

# “CTO: The Last Frontier in PCI”

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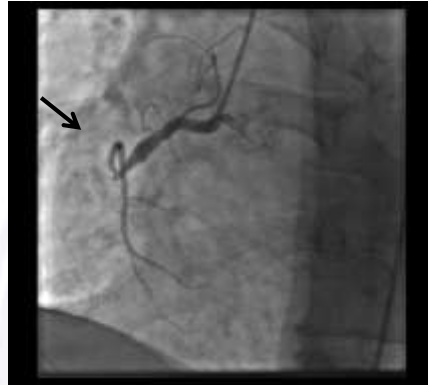
## Disclosure Statement

- Boston Scientific
- Consultant/ Advisory Board



# CTO Care Background

- The "final frontier" in PCI
- Highly variable treatment based upon institutional and operator characteristics
- Barriers to PCI
  - Poor understanding of benefits
  - Low success rates
  - High complication rates
  - Economic disincentives

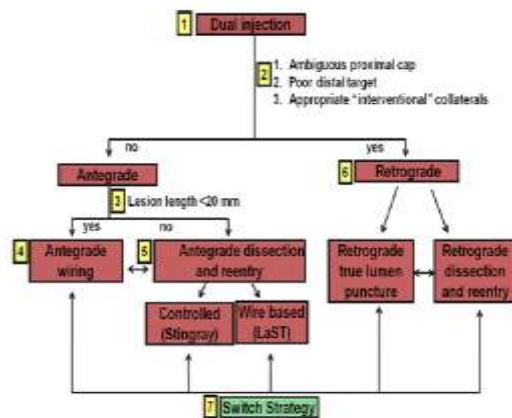


Fefer et al J Am CollCardiol:2012; 59:991-7  
 Grantham et al J Am CollCardiol: Cardiovasc Interv2009; 2:479-486



