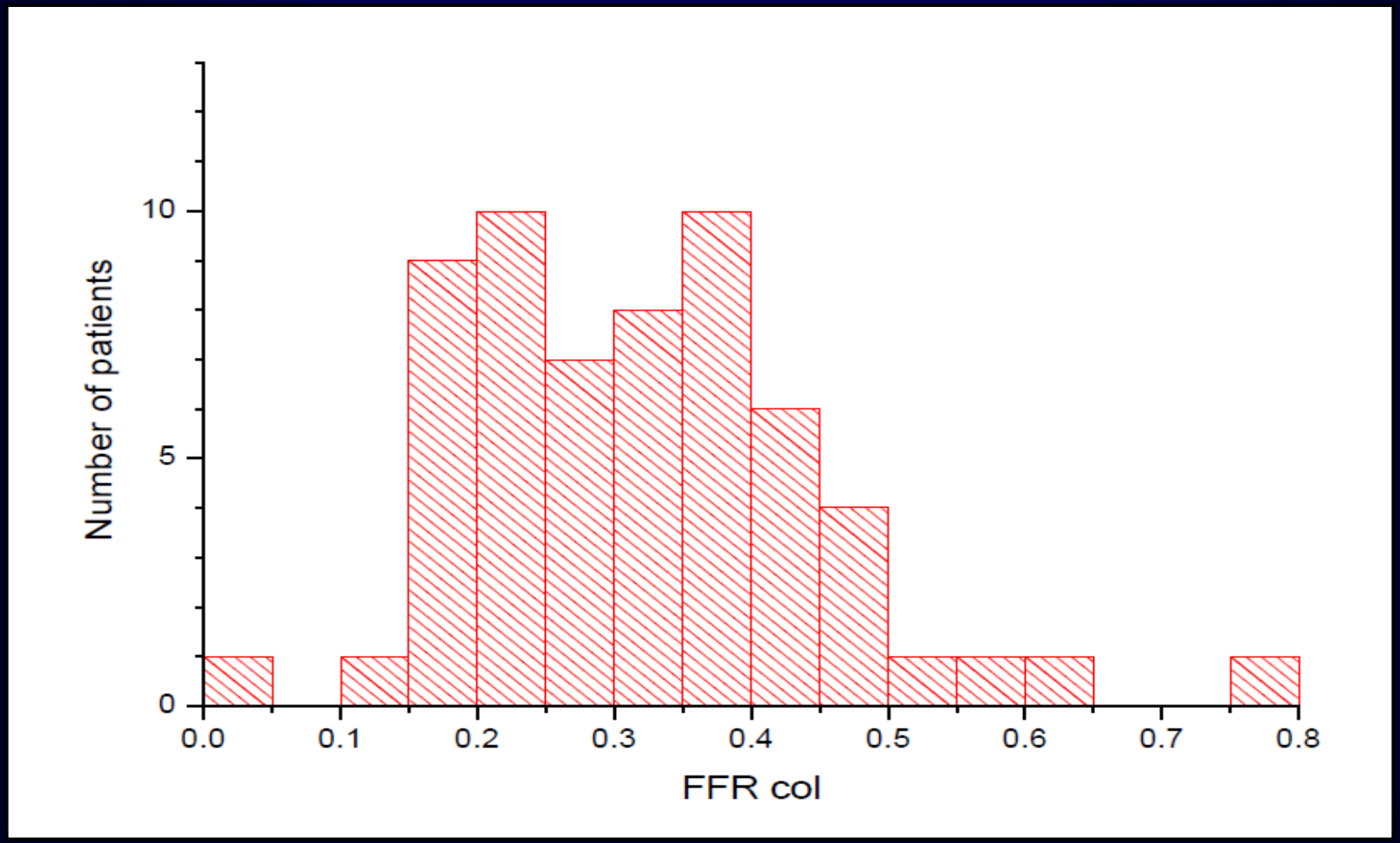
Can't Get Any Worse:
Double Jeopardy



Van der Schaff RJ et al. Am J Cardiol 2006

Well Collateralized

FFR in 59 pts after successful wire crossing of a CTO



Werner GS et al, European Heart Journal 2006

Myocyte Doesn't Care

Propensity matched noninferiority comparison of CTO-PCI to nonCTO-PCI in the 10 center PRISM-OPS registry

