Application and Outcomes of the Hybrid Approach to CTO-PCI

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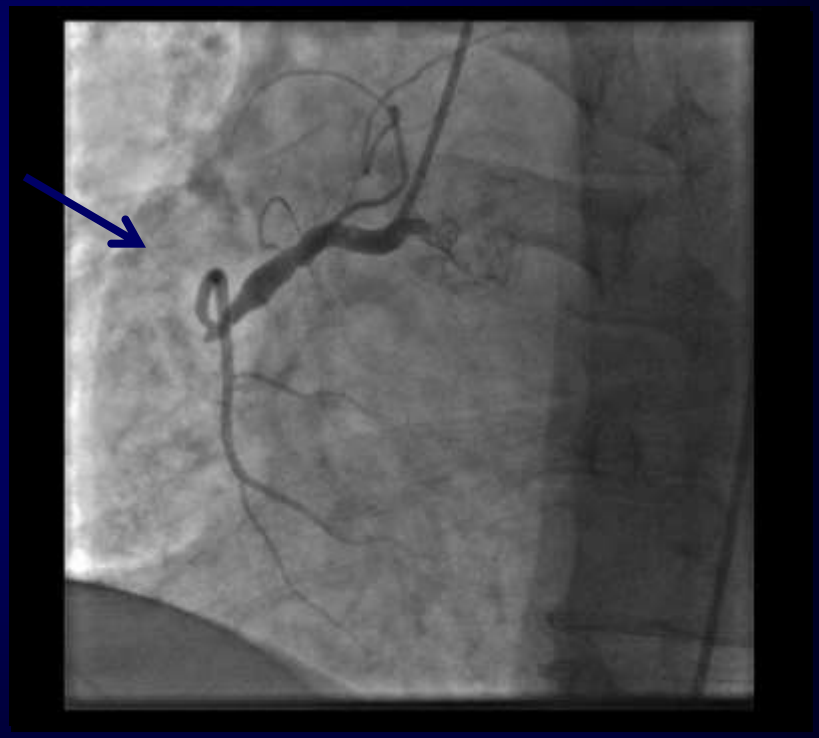
Disclosure Statement of Financial Interest

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	

CTO Care Background

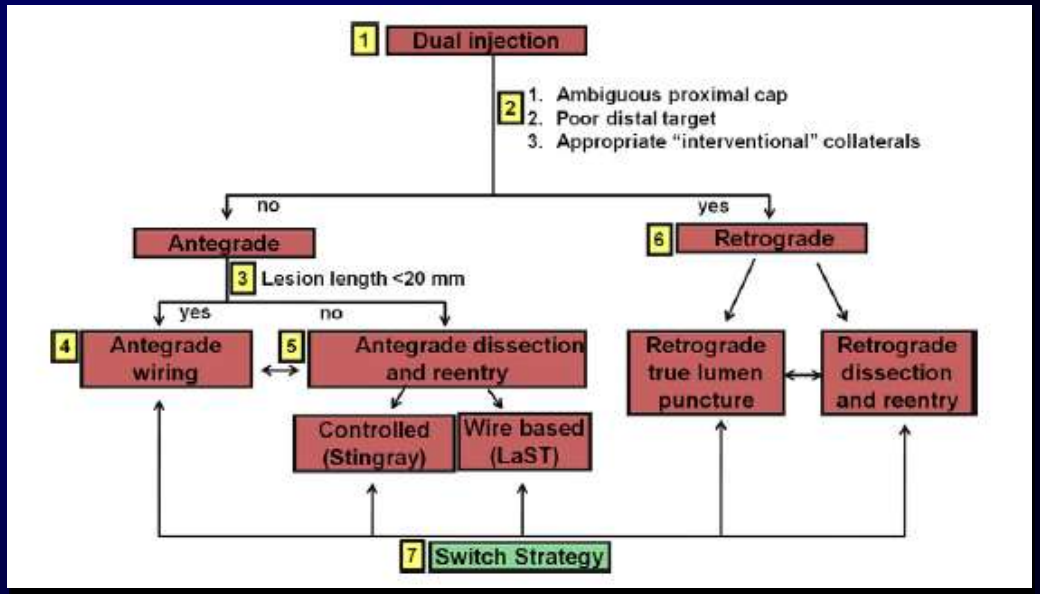
- The "final frontier"
- Treatment with PCI varies based upon institutional and operator characteristics
- Barriers to PCI
  - Poor understanding of benefits
  - Low success rates
  - High complication rates
  - Economic disincentives



Fefer et al J Am Coll Cardiol:2012; 59:991-7
Grantham et al J Am Coll Cardiol: Cardiovasc Intv 2009; 2:479-486

The Hybrid Approach to CTO-PCI

- 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

The Hybrid Algorithm

Four things determine how many and which option to begin with

1. **Proximal Cap Anatomy**
   - Defined or Ambiguous?
2. **Target**
   - Favorable for reentry?
3. **Collaterals**
   - Useable or not?

Direction

4. **Occlusion length**
   - <20mm or ≥20mm?

Crossing strategy

OPEN CTO

Outcomes, **P**atient health status, and **E**fficiency
i**N** **C**hronic **T**otal **O**cclusion hybrid procedures

Co PIs	James Sapontis, Bill Lombardi
Manager	Karen Nugent
Statistician	Kensey Gosch
Core Lab	Federico Gallegos
Steering	Rutherford, Spertus, Cohen, Marso, Moses, Grantham, Lombardi, Karmpaliotis

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

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OPEN CTO Design

Design

- **DESIGN:** Prospective, non-randomized, single-arm, multi-center clinical evaluation of the Hybrid CTO-PCI
- **OBJECTIVE:** To evaluate the Success, safety, efficiency, appropriateness, health status outcomes, and costs of CTO-PCI
- **PRINCIPAL INVESTIGATOR**
- J. Aaron Grantham, MD, FACC Saint Luke's Mid America Heart Institute, Kansas City, Mo. USA