# 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 CollCardiolIntv2012;5:367-79



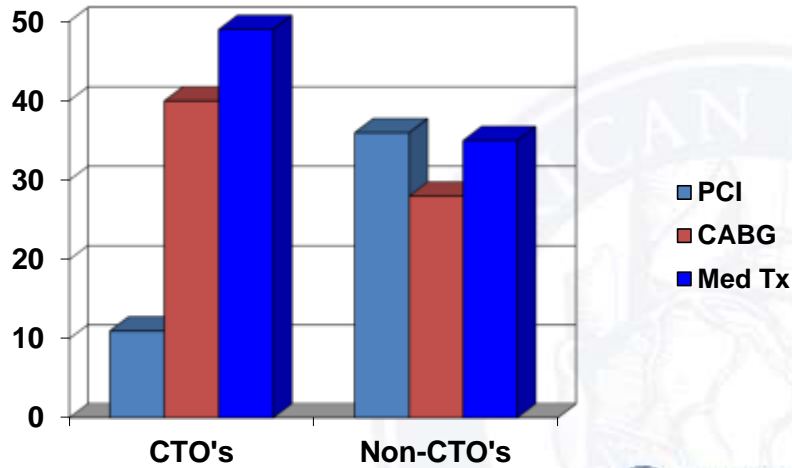
**PCI CTO techniques have advanced**



**PCI CTO techniques have advanced  
But does it confer any advantage?**



## 2005 treatment in the U.S.



Source: Am J Cardiol 2005;95:1088-1091



## CTO-PCI Indications Evidence for underutilization of PCI

- 14,439 patients underwent coronary angiography

- Excluded prior CABG
  - 54% had a CTO

- Excluded STEMI
  - 10% had a CTO

- 2,630 CTOs (18.4%)
  - Attempt rate of only 10%
  - Success rate 70%

- Yet 87% reported >CCS class I angina

- 87% reported CCS class II or greater angina

- 40% had previous documented MI

- >50% had normal LV systolic function



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

## CTO Volume projections

- **British Society Registry**

- 4% of all PCIs

- **Canadian Registry**