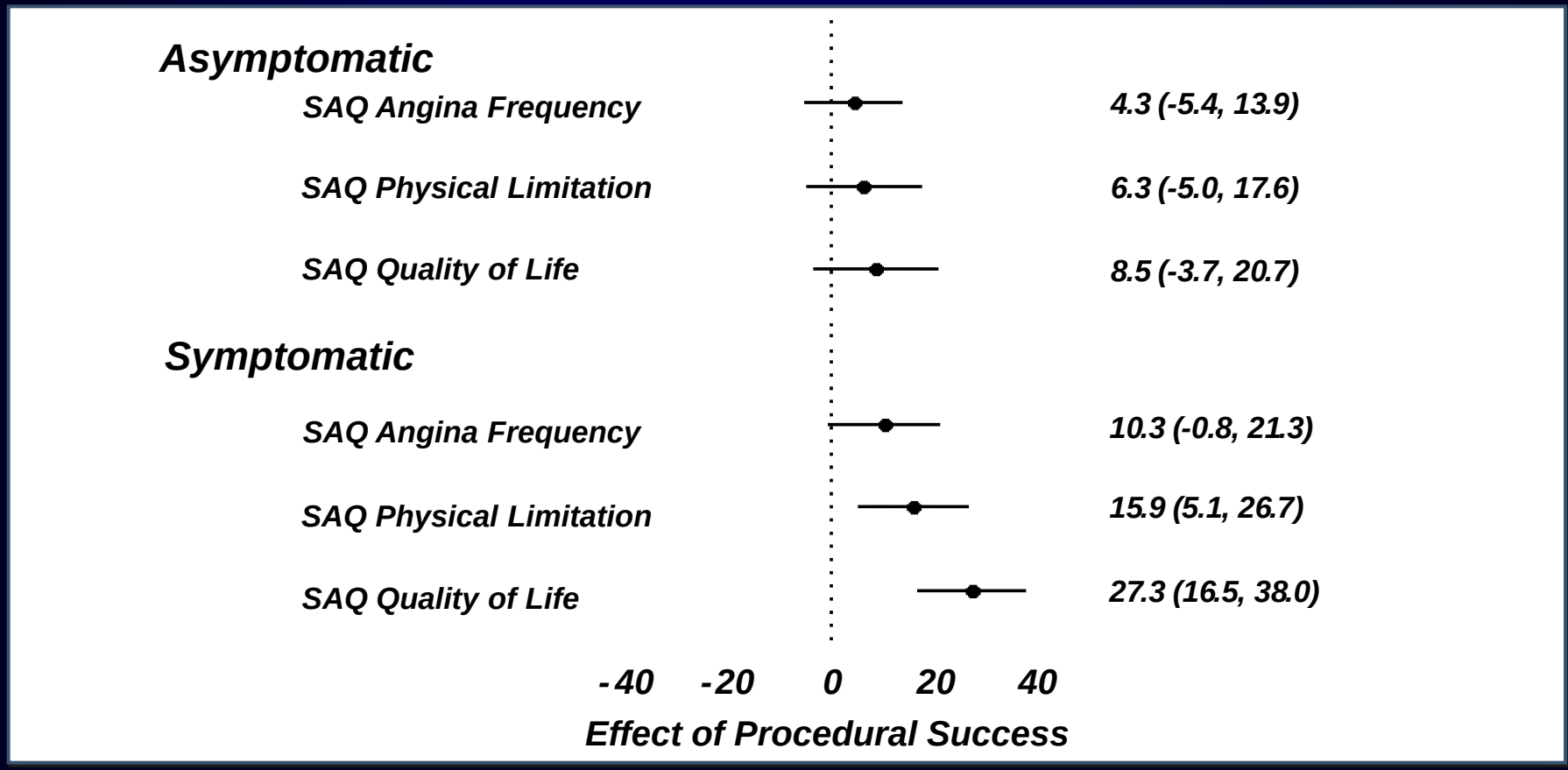
TABLE III. Health Status Assessments at Baseline and 6 months after PCI—Overall Cohort

Health status measure		CTO $n=167$	Non-CTO $n=2,521$	*P*-value
SAQ physical limitation score	Baseline	73.0 ± 25.9	77.4 ± 24.0	0.039
	6 month[a]	95.7 ± 13.3	96.2 ± 12.2	0.67
SAQ angina frequency score	Baseline	69.6 ± 27.6	72.6 ± 23.9	0.12
	6 month[a]	91.3 ± 18.3	93.4 ± 15.1	0.17
SAQ quality of life score	Baseline	53.2 ± 26.0	56.5 ± 25.8	0.11
	6 month[a]	80.3 ± 20.9	80.6 ± 20.0	0.875
Rose dyspnea score	Baseline	1.9 ± 1.5	1.7 ± 1.5	0.16
	6 month[a]	1.0 ± 1.3	0.9 ± 1.3	0.31
EQ5D visual analog scale	Baseline	66.4 ± 22.1	70.8 ± 19.5	0.005
	6 month[a]	71.9 ± 18.8	75.3 ± 17.7	0.026

