

**A Rigorous Look at  
Complications in CTO-PCI:  
Data from the OPEN CTO Registry**

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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

- Grant/Research Support
- Consulting Fees/Honoraria
- Major Stock Shareholder/Equity
- Royalty Income
- Ownership/Founder
- Intellectual Property Rights
- Other Financial Benefit

## Company

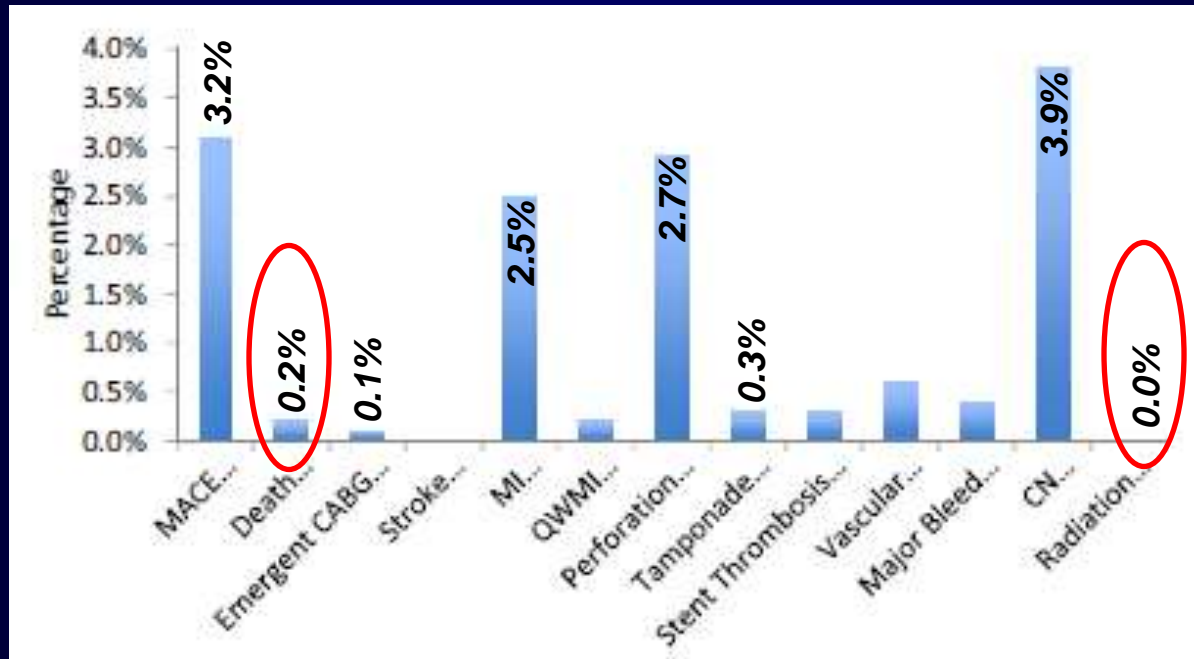
- Boston Scientific, Asahi Intecc, Vascular Solutions
- Boston Scientific, Abbott Vascular, Asahi Intecc
- None
- None
- US patent#14/575,977
- None

# Complications Happen

- If you don't have complications, you aren't trying hard enough"
  - *Dr. Antonio Colombo*
- “To be good at CTO-PCI the interventionalist must learn how to successfully solve the inevitable procedural complications”
  - *Dr. Etsuo Tsuchikane*

# CTO-PCI Complications Data

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



# Complication Rates

## CTO-PCI Compared to Non CTO-PCI

	CTO PCI (N=18,061)	PCI (N=787,980)
MACE	3.2% (0-19%)	4.53%
Death	0.2% (0-3.6%)	0.65% (elective)
Emergent CABG	0.1% (0-2.3%)	0.18%
Perforation	2.7% (0-11.9%)	NR
Tamponade	0.3%	0.07%
Access site bleed	NR (major 0.3%)	0.42%
Stroke	0.0%	0.17%
Radiation injury (range)	0.0% (0-11%)	NR

*Patel et al J Am Coll Cardiol 2013)*

*Dehmer et al J Am Coll Cardiol 2012;60:2017-31)*



**O**utcomes, **P**atient health status, and **E**fficiency  
**i**n **C**hronic **T**otal **O**clusion hybrid procedures

**Co PIs** James Sapontis, Bill Lombardi  
**Manager** Karen Nugent  
**Statistician** Kensey Gosch  
**Core Lab** Federico Gallegos  
**Publications** Spertus, Cohen, Marso, Yeh,  
Nicholson, Federici, McCabe,  
Karpaliotis, and Grantham