1000 consecutive patients enrolled between Feb 2014 and July 2015 at 12 clinical sites in the US

↓

Comprehensive baseline clinical, angiographic, and HS assessment

↓

Clinical follow-up at 1,6, 12 months

Success	Failure
Angina	Dyspnea
Efficient	Inefficient
Complicated	Uncomplicated

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OPEN CTO Sites

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

Rigor Used in OPEN CTO

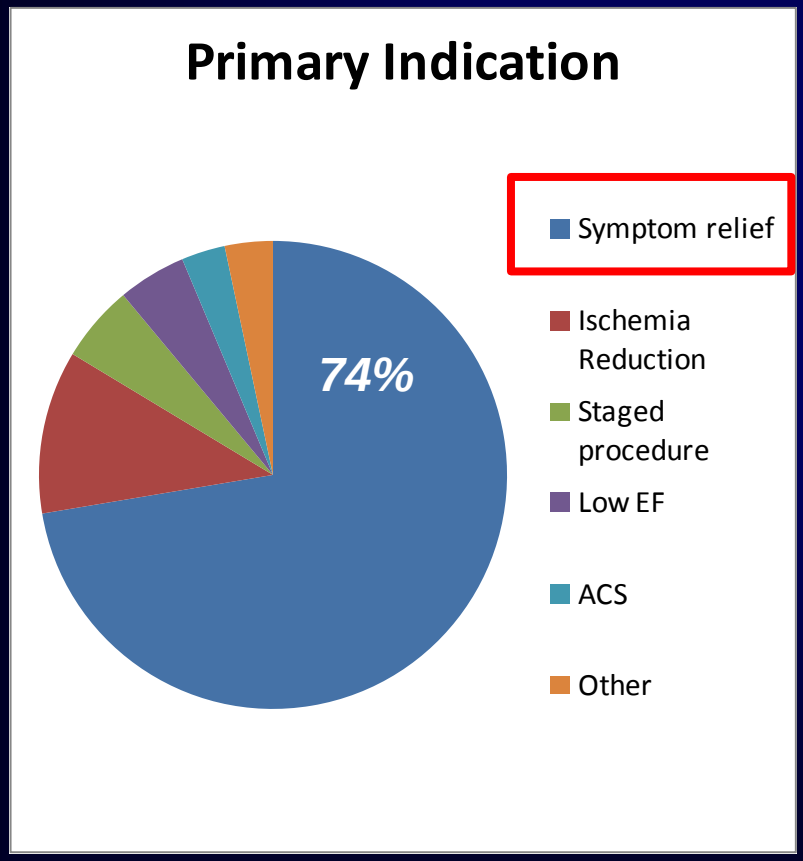
- Auditing through NCDR
  - Truly consecutive, unselected, fully reported
- Angiographic core lab analysis
  - Unbiased QCA
- Centralized call center follow up (96%)
- CEC adjudication
- Broad spectrum of operators using a single methodological approach

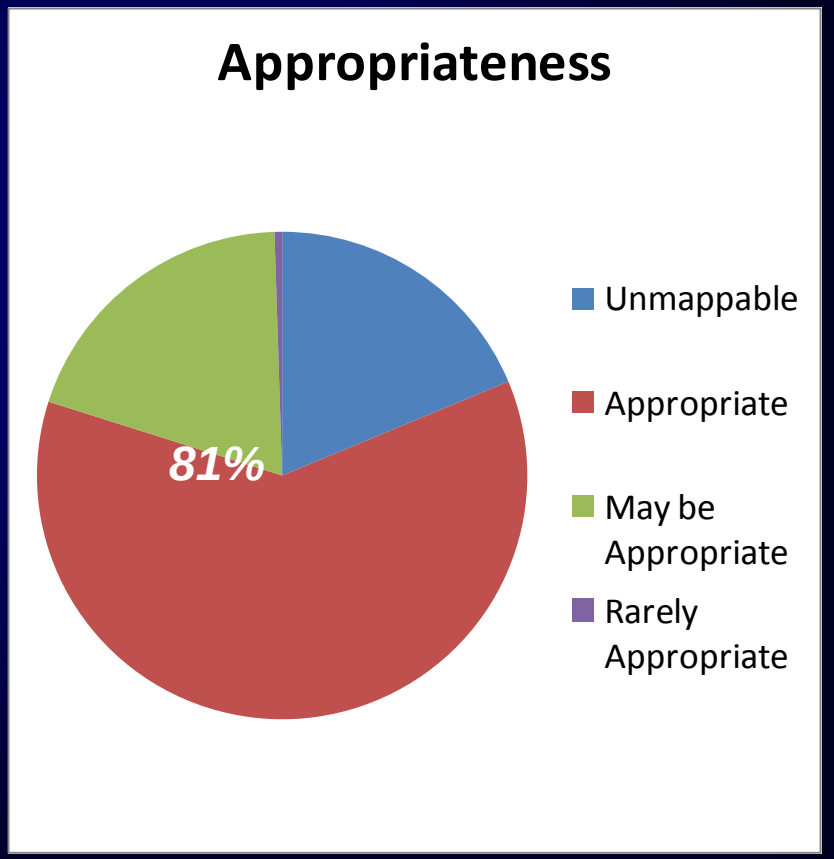
Baseline Patient and Lesion Characteristics in OPEN CTO

Patient Characteristic	
Age (yrs)	65.4 ± 10.3
Male sex (%)	80.2%
BMI (Kg/m2 BSA)	30.8 ± 9.1
Heart Rate (bpm)	68.5 ± 12.8
Smoking (ever)	64.5%
Diabetes(%)	41.4%
Hypertension(%)	86.9%
Prior MI(%)	48.4%
Prior CABG(%)	36.9%
Prior PCI(%)	66.0%
Prior CHF(%)	22.6%
PAD(%)	17.4%
CKD>stage 1(%)	13.3%
EF (%)	51.1 ± 13.7