Safley, Grantham et al, ePub ahead of print CCI DOI: 10.1002/ccd.25303, 2013

QoL after CTO-PCI

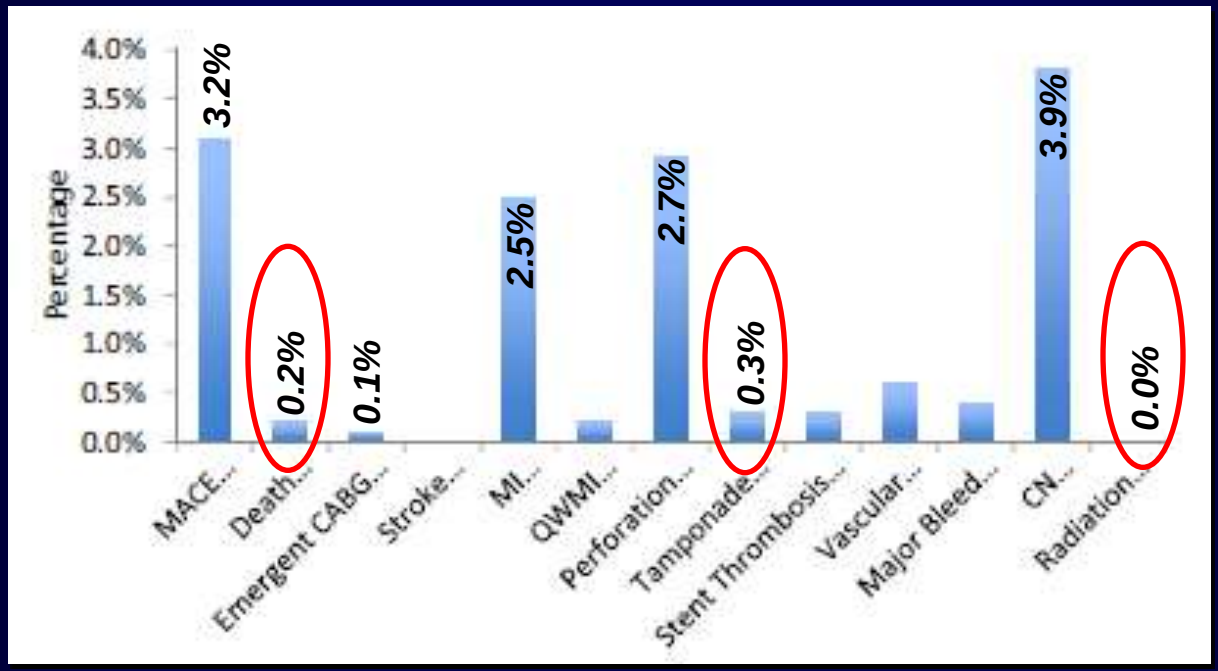
125 pts completed the Seattle Angina Questionnaire (SAQ) before and one month after PCI. 69 procedural success (55%), 56 failures (45%)



Grantham JA. et al, Circulation: QCOR 2010;3:284-90

CTO-PCI is too risky

A weighted meta-analysis from 18,061 patients in 65 CTO PCI studies



Patel, JACC: Cardiovasc Int, 2013

Appropriateness of CTO-PCI

Single vessel C ***No med Rx***

Angina

Risk

	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

Single vessel ***O Max Med Rx***

Angina

Risk

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

Modified from Patel et al J Am Coll Cardiol 2009;53:530-553

Indications for CTO-PCI

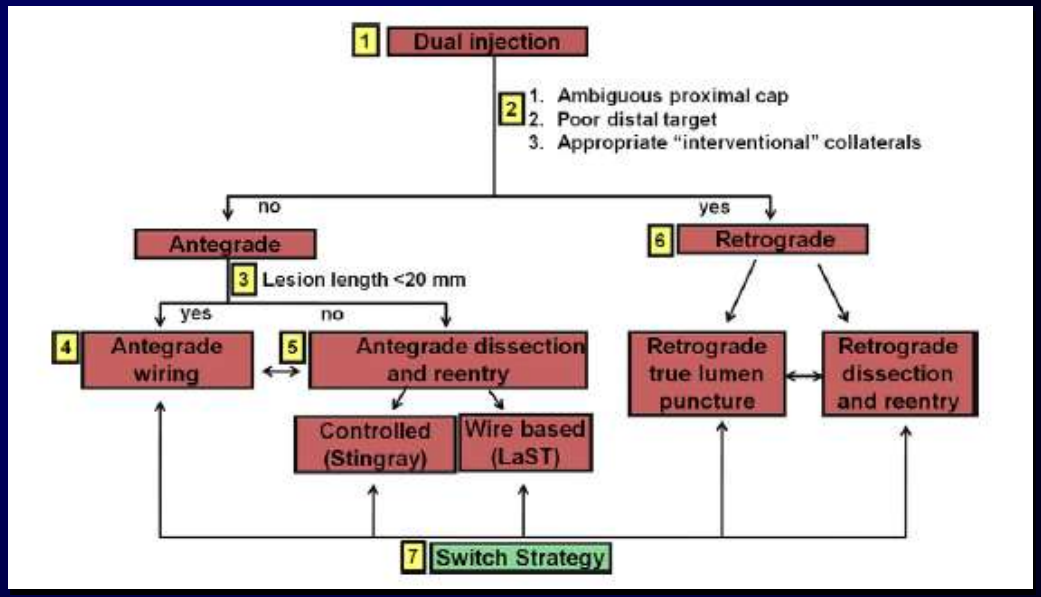
Chronic Total Occlusions

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

The Hybrid Approach to CTO-PCI

increasing success and efficiency

- Systematic
- Adoption of four strategies
- Sequence based on probability of success
- Rapid decision making



