Indications for CTO-PCI: Clinical Rationale and Appropriateness

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Disclosure of Statement of Financial Interests

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	• BSCI, MDT, Asahi
• Consulting Fees/Honoraria	• BSCI, Asahi
• Major Stock Shareholder/Equity	• None
• Royalty Income	• None
• Ownership/Founder	• CTOFundamentals.org
• Intellectual Property Rights	• None
• Other Financial Benefit	• None

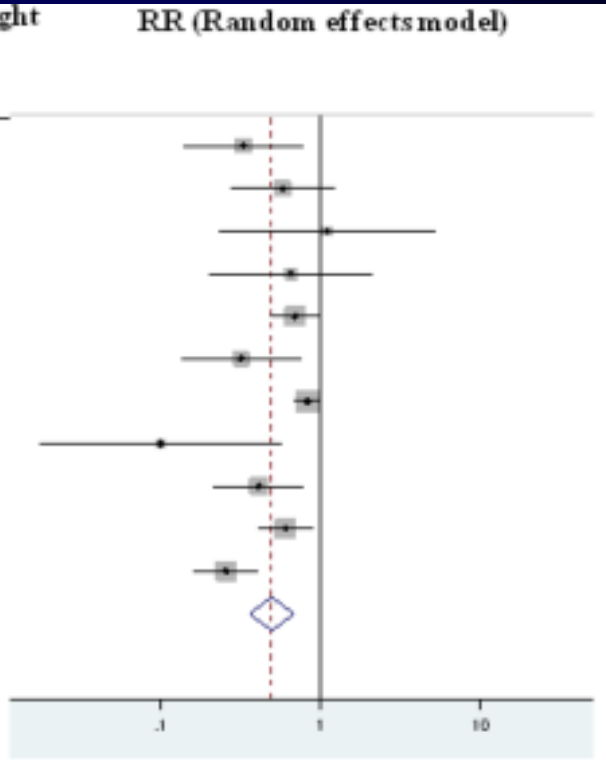
Benefits of Revascularization

Quality of Life

Quantity of Life

Quantity of Life

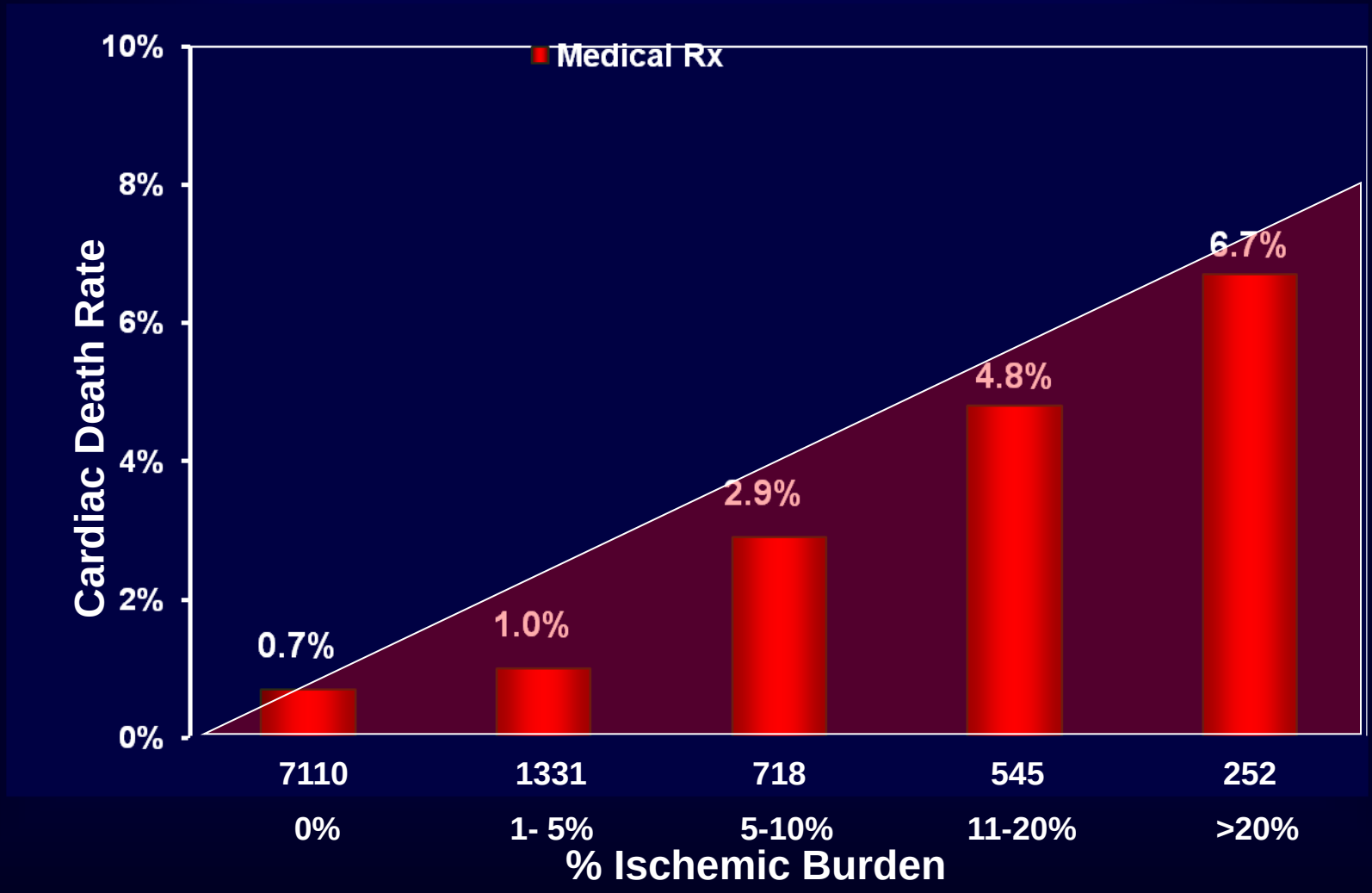
Study	PCI successful n/N	PCI failed n/N	RR(95%CI)	%Weight
Aziz	9/377	12/166	0.33(0.14-0.77)	7.63