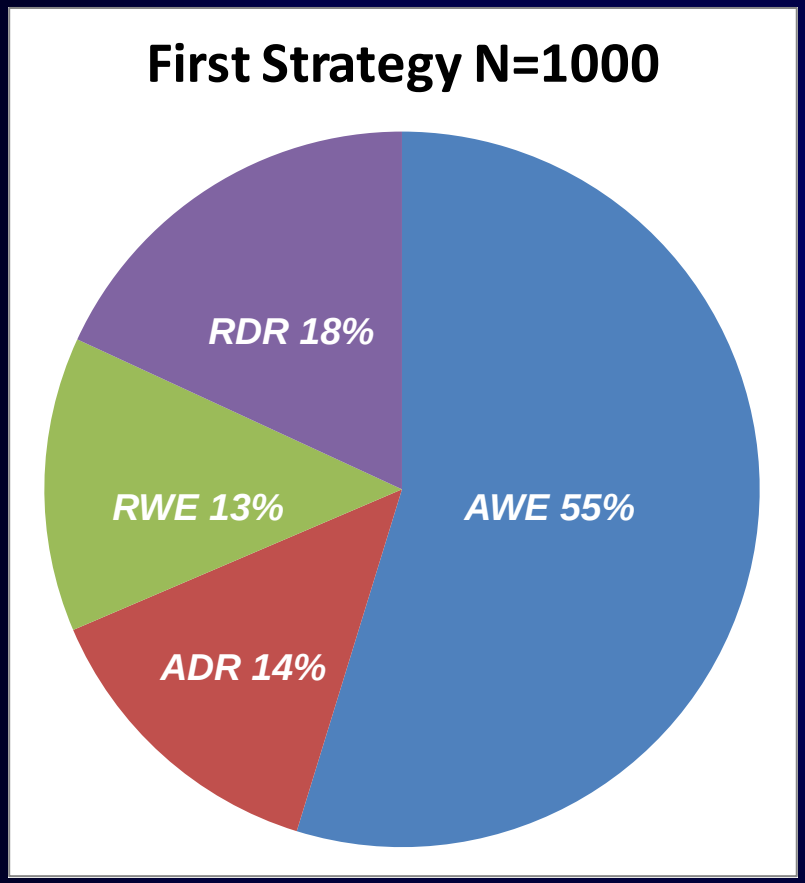
Angiographic Characteristic	
CTO only (%)	86.2
Complete Revasc (%)	82.3
Target Vessel RCA (%)	60.5
LAD (%)	19.6
LCX (%)	13.3
Occlusion Length (mm)	29.9 ± 24.3
Length>20 mm (%)	54.8
Total lesion length (mm)	63.4 ± 28.6
JCTO score <3 (%)	81.2
JCTO score ≥3 (%)	19.7