Brilakis et al J Am Coll Cardiol Intv 2012;5:367–79

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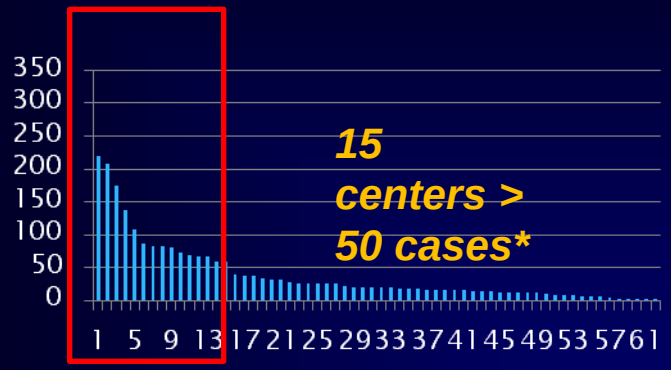
CTO-PCI adoption in NA

2011

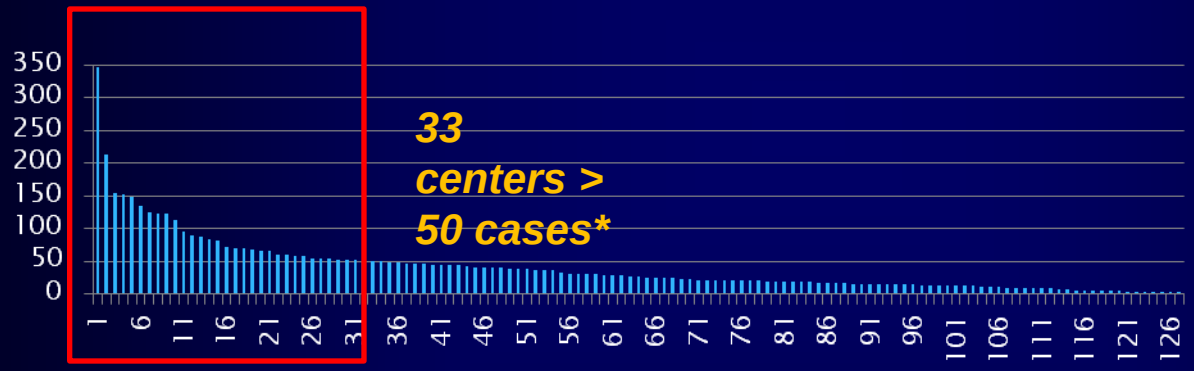


*15 centers > 50 cases**

*2,375 CTOs**
62 centers

2014 N=124

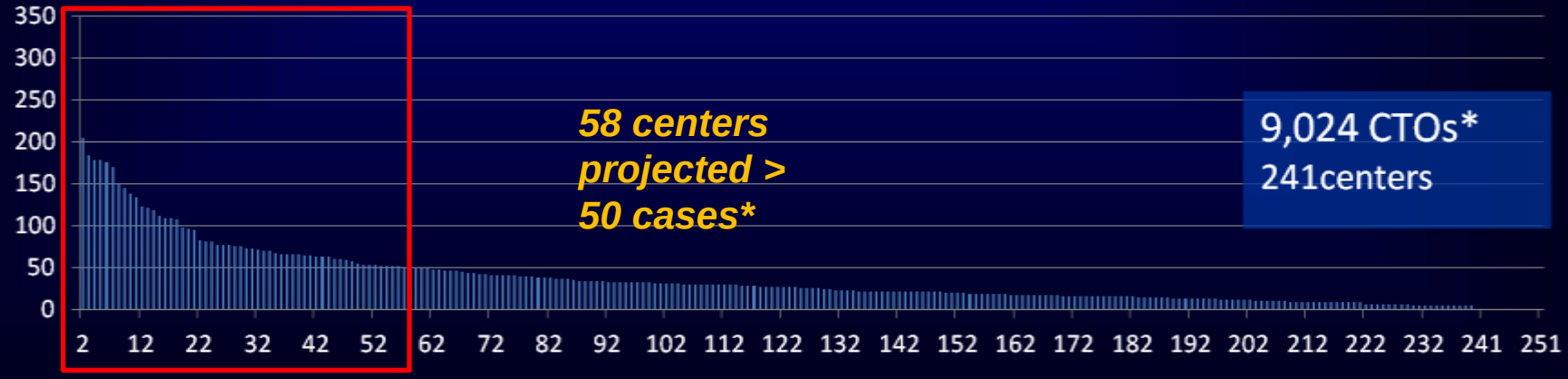
2012



*33 centers > 50 cases**

*5,208 CTOs**
127 centers

2013



*58 centers projected > 50 cases**

9,024 CTOs*
241centers

*Industry estimate. Data on file.