- CTO attempt 10% of all PCI
- CTO attempt varied from 1% to 16% of all volume

- **ACC STENT Registry**

- 4% of all PCIs
- High volume sites – 14%
- Japan 14%



## What has limited adoption of CTO PCI?

- **Procedure Time?**

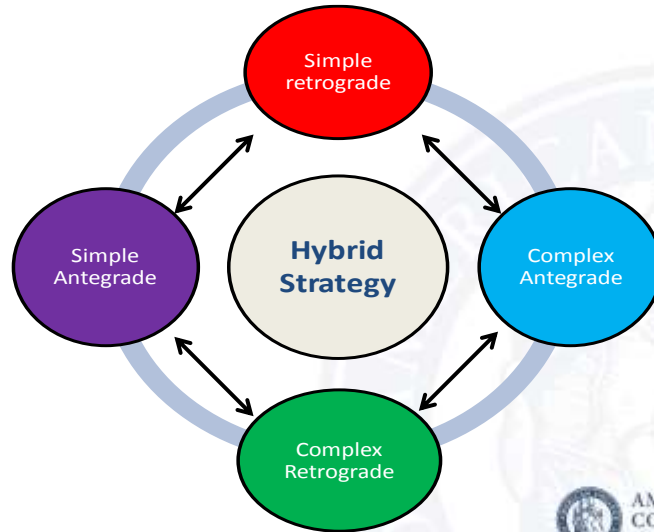
- **Complexity of procedure?**

- **Suboptimal Success?**

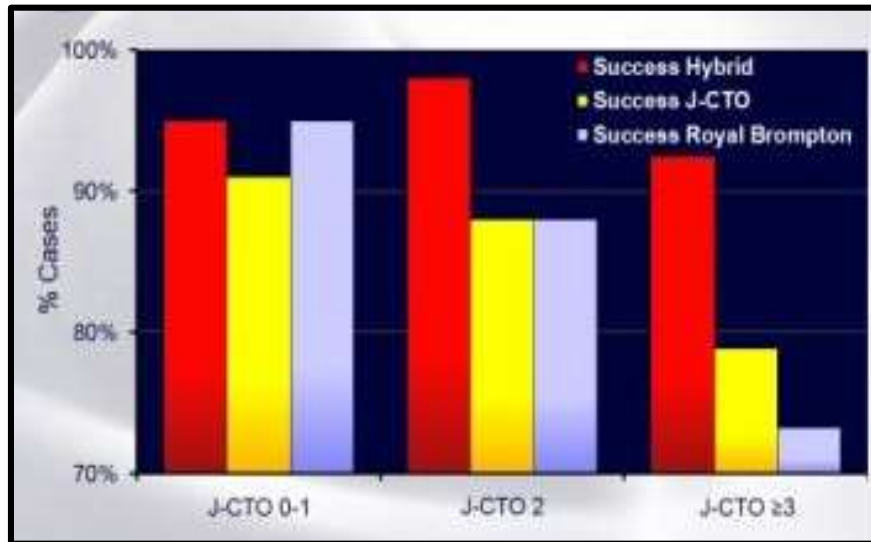
- **Clinical Justification?**



## Hybrid CTO PCI Strategy



## Better Success with Hybrid Approach



# The Hybrid Algorithm

Four things determine how many and which option to begin with

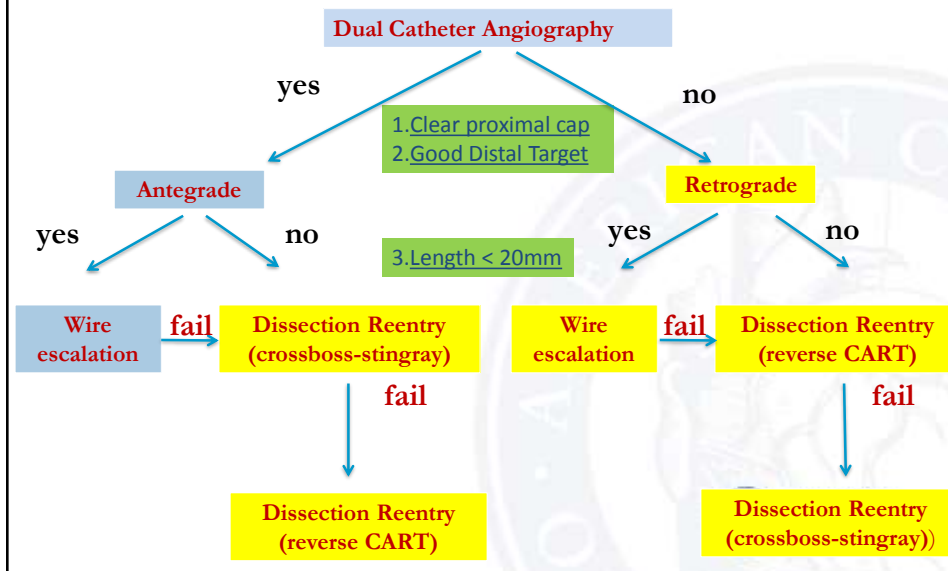
1. **Proximal Cap Anatomy**  
- Defined or Ambiguous?
2. **Target**  
- Favorable for reentry?
3. **Collaterals**  
- Useable or not?
4. **Occlusion length**  
- <20mm or ≥20mm?

**Direction**

**Crossing strategy**

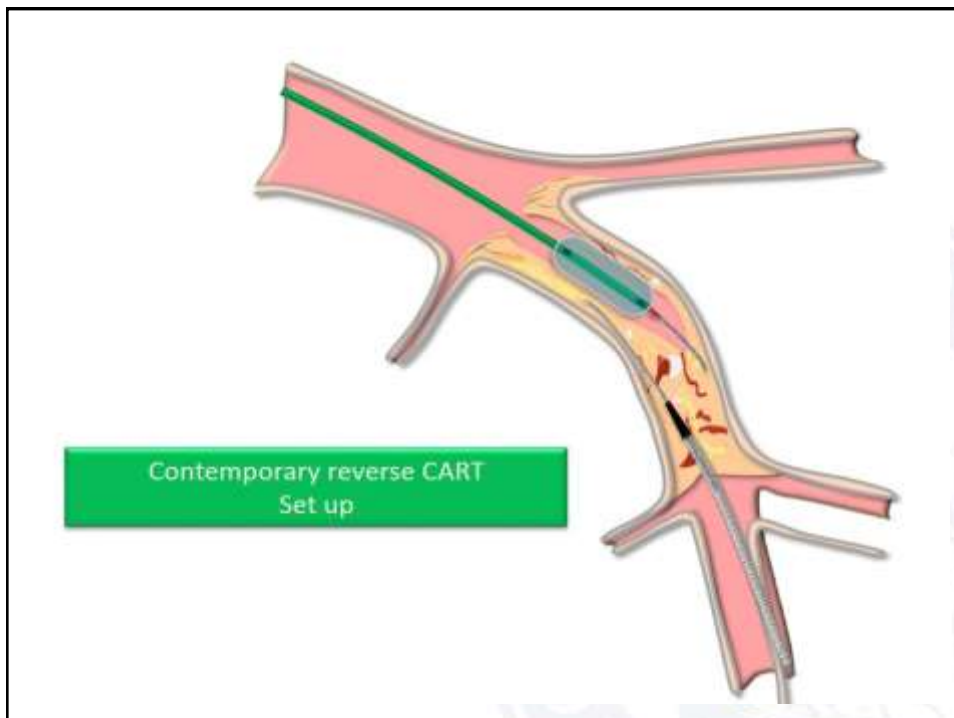
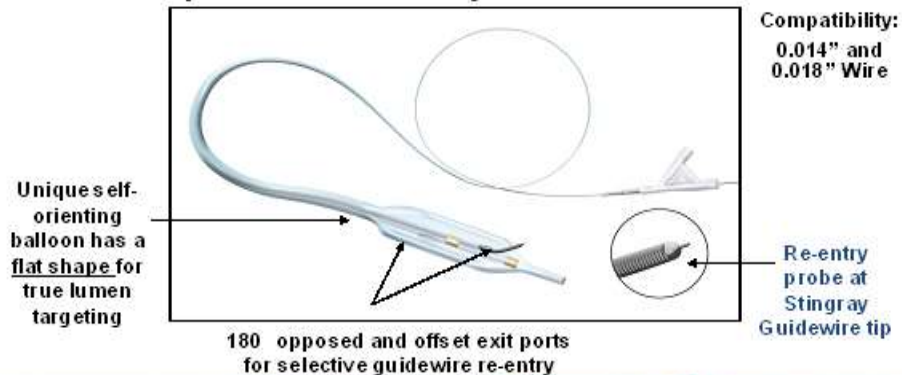