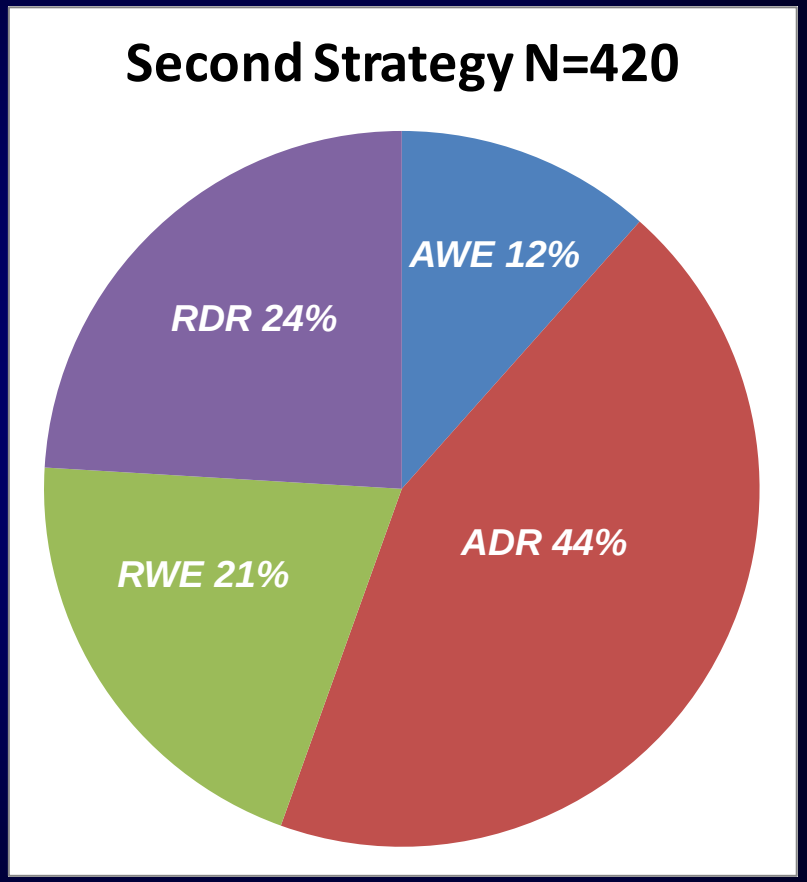
Indications and Appropriateness





Hybrid Algorithm Use

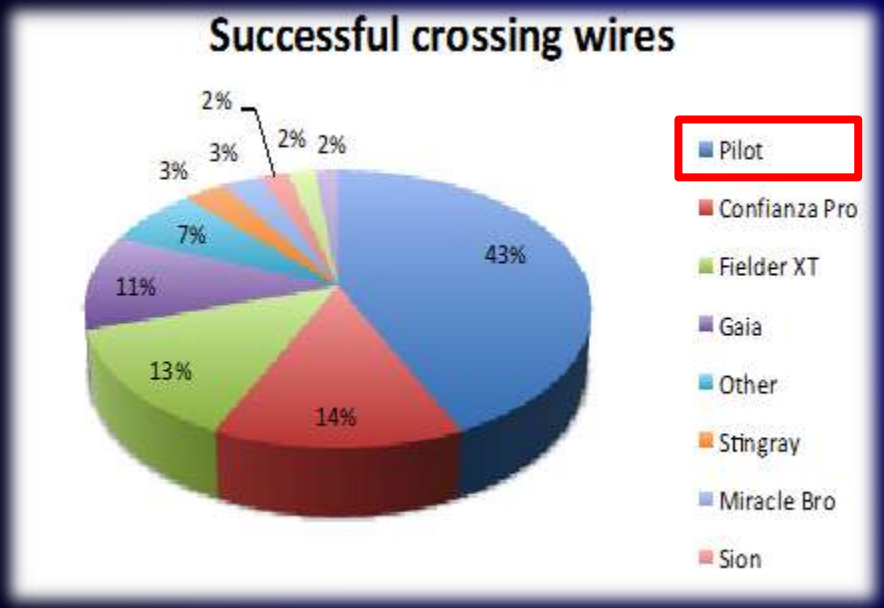




Success rate 58%

Success rate 55%

Device Use



General Equipment (% per 1000)	Per case
Sheaths	3±1.3
Guides	3.2±1.0
Guidewires	9.6±6.2
Balloons	4.9±3.0
Corsair (83%)	1.6±0.9
Fine Cross (10%)	1.2±0.5
Ancillary Equipment	
Rotablator (6%)	1.8±1.7 burrs
Guideliner (36%)	1.2±0.5
Laser (14%)	1.1±0.3
Covered stents (4%)	2.3±0.9
Coils (0.4%)	1.5±1

Procedural Results in OPEN CTO

89%

119 ± 72 min

2.5 ± 1.9 Gy

265 ± 194 ml

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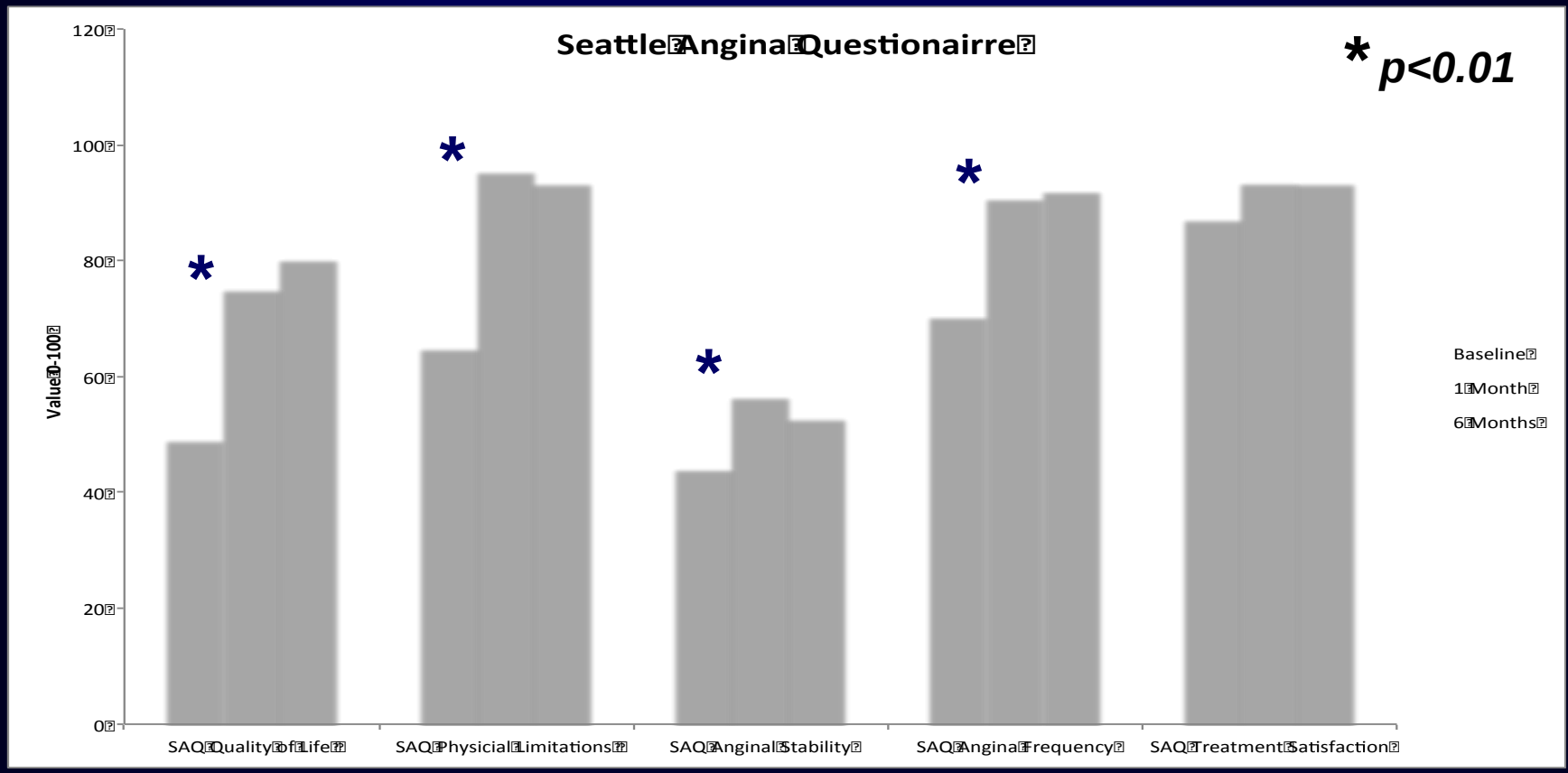
Early Health Status Changes in CTO-PCI

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
Skin change was patient reported during follow up calls