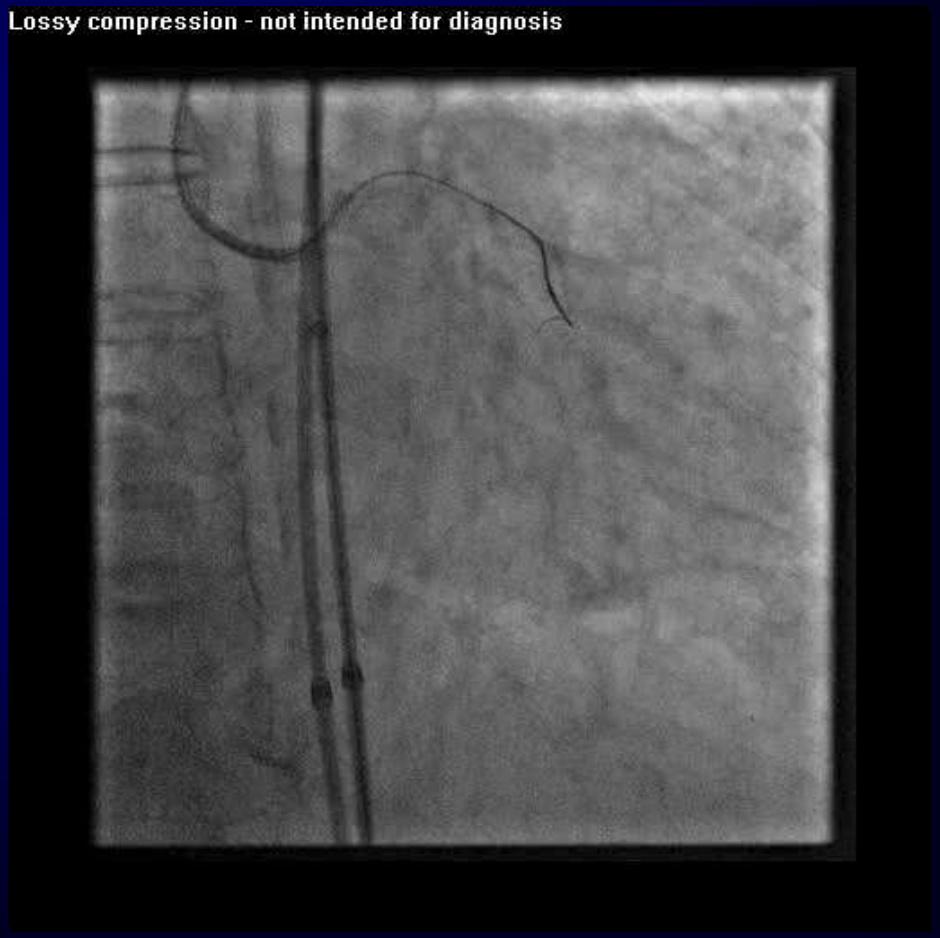
Contemporary Case Example

- 70 yr old man
- CTO RCA 2011
- EECP- no better
- Carvedilol, Isosorbide, Ranolazine
- CCS 3 angina
- RCA ischemia 12% myocardium

Impenetrable proximal cap

Corsair
BAM
Laser
Rotoblator
Go around

Septal surfing failed



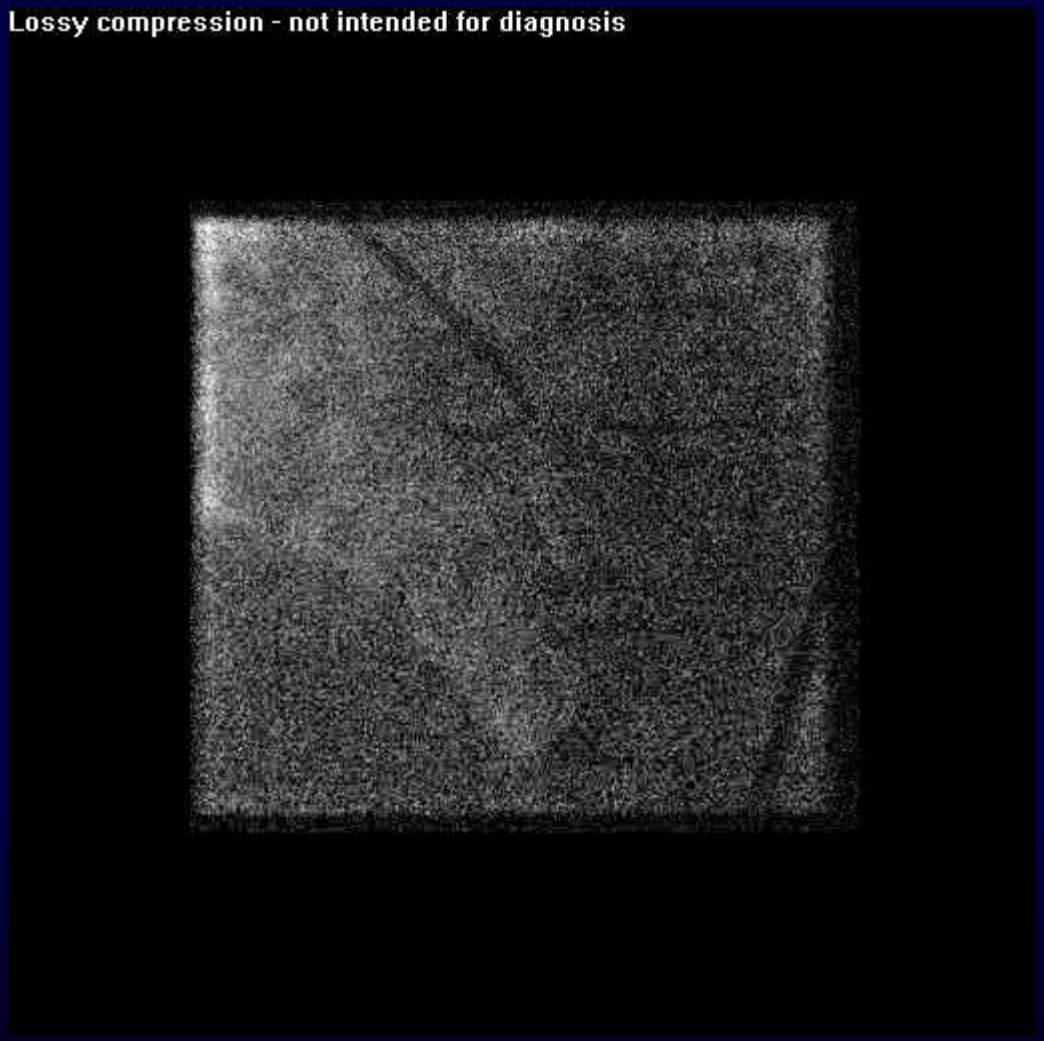
Go around “move the cap”