## The Hybrid Algorithm for CTO PCI *provisional approaches*



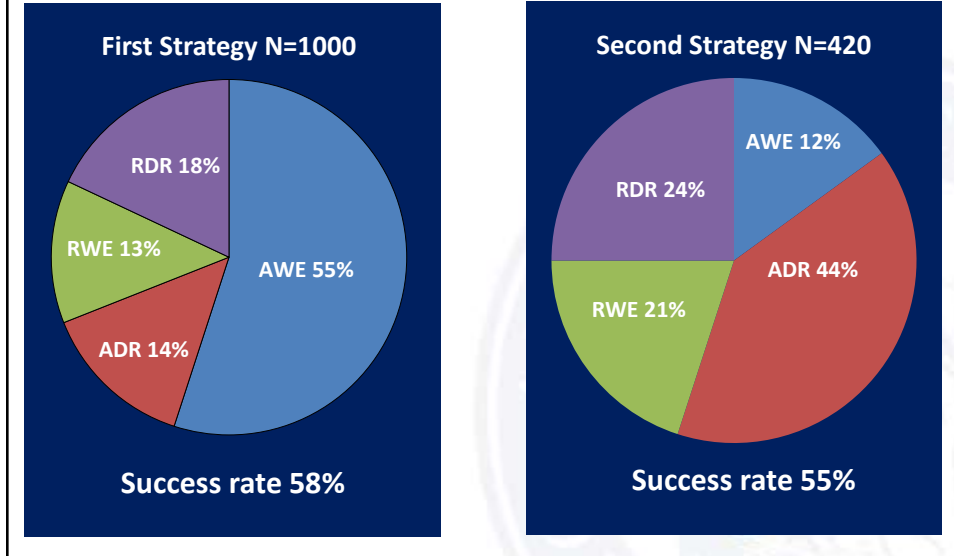
## Controlled antegrade dissection and Reentry

Stingray System (catheter and guidewire) is designed to accurately target and re-enter the true lumen from a subintimal position in coronary arteries

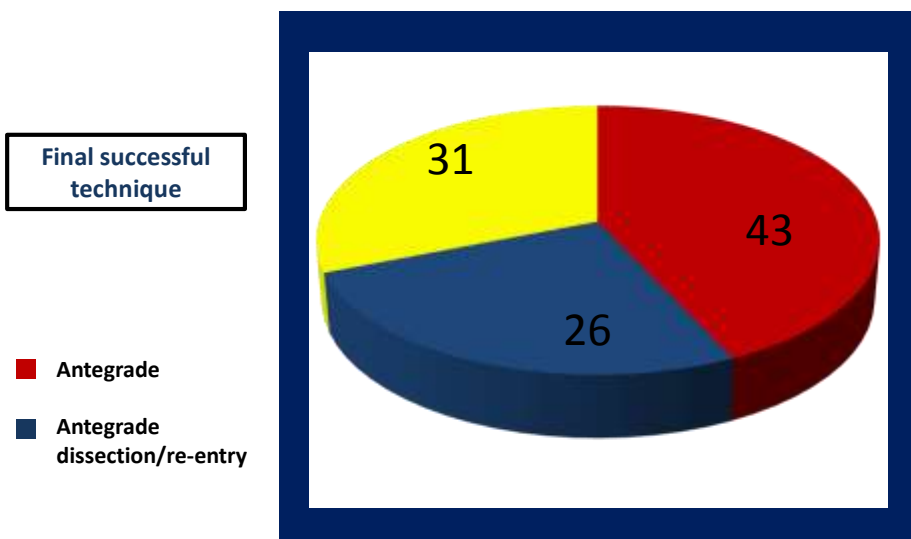




## Hybrid Algorithm Use



## PROspective Global REGistry for the Study of CTO interventions



Christopoulos. Int J Cardiology 2015; published online before print

## Rationales for CTO Recanalization

- Relief of angina
- Improvement of ventricular function
- Reduced incidence of late CABG
- Improvement in event free survival
- Reduced consequences of future ACS “Double Jeopardy”