Unpublished Data from OPEN CTO

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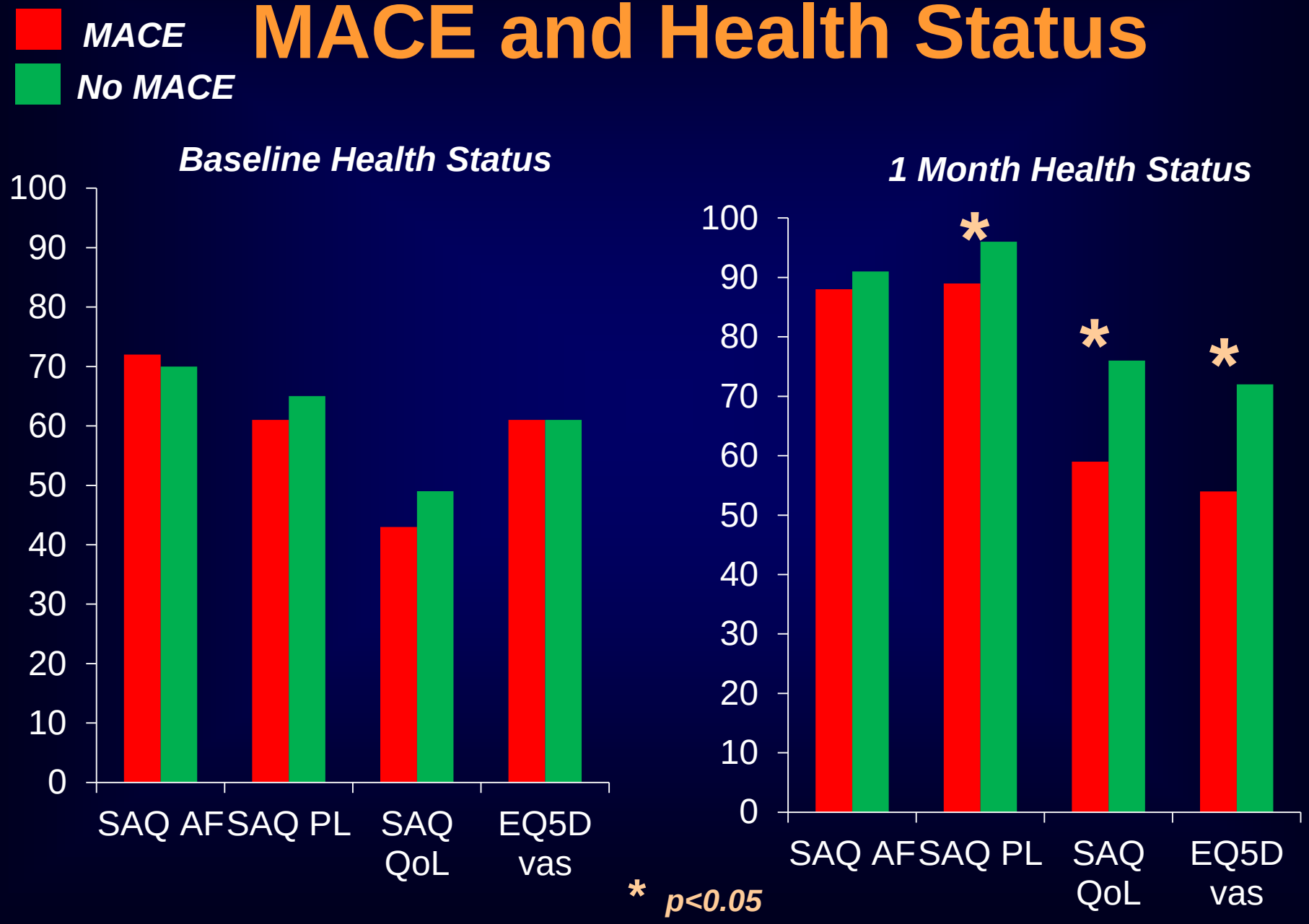
MACE and Health Status



Procedural Deaths

Patient	In Hosp	Perforation	Periproc MI	Post CABG
1	Yes	No	Yes	Yes
2	Yes	No	Yes	No
3	Yes	Yes	No	No
4	Yes	Yes	No	Yes
5	Yes	Yes	No	No
6	Yes	Yes	No	No
7	Yes	Yes	No	Yes
8	Yes	Yes	No	Yes
9	Yes	Yes	No	Yes

All 9 deaths were associated with a complication

4/7 deaths associated with perforation were in post CABG patients

Unpublished Data from OPEN CTO

Procedural Mortality

- 0.9% (95% CI 0.6-1.2%)
  - Mortality in NCDR registry 0.65%
  - Expected mortality by NCDR risk model 0.41%
  - Expected mortality of surgery from STS risk calculator 1.67%

Conclusions

- Patients with CTOs report significant health status impairment
- Hybrid CTO-PCI
  - high technical success
  - reasonable efficiency
  - significant health status improvement
- CTO-PCI risk may be higher than nonCTO-PCI
- OPEN CTO will provide the most rigorous and reliable assessment of Hybrid CTO-PCI practice and outcomes to date

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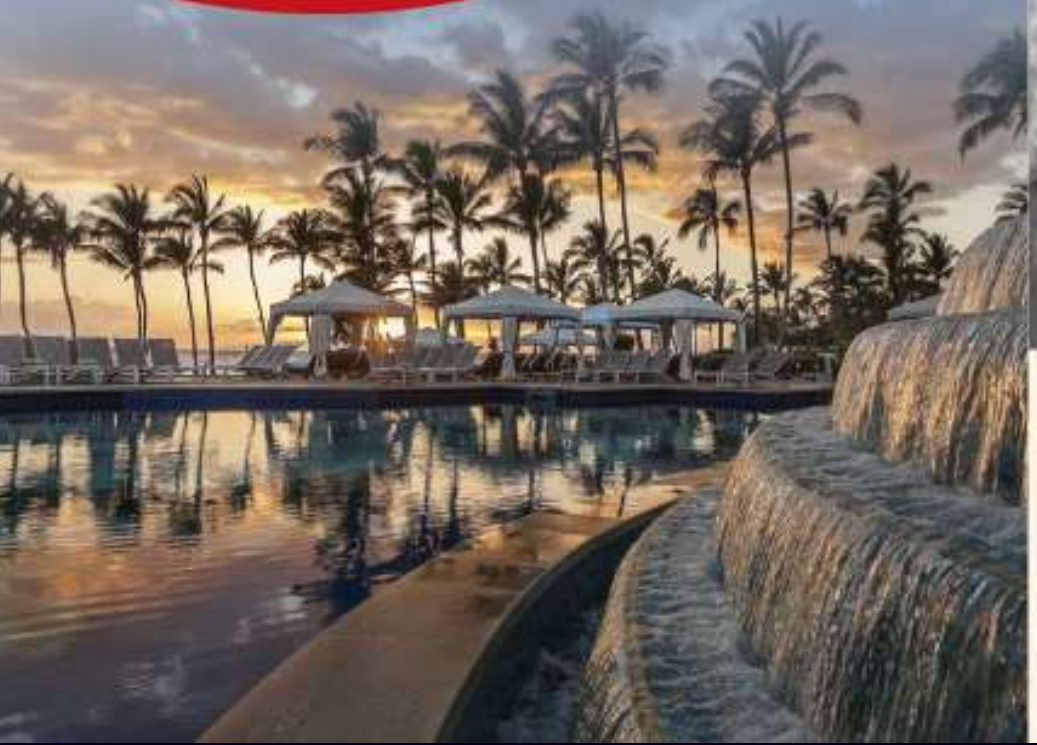