Scratch and go BASE

Knuckle around

Finish with crossboss

Stingray re entry balloon

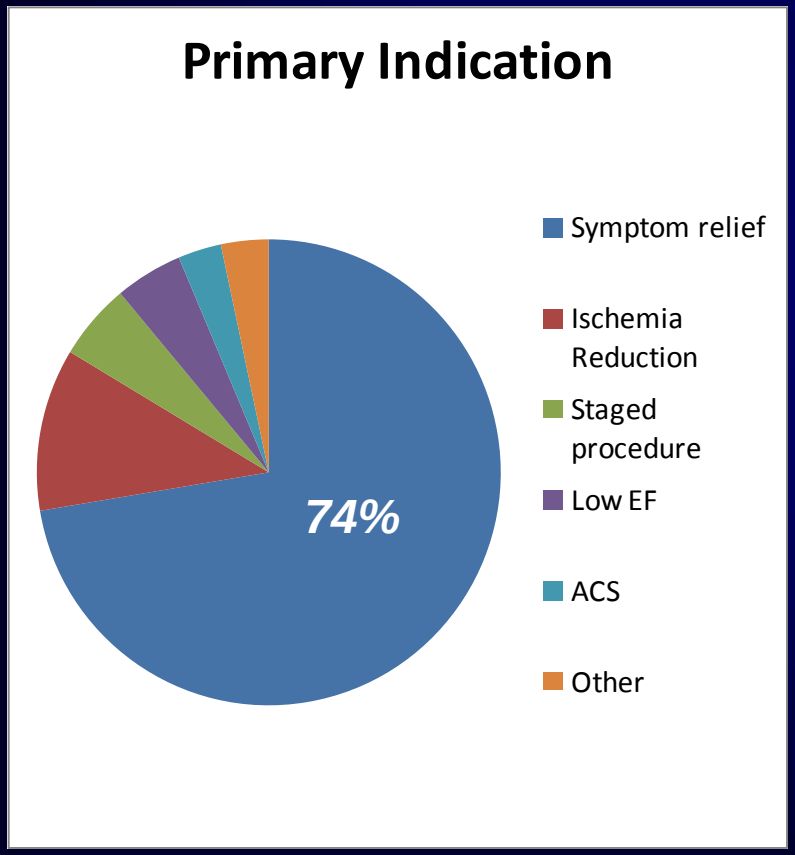


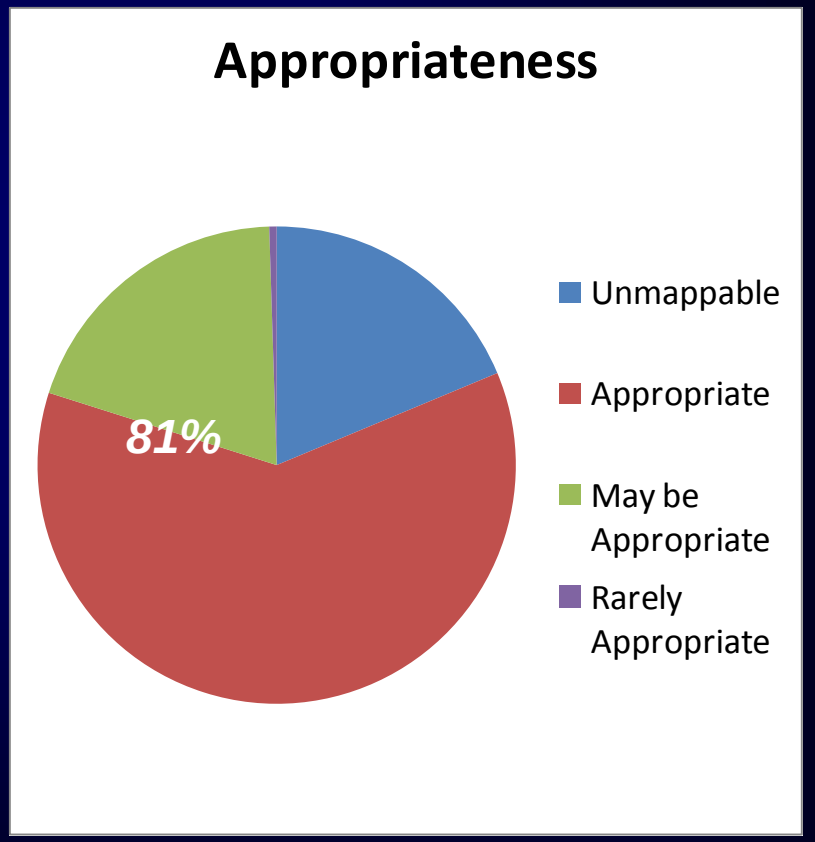
Stick then swap for Pilot 200

Final result

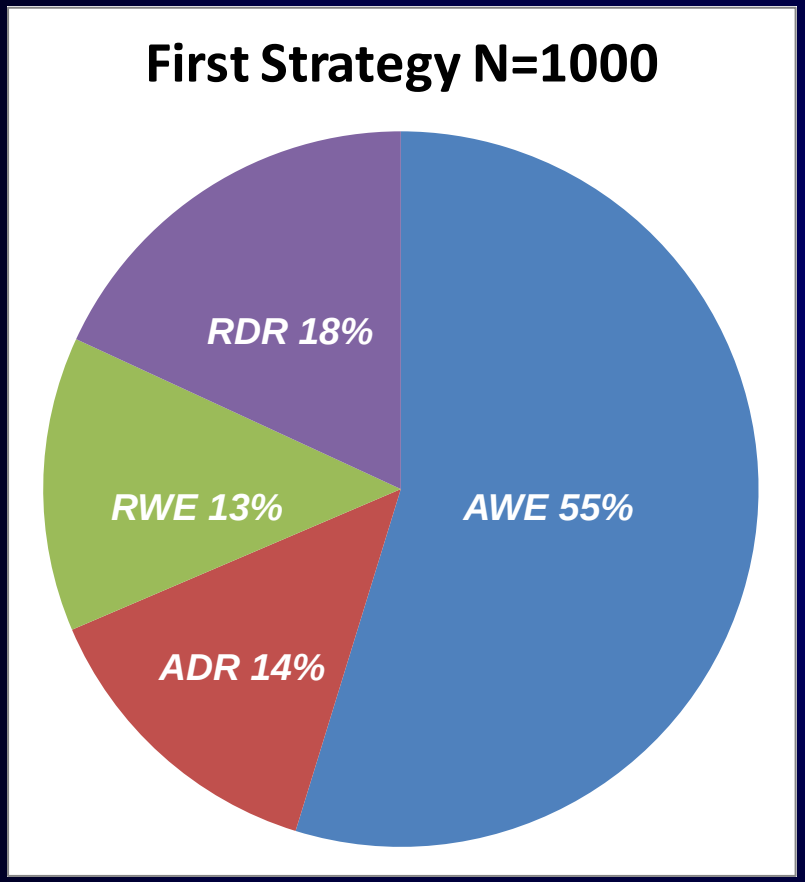
67 minutes
1.2Gy
135 cc contrast

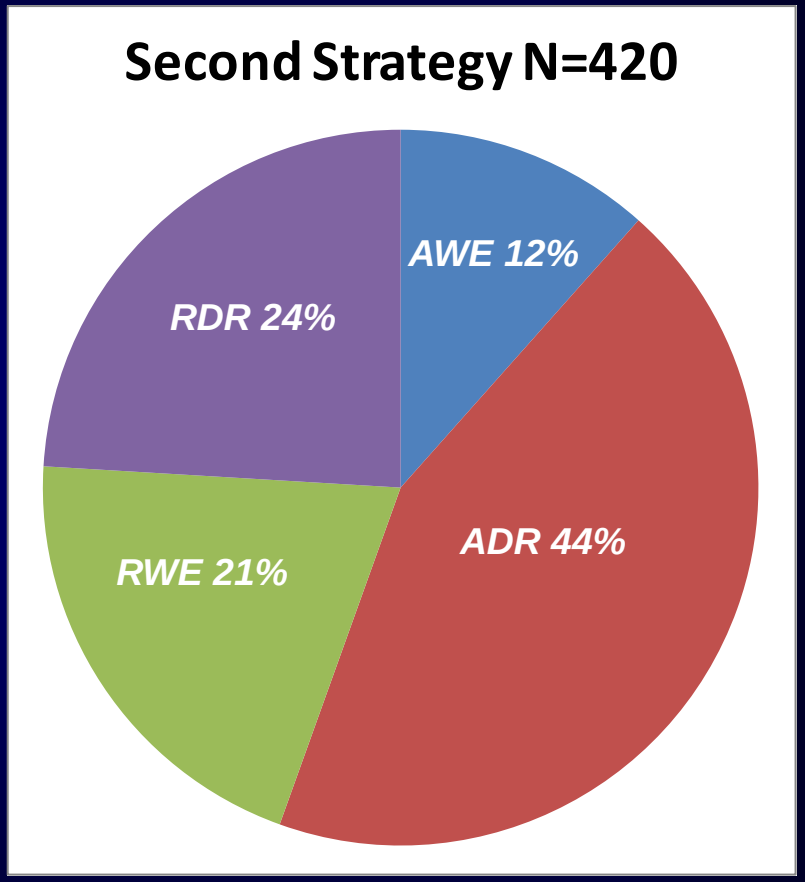
Indications and Appropriateness





Hybrid Approach





Success rate 58%

Success rate 55%

OPEN CTO Results

89%

119 ± 72 min

2.5 ± 1.9 Gy

265 ± 194 ml