Borgia	19/237	9 /65	0.58(0.28-1.22)	8.68
de Labriolle	7/127	2 /40	1.10(0.24-5.01)	3.41
Lee	8/251	4 /82	0.65(0.20-2.11)	5.07
Mehran	74/1226	49/565	0.70(0.49-0.98)	13.88
Noguchi	7/134	15/92	0.32(0.14-0.76)	7.51
Prasad	220/914	101/348	0.83(0.68-1.01)	15.60
Chen	2/132	3/20	0.10(0.02-0.57)	2.80
Valenti	17/344	17/142	0.41(0.22-0.78)	9.88
Yi	135/1202	24/130	0.61(0.41-0.90)	13.23
Jones	26/582	44/254	0.26(0.16-0.41)	12.30
D+L pooled RR	654/5526	280/1904	0.50(0.36-0.68)	100



Heterogeneity chi-squared = 33.11 (d.f. = 10) p = 0.000
I-squared (variation in RR attributable to heterogeneity) = 69.8%
Estimate of between-study variance Tau-squared = 0.1572

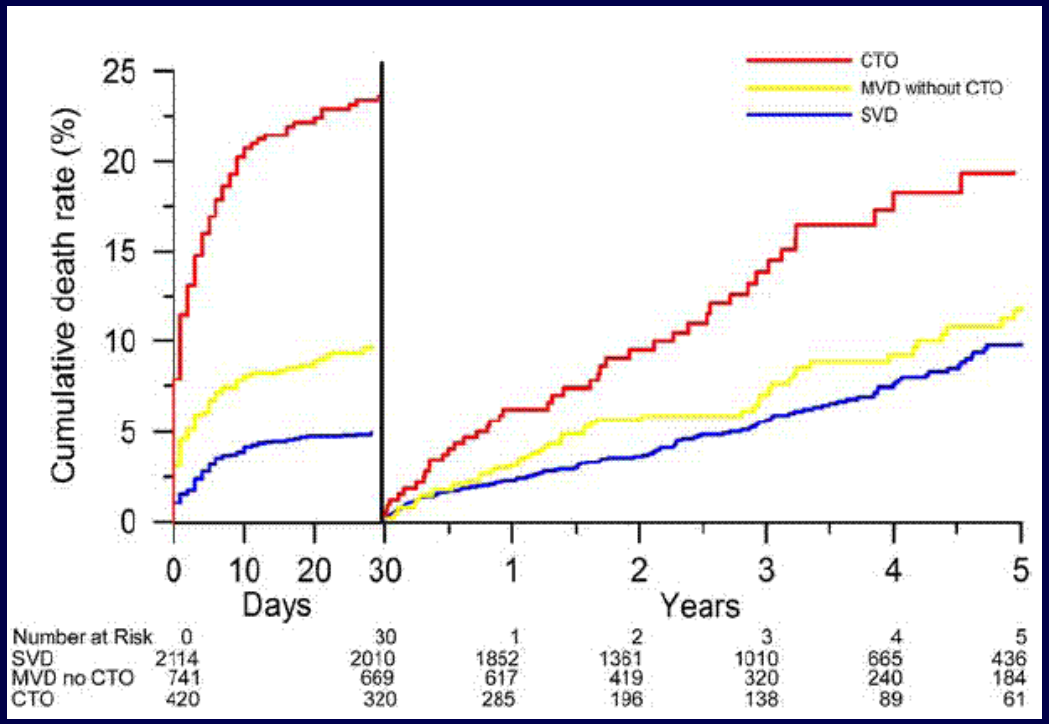
Khan M et al Catheter Cardiovasc Intv 2013;82:95-107