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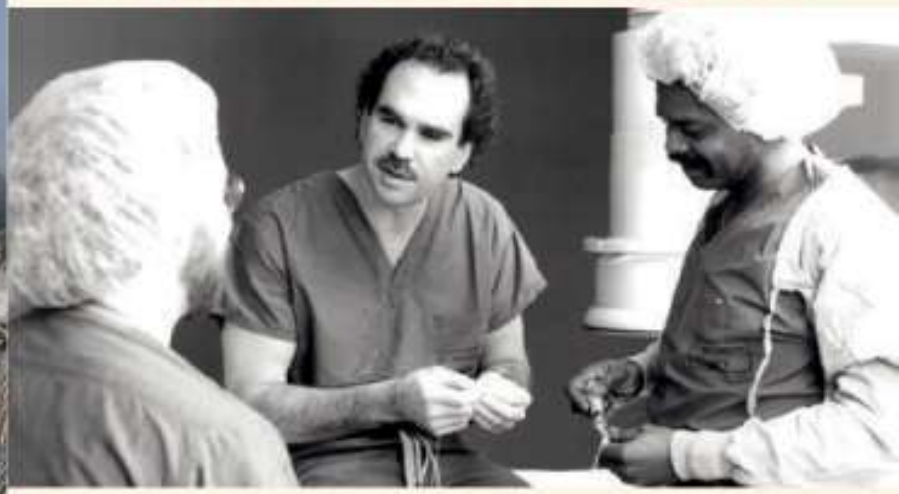