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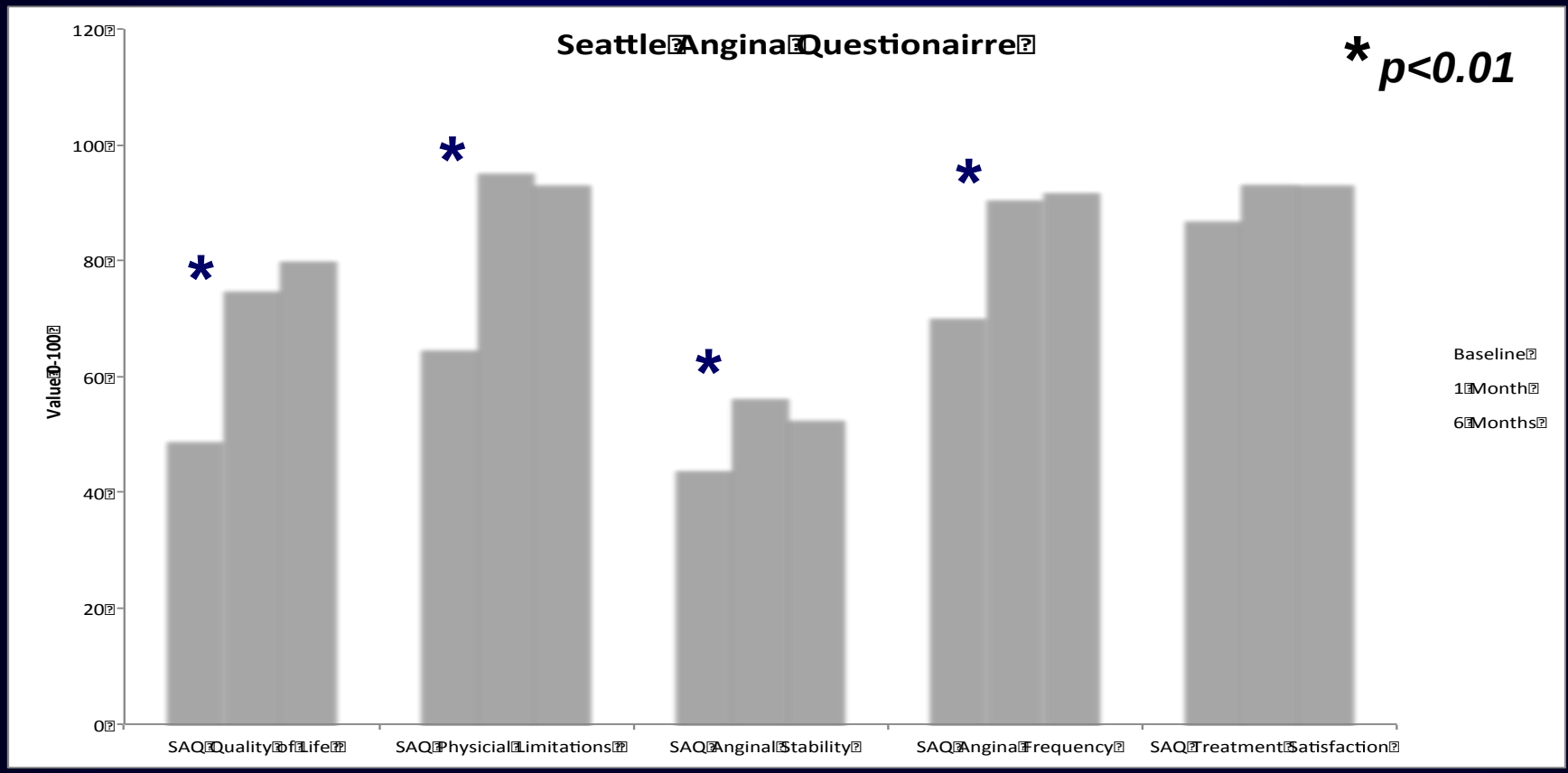
Early Health Status Changes in CTO-PCI

Patient Reported Health Status



OPEN CTO
Outcomes, Patient health status, and Efficiency in Chronic Total Occlusion hybrid procedures

Complications in OPEN CTO

Procedural	Frequency	30 Day	Frequency
MACE	4.4%	Death	1.3%
Death	0.9%	Rehospitalization	14.7%
MI	2.6%	Unplanned	12.1%
Emergent surgery	0.6%	Revascularization	2.6%
Stroke	0.0%	Planned	2.6%
Perforation	6.0%	PCI	2.3%
Clinical perforation	3.9%	CABG	0.3%
Bleeding Access	4.0%	Skin change	2.9%

Procedural MACE includes Death, MI, Emergent Surgery, Stroke and Clinical Perforation

Unpublished Data from OPEN CTO

Conclusions

- CTOs are common
- CTO treatment is variable
- Patients with CTOs report significant health status impairment
- Hybrid CTO-PCI
  - High Success
  - Efficiency
  - Significant health status improvement
- Appropriately aggressive CTO-PCI should be the goal
- Ask yourself, “if it was 80% occluded would I do it?”