Quantity of Life
Ischemia



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

Quantity of Life
Double Jeopardy



Age>60	1.9 (1.0-3.4) p=.03
CTO	3.5 (1.6-7.8) p<.01
MVD without CTO	1.3 (0.6-2.6) p=.64

Classen et al JACC:Cardiovasc Int, 2010

Quantity of Life
VACTO Trial

- 162 pts with incomplete revascularization of major coronary arteries
- 44% with CTO 56% without
- Appropriate ICD therapy (33% vs 15% at 3 yr)

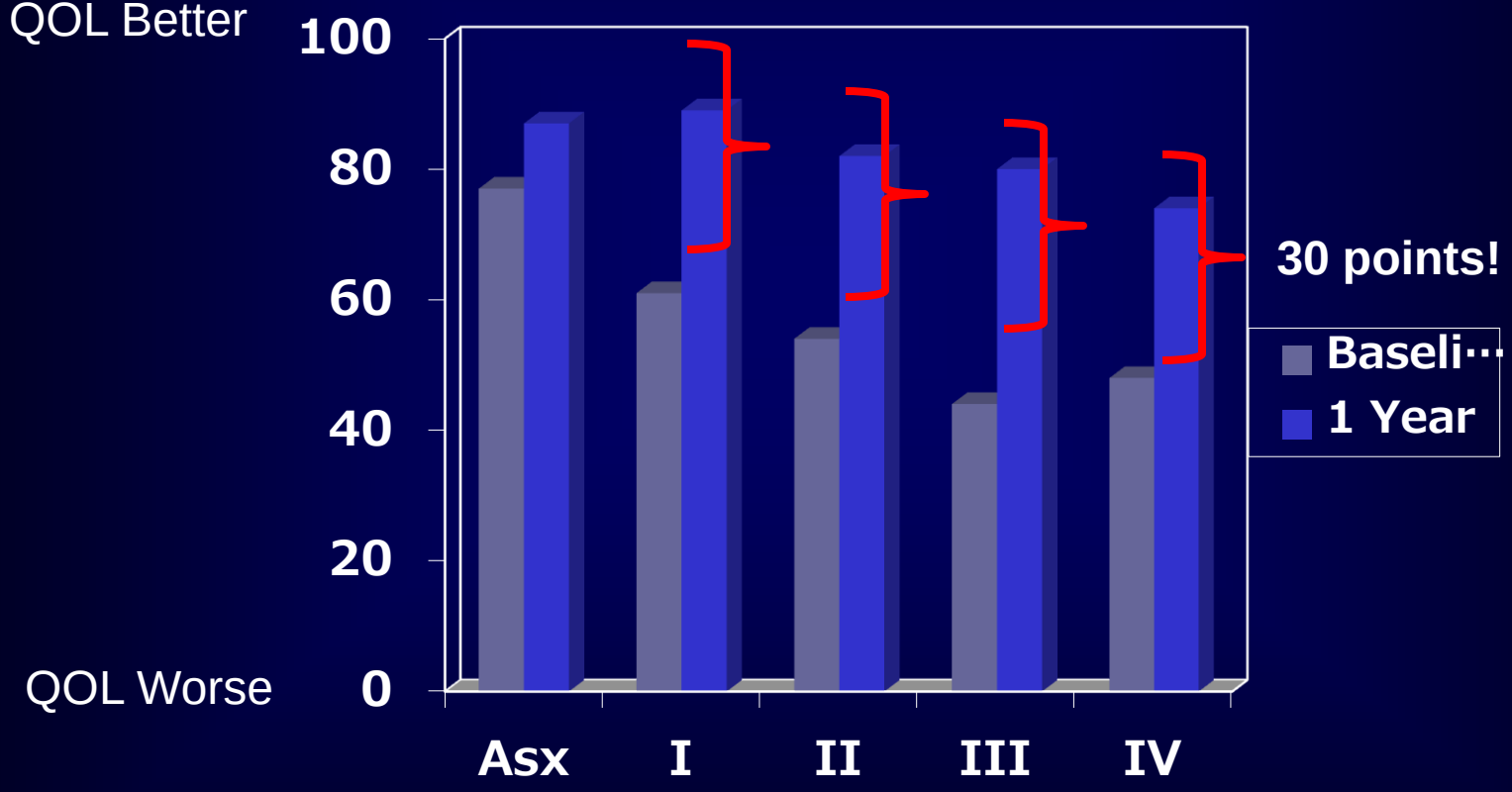
Table 4. Multivariable predictors of mortality