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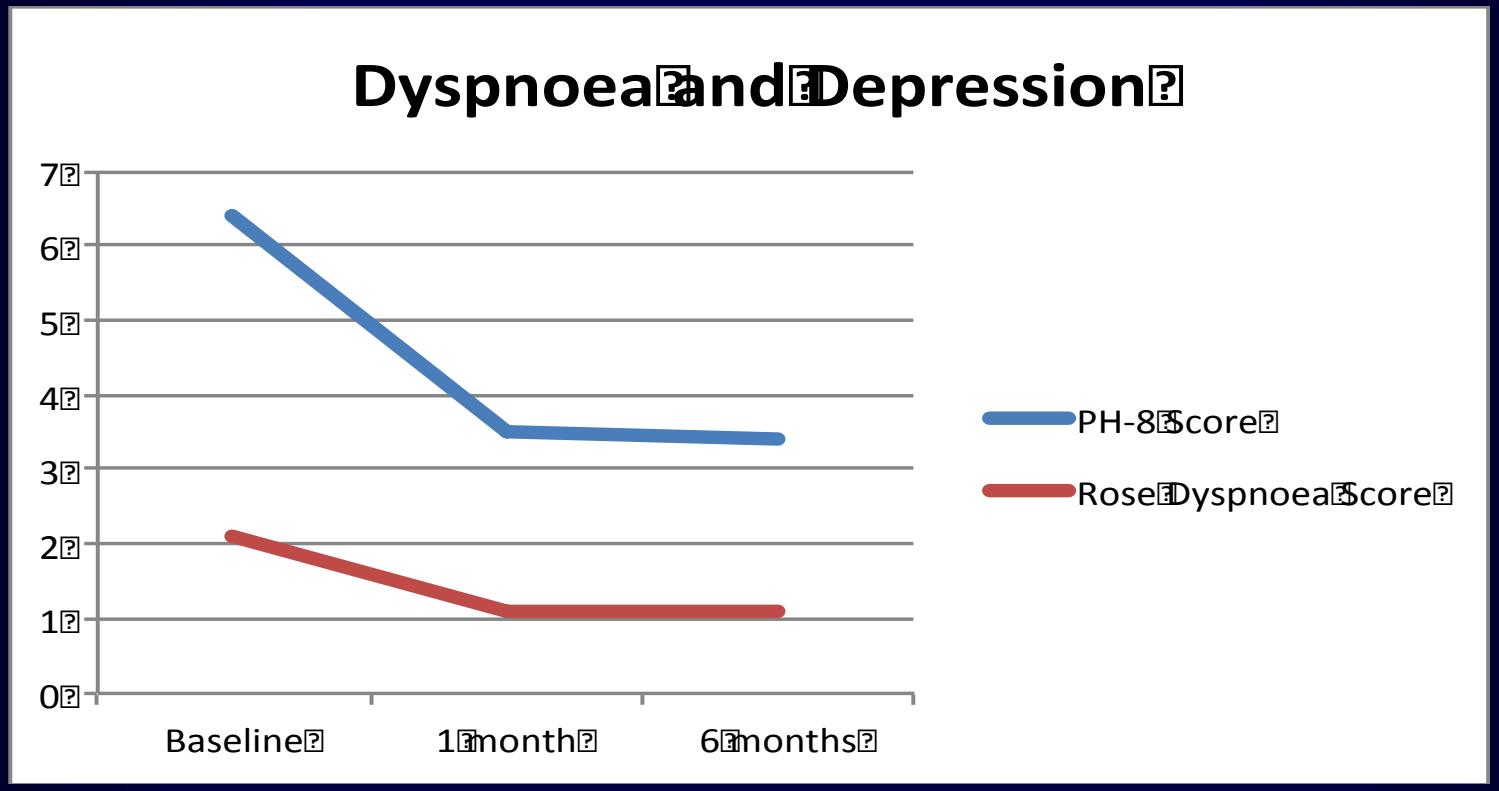
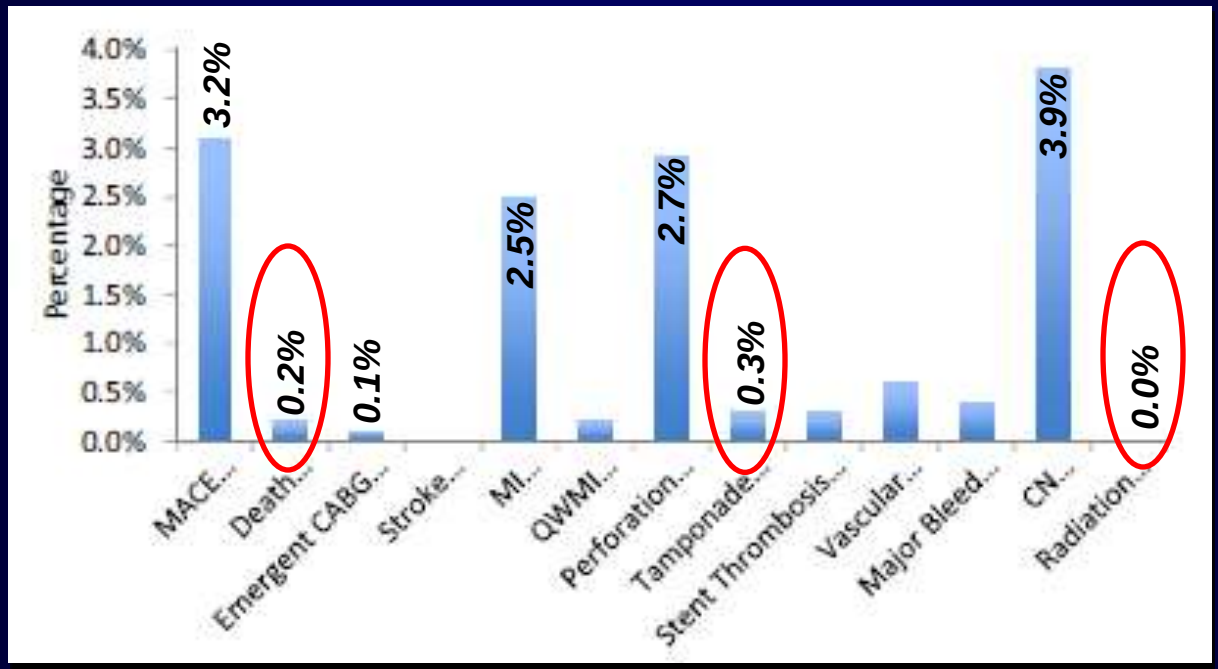