## Meta-Analysis of CTO Outcomes

*13 Observational Studies, 7288 patients  
weighted Average f/u 6 yrs*

	OR for Success vs. Failure	95% CI	p
Mortality	0.56	0.43-0.72	<0.001
MI		0.44-1.25	0.26
Subsequent CABG	0.22	0.17-0.27	<0.001
Residual or Recurrent Angina	0.45	0.30-0.67	0.001

Joyal et al, Am Heart J 2010;160:179-87

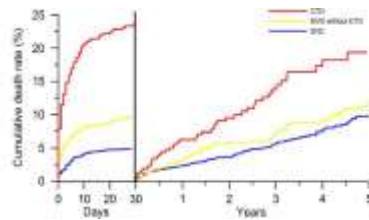


## CTO Treatment and Improved Long-term Survival (all p<.05)



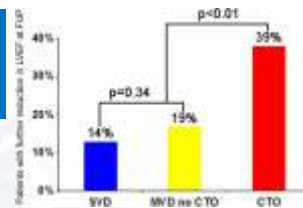
Hoye et al. EHJ 2005

## Mortality in STEMI patients Undergoing Primary PCI with Concurrent non-IRA CTO

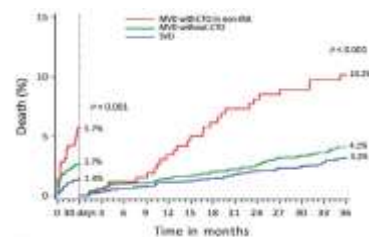


### Amsterdam Registry

- CTO 13%
- CTO was associated with LVEF <0.40 and with further reduction at 1 yr

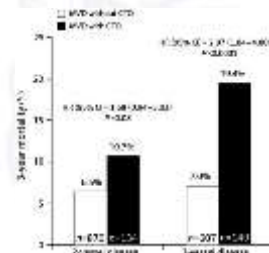


Claessen BE et al. JACC Interv. 2009;2:1128-34



### HORIZONS-AMI RCT

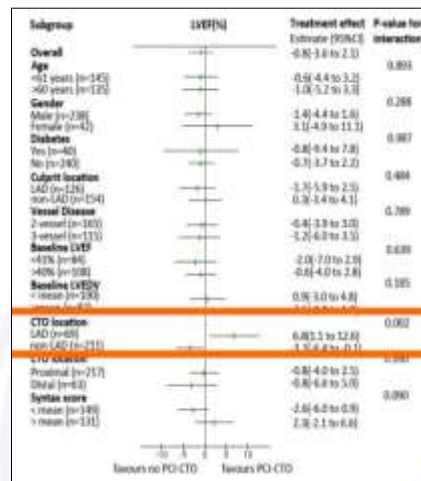
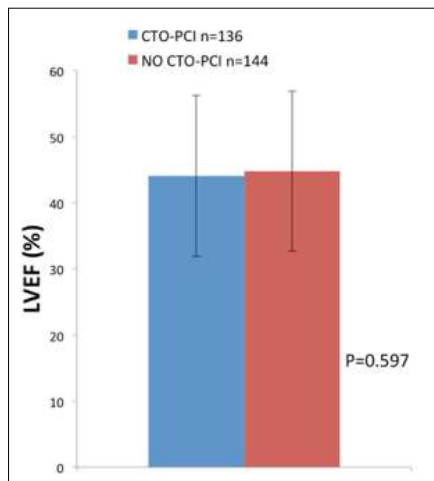
- MVD w/o CTO 45%
- MVD w/ CTO 8.6%
- CTO Independent predictor of early (0-30 days) and long-term (30d - 3 yrs) mortality