Variable	Multivariable analysis	
	HR (95% IC)	P
Absence of β-blocker	6.3 (1.4 – 28.0)	0.02
CTO	5.6 (1.4 – 21.8)	0.01
NYHA class ≥ 3	4.7 (1.3 – 17.1)	0.02
Age (per 5-y increase)	1.5 (1.0 – 2.3)	0.05

CTO = chronic total occlusion; NYHA = New York Heart Association.

Nombelo-Franco *Circ Arrhythm Electrophysiol* 2012

Quality of Life after PCI



McNulty et al AHA 2012

Quality of Life after CTO-PCI

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

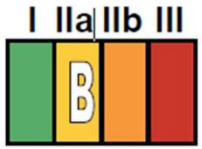
TABLE III. Health Status Assessments at Baseline and 6 months after PCI—Overall Cohort

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

ACCF/AHA/SCAI Guideline for 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.

Levine et al J Am Coll Cardiol 2011;58:e44-122

Appropriate Indications
(on two drug therapy)

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Single vessel CTO

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	I	U	U

1 or 2 vessel disease
(No proximal LAD)

Angina →

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

CTO-PCI appropriateness is based on patient symptoms and risk.
Systematic downgrading of appropriateness

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

Inappropriate CTO-PCI

(not on 2 drug therapy)

Single vessel CTO

Angina ↑ / Risk ↑

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

1 or 2 vessel disease
(No proximal LAD)

Angina ↑ / Risk ↑

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

Not on 2 anti anginal drugs: CTO-PCI may not be appropriate

2014 update of AUC due this Summer

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

Summary

- CTO-PCI is indicated:
  - interested patient, any residual symptoms despite medical therapy
- CTO-PCI should be considered for
  - Patients not low risk irrespective of symptoms
    - Reduced LV function
    - Significant Ischemic burden
    - Entertaining transplant, LVAD, AICD (with viability)

What is Really Happening?