# 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

Angina

Efficient

Complicated

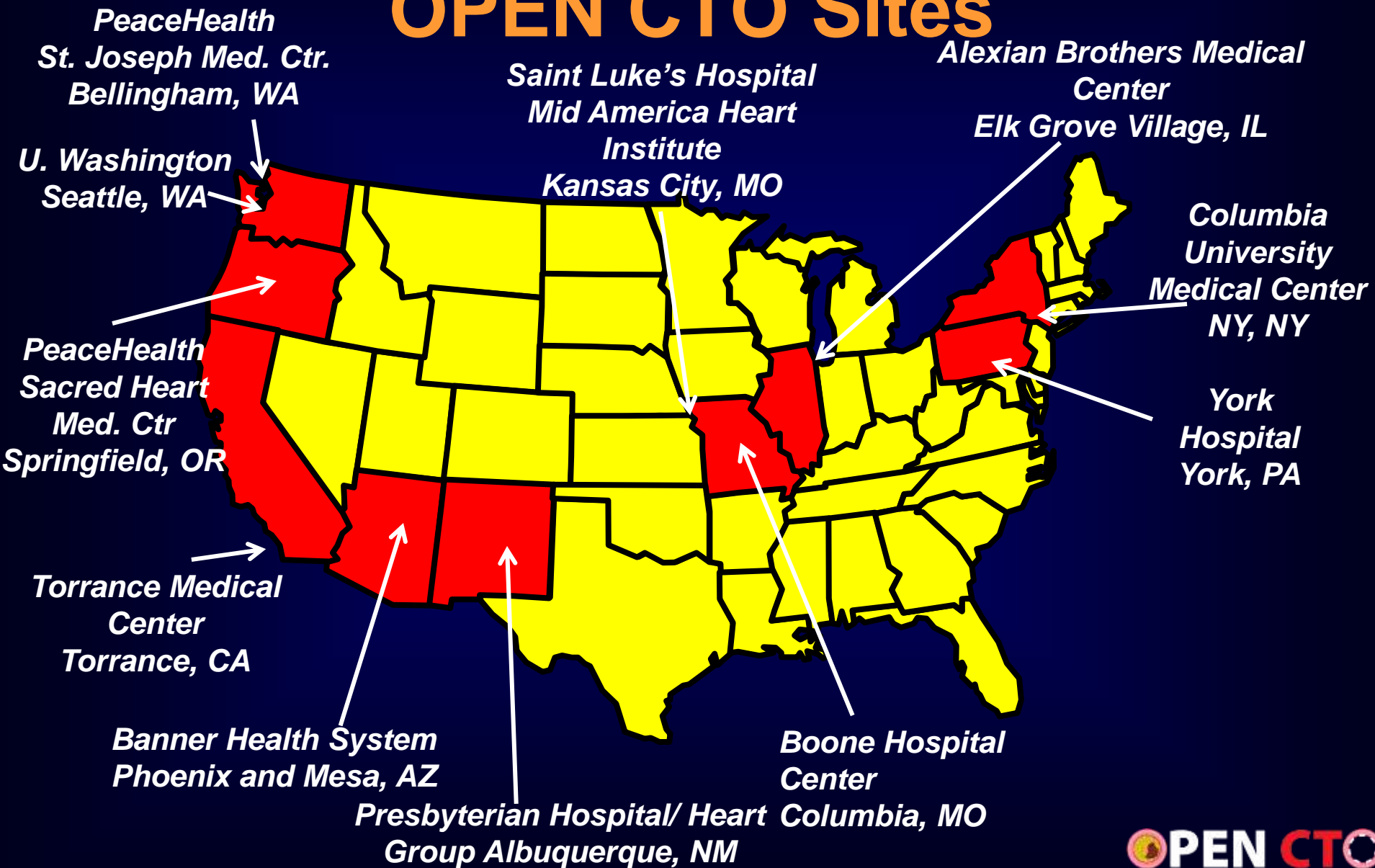
Failure

Dyspnea

Inefficient

Uncomplicated

# OPEN CTO Sites





# 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/m <sup>2</sup> 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