Claessen BE et al. Eur Heart J 2012;33:768-75

## EXPLORE: MRI-Assessed LVEF at 4 months

280 STEMI pts with CTO randomized: CTO PCI (72% success) vs. no CTO PCI



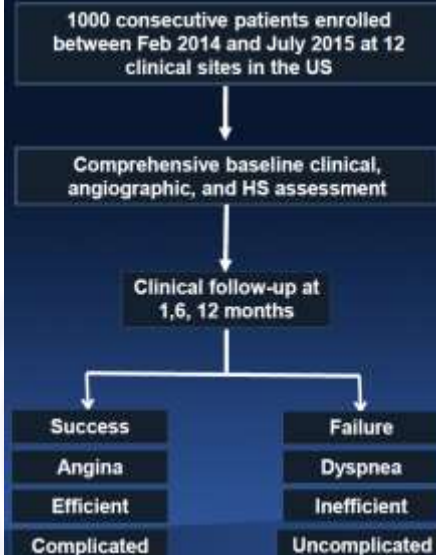
	CTO-PCI (n=136)	No CTO-PCI (n=144)	Difference (95%CI)	p
LVEF (%)	44.1 (12.2)	44.8 (11.9)	-0.8 (-3.6 to 2.1)	0.597

Henriques JPS et al. J Am Coll Cardiol. 2016;68(15):1622-32

## 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

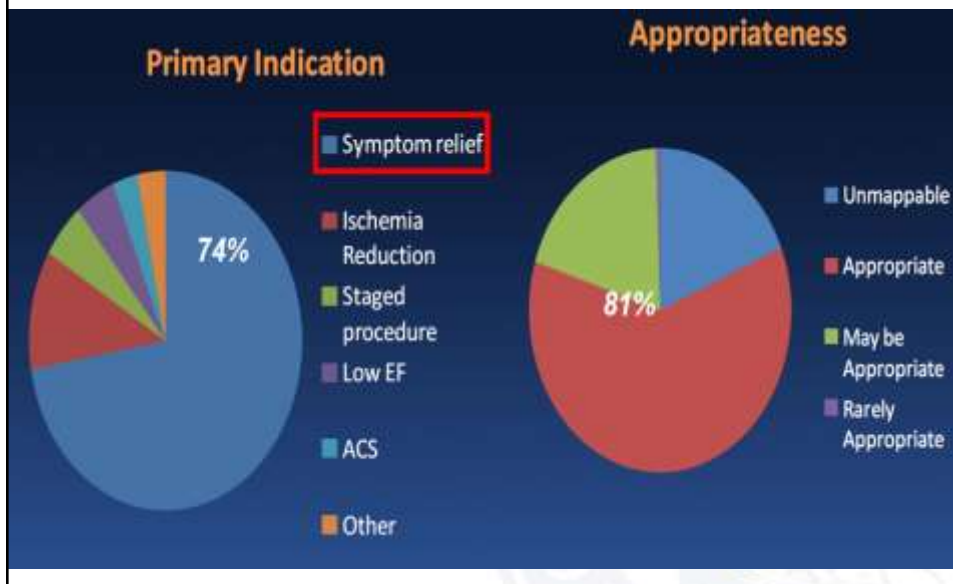


## Baseline Patient and Lesion Characteristics in OPEN CTO

Patient Characteristic	Value	Angiographic Characteristic	Value
Age (yrs)	65.4 ± 10.3	CTO only (%)	86.2
Male sex (%)	80.2%	Complete Revasc (%)	82.3
BMI (Kg/m <sup>2</sup> BSA)	30.8 ± 9.1	Target Vessel RCA (%)	60.5
Heart Rate (bpm)	68.5 ± 12.8	LAD (%)	19.6
Smoking (ever)	64.5%	LCX (%)	13.3
Diabetes(%)	41.4%	Occlusion Length (mm)	29.9 ± 24.3
Hypertension(%)	86.9%	Length >20 mm (%)	54.8
Prior MI(%)	48.4%	Total lesion length (mm)	63.4 ± 28.6
Prior CABG(%)	36.9%	JCTO score <3 (%)	81.2
Prior PCI(%)	66.0%	JCTO score ≥3 (%)	19.7
Prior CHF(%)	22.6%		
PAD(%)	17.4%		
CKD >stage 1(%)	13.3%		
EF (%)	51.1 ± 13.7		