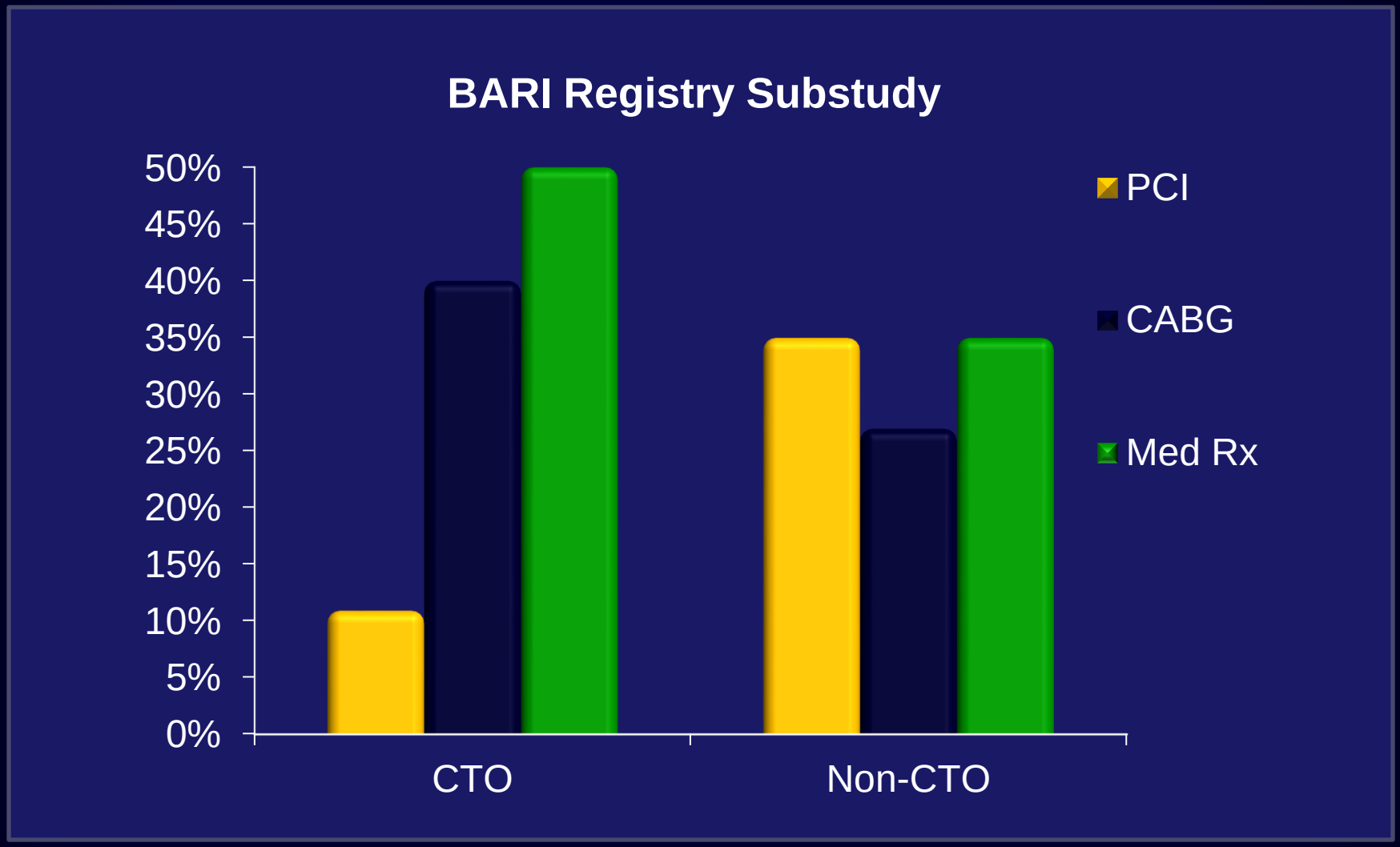
Real world stent registries

Trial	N	%CTO
ARRIVE 1	2586	1.8
ARRIVE 2	4933	2.0
eCYPHER	14316	2.9
XIENCE V	5054	2.6

Contemporary US CTO centers

Site	Inappropriate PCI rate	%CTO
Peacehealth		21
MAHI	3.2%	11
Piedmont		12
Dallas VA		15

What is Really Happening?



Christofferson et al. Am J Cardiol 2005.