# Procedural Results in OPEN CTO



89%



$119 \pm 72$  min



$265 \pm 194$  ml



$2.5 \pm 1.9$  Gy

# 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%

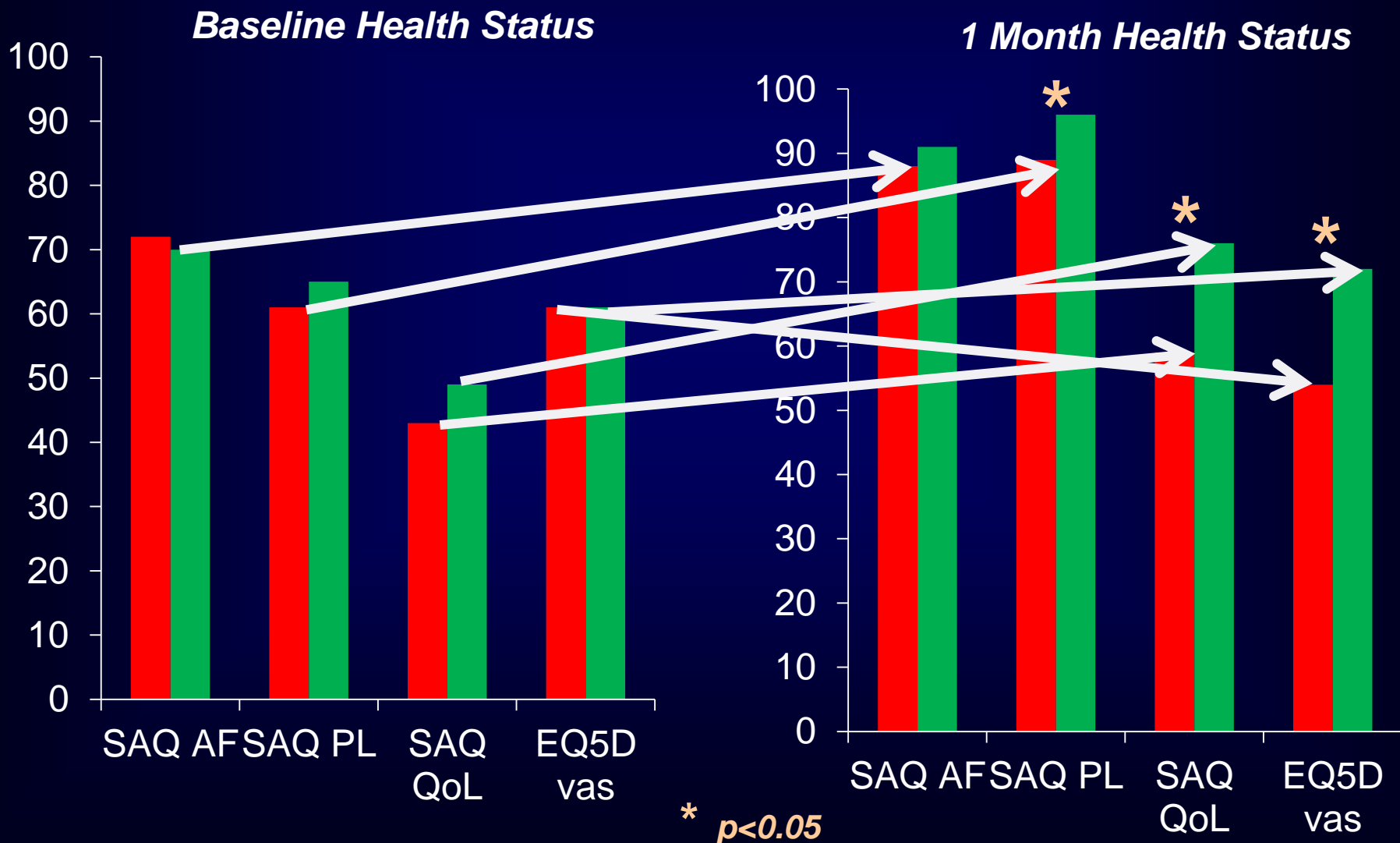
*Procedural MACE includes Death, MI, Emergent Surgery, Stroke and Clinical Perforation  
Skin change was patient reported during follow up calls*

# 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

# MACE and Health Status

■ MACE  
■ No MACE



# Procedural Mortality

- **0.9% (95% CI 0.6-1.2%)**
  - Mortality in NCDR registry 0.65%
  - Expected mortality by NCDR risk model 0.41%
  - STS risk estimate for OPEN patients 1.67%

# 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***



# Radiation Skin Injury

- **29 (2.9%) patients admitted to skin discoloration on their back at 1 month**



	Yes (N=31)	No (N=969)*
Air Kerma (Gy) Mean	2.4±1.7	2.5±1.9
Air Kerma (Gy) Range	0.3-7.9	0.2-14.6
DAP (Gy/cm <sup>2</sup> ) Mean	22,568±24,511	22,815±19,450
DAP (cGy/cm <sup>2</sup> ) Range	7-435,170	2-77,881

***No differences in Xray dose between those who reported and those who didn't report skin changes at one month***

***Of the 29 who reported at 1 month only 4 reported at 6 months***

# Conclusions

- **CTO-PCI complication rates are higher than nonCTO-PCI rates**
- **CTO-PCI complications are associated with worse health status outcomes at 1 month**
- **Post CABG patients are not protected from perforation**
- **Better assessment of radiation injury is needed**