A decrease in score represents improvement in symptoms

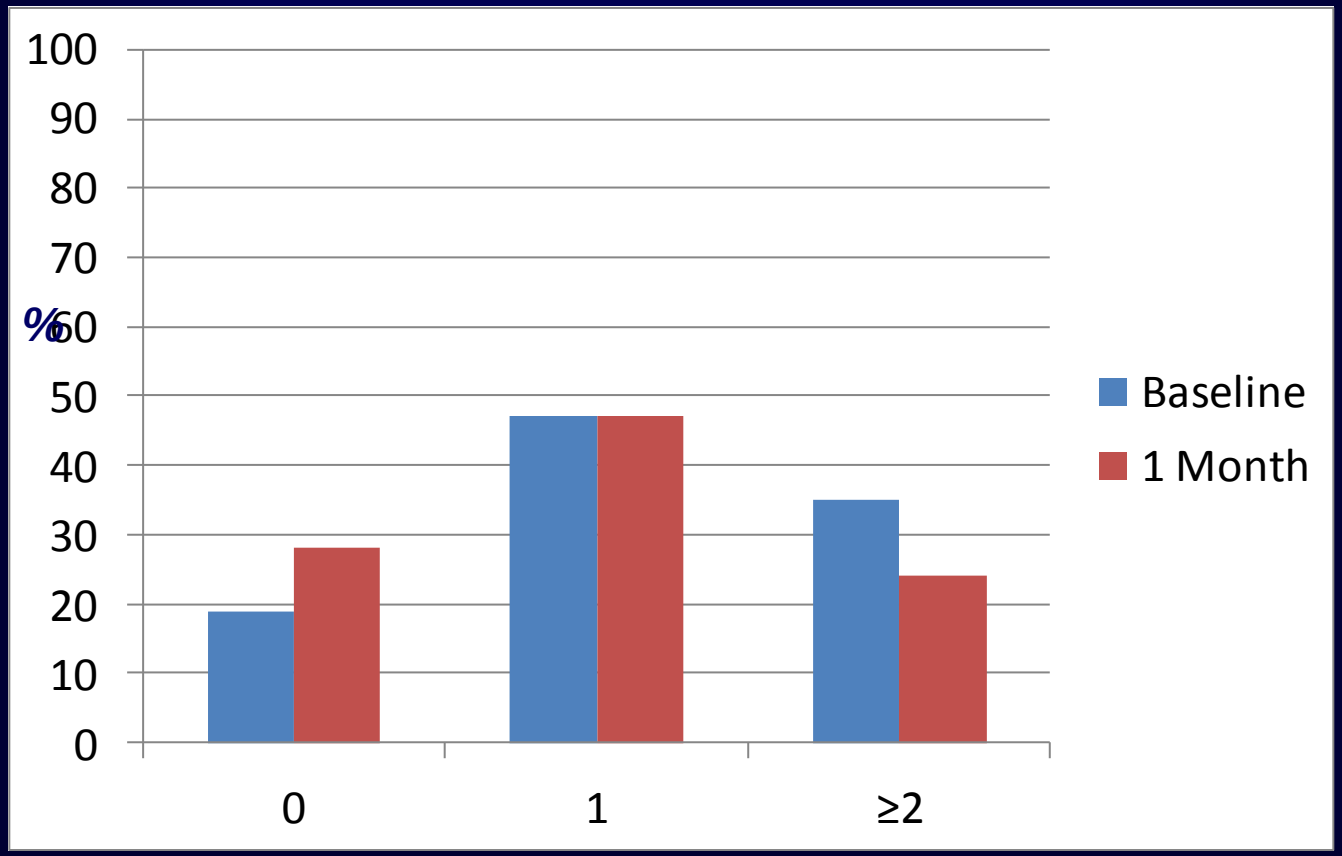
CTO-PCI Safety

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



Patel, JACC: Cardiovasc Int, 2013

Anti anginal Medication Use in OPEN CTO

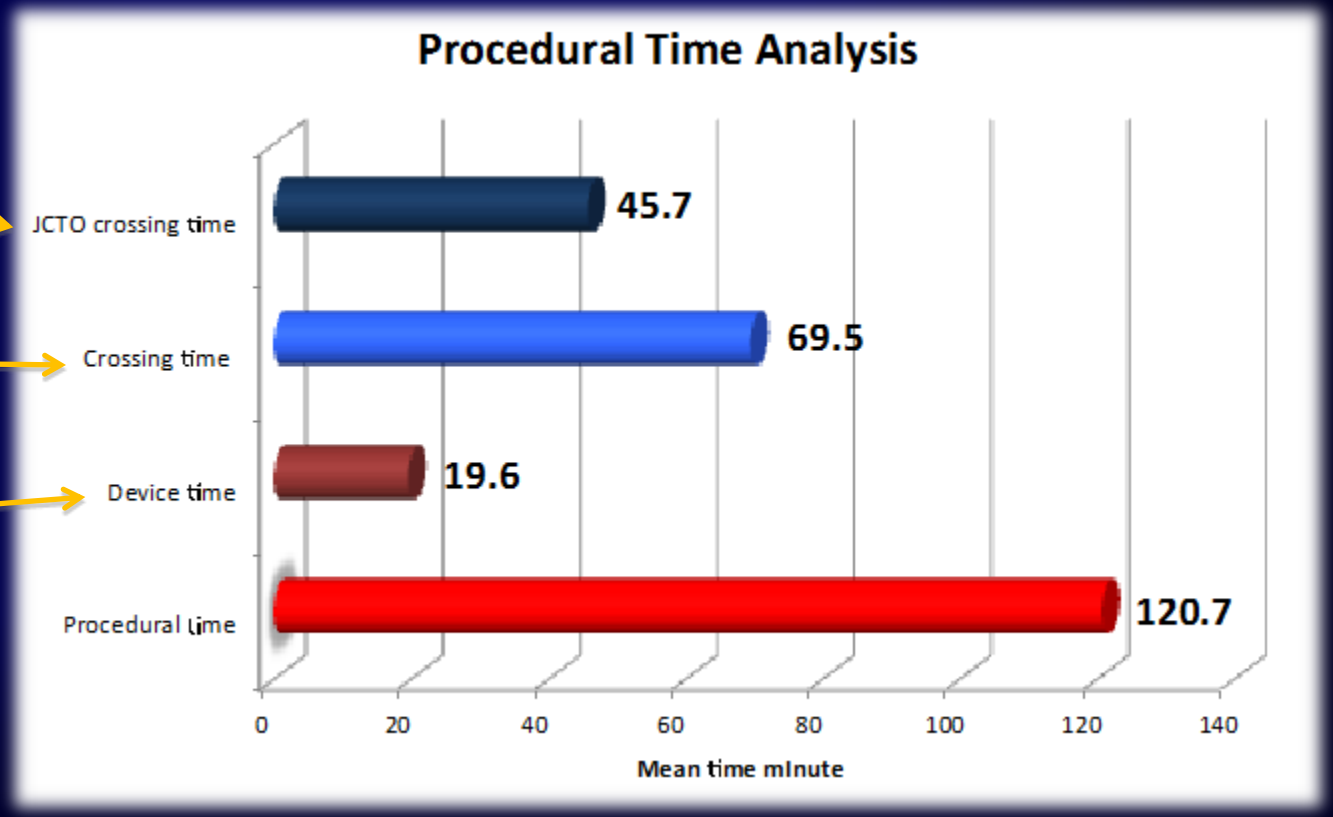


Mean HR 68 bpm SBP 127

Time between insertion of a device into catheter and crossing into true lumen

Time between local and crossing into distal true lumen

Time between local and insertion of a device into catheter



MACE vs No MACE

	MACE (N=44)	No Mace(N=956)	P value
Age	68.9 ± 9.7	65.2 ± 10.3	0.02
BMI	28.9 ± 6.4	30.5 ± 6.0	0.08
History of MI	28 (63.6%)	456 (47.7%)	0.04
Prior Valve Rep	3 (6.8%)	13 (1.4%)	0.03
Procedure Time	163.6 ± 71.0	118.7 ± 63.4	< 0.01
Fluoroscopy Time	68.2 ± 29.6	49.6 ± 34.1	<0.01
Total Radiation	3.2± 2.1	2.5 ± 1.9	0.02
Complete Revasc	21 (56.8%)	737 (89.3%)	<0.01
Balloons Number	6.7 ± 4.1	4.8 ± 2.9	<0.01
Laser Catheter	11 (25.0%)	130 (13.6%)	0.03