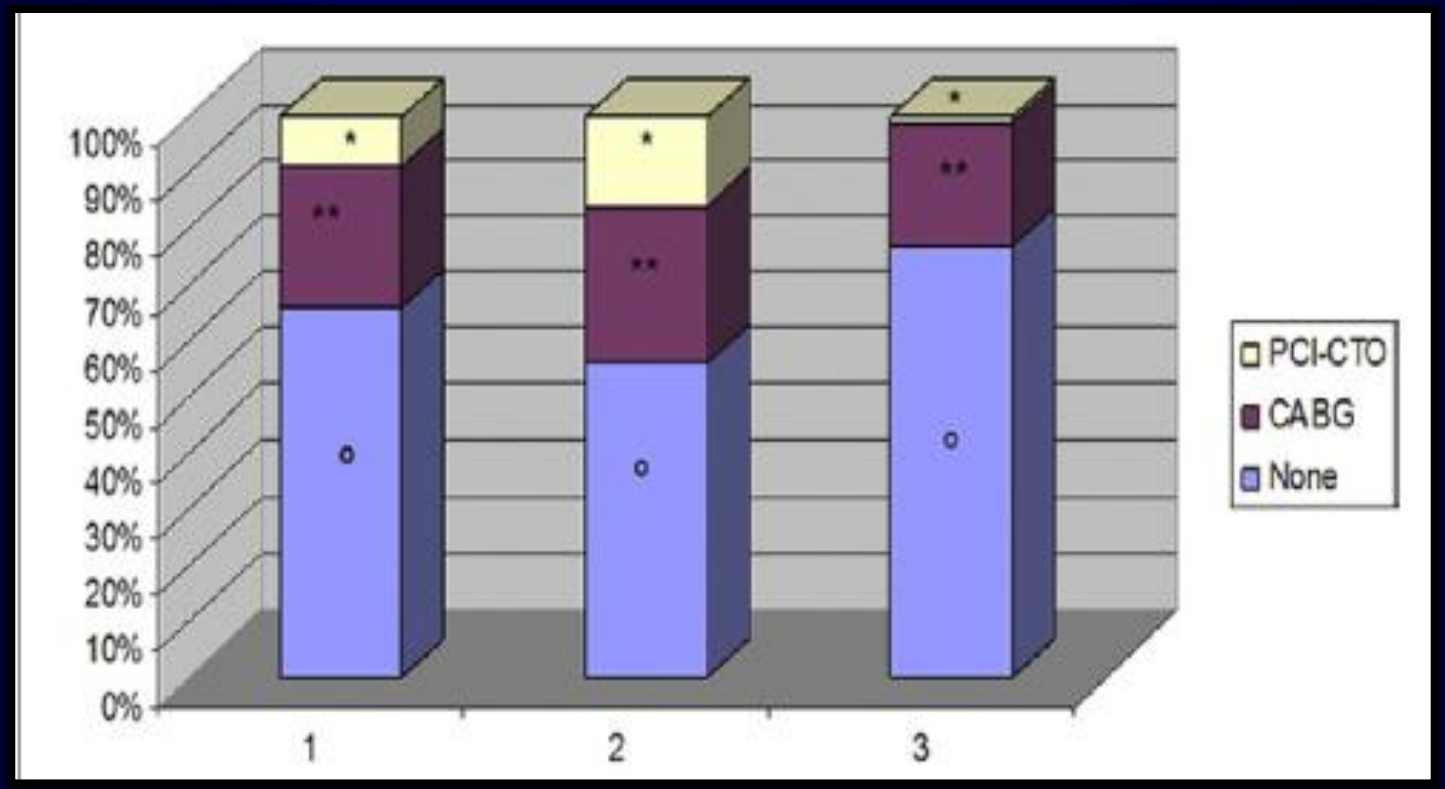
What is Really Happening?

	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

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

What is Really Happening?

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



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

What is Really Happening?

- **Acuity trial substudy**

	rSS=0	rSS>0-2	rSS>2-8	rSS>8	
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

Current State of Care of Patients with CTO

- Revascularization is offered less often and with surgery
- Revascularization with PCI is variable
  - Depends on operator experience and institutional treatment biases
- Revascularization with PCI dictated by angiogram not patient needs

What You Told Us…

- **You want to do more CTO-PCI (appropriately)**

2. Which best describes plans for a CTO program at your institution?

	Response Percent
Initiate program in next 2 years	18.6%
Established program, looking to enhance it	**65.1%**
Established program, no plans for expansion	14.0%
No plans to initiate a CTO-PCI program	2.3%

What You Told Us…

- **You need solutions to economic disincentives**

3. What is/was the biggest barrier to starting a CTO-PCI program?

	Response Percent
Economic:Hospital administrator concerns over cost	16.7%
Economic::Practice colleagues concerned with long procedures and lost productivity	**38.9%**
Clinical: Inadequate evidence for CTO-PCI indications and appropriateness	16.7%
Clinical: Safety concerns regarding CTO-PCI	13.9%
Clinical:No systematic approach to CTO-PCI	13.9%

What You Told Us…

- **You need an efficient technique and time to learn it**

Q3. What is/was the biggest barrier to starting a CTO-PCI program?	
1	Concurrent day-to-day practice obligations limiting my time in the lab and the ability to learn/apply new techniques
2	Getting referrals
3	Recruitment of suitable patients. Need of education and technical support learning the different approaches and devices
4	Not all physicians in our hospital are apdated about CTO-PCI benifits
5	procédure times rx exposures diificulties
6	We don't have serious barrier.
7	Time to perform more cases - have to develop a sustainable model. At present demand exceeds access

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OPEN CTO

Outcomes, Patient health status, and Efficiency iN Chronic Total Occlusion hybrid procedures

Primary Investigators	• J. Aaron Grantham (PI) • William L. Lombardi (Co-PI) James Sapontis (Co-PI)
Overview	• 10 US sites • 1000 patients • Multi-center, prospective, single arm observational registry
Aims	• Safety, success, efficiency of hybrid approach • Health status effects of CTO-PCI • Indications and appropriateness of CTO-PCI • Economic analysis
Status	• Enrolling 2014
Sponsors	• Boston Scientific • Saint Luke's Mid-America Heart Institute

Angiographic core lab, Events adjudication, NCDR auditing

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