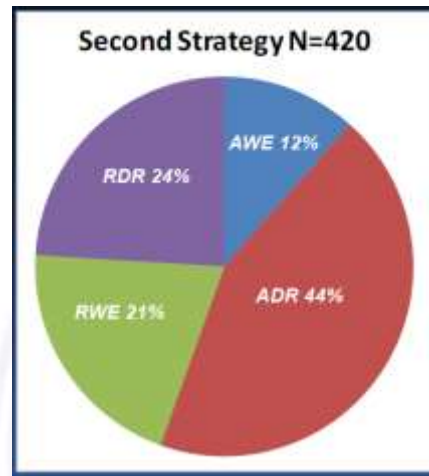
## Indications and Appropriateness



## Hybrid Algorithm Use



**Success rate 58%**



**Success rate 55%**



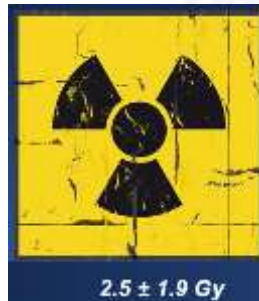
## Procedural Results in OPEN CTO



**89%**



**119 ± 72 min**



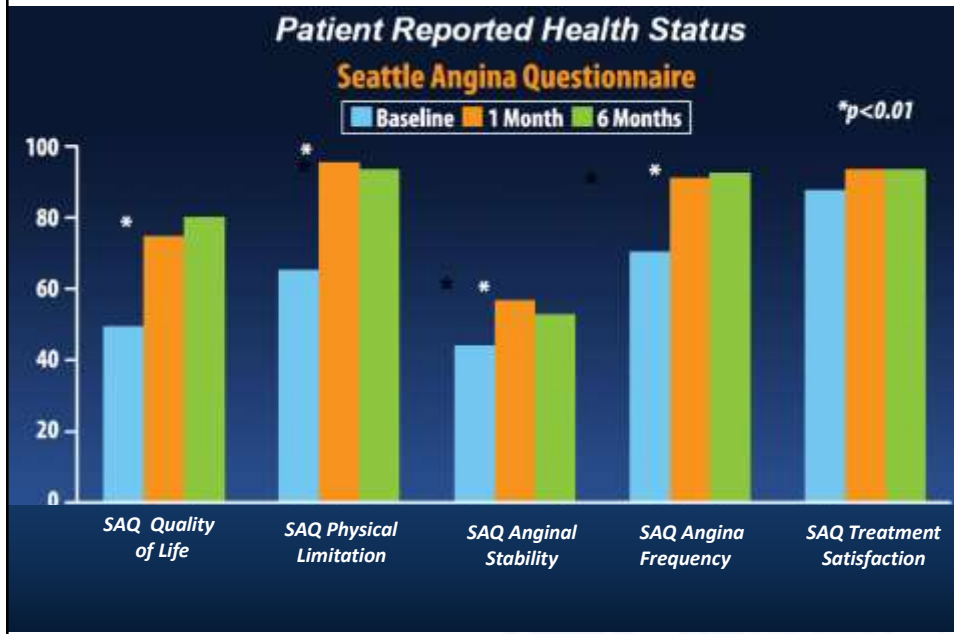
**2.5 ± 1.9 Gy**



**265 ± 194 ml**



## Health Status Changes in CTO-PCI



## What have we learned?

### The 5 Ds

Dyspnea

Depression

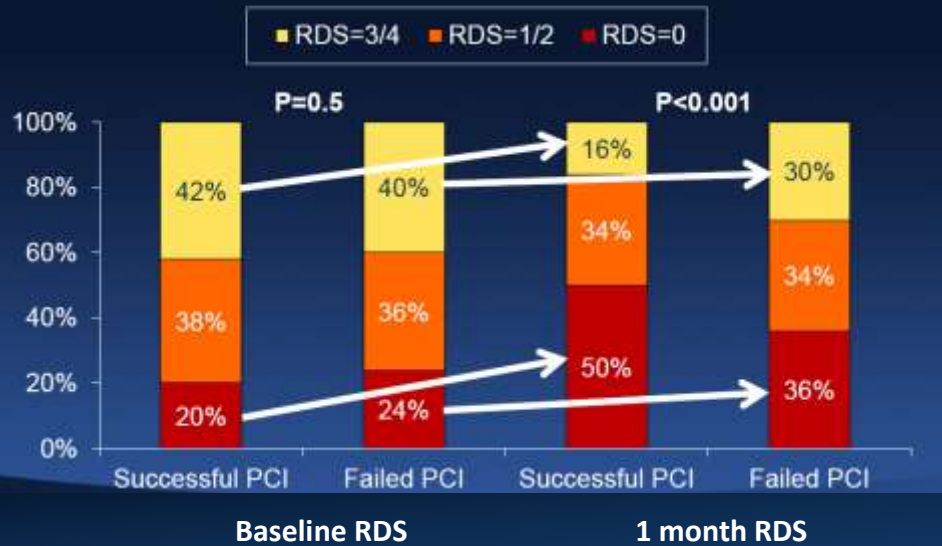
Diabetes

Death

Definition  
of Success

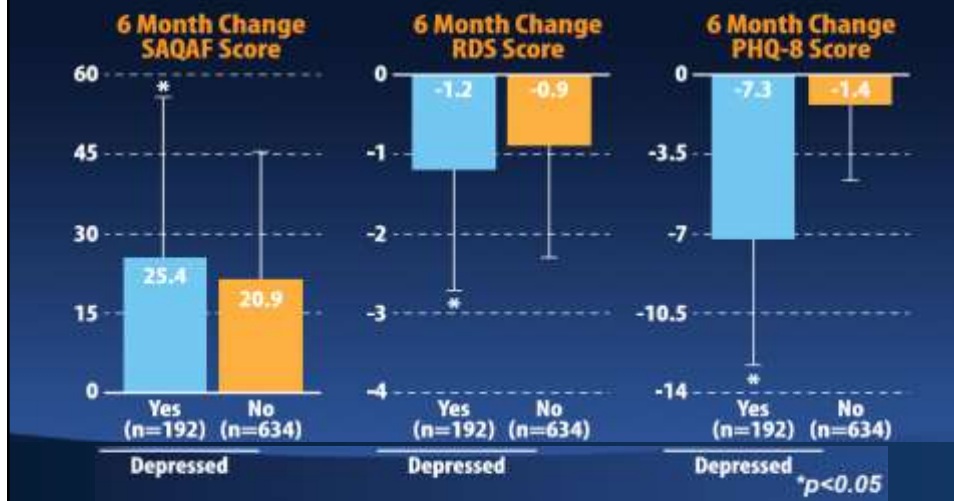
## Effect of Successful CTO PCI on Dyspnea: Qintar and Arnold

80% reported dyspnea at baseline , 70% reported improved dyspnea



## Depression: Yeh and Jaffer

23% depressed at baseline, 76% of them not depressed after CTO-PCI





## Diabetes Outcomes Salisbury and Kosiborod

41% diabetic at baseline

	Diabetes (n=412)	No Diabetes (n= 588)	P-value
Change in SAQ Summary Score*	1.31 Points	(95% CI -0.92, 3.53)	0.250
Change in SAQ Quality of Life*	2.61 Points	(95% CI -0.48, 5.69)	0.097
Change in SAQ Angina Frequency*	0.26 Points	(95% CI -2.40, 2.92)	0.848

## Deaths and Adverse Events Riley and McCabe

Patient	In Hosp	Perforation	Periproc MI	Post CABG
1	Yes	Yes	Yes	Yes ←
2	Yes	Yes	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  
5/9 deaths associated with perforation were in post CABG patients*

*Unpublished Data from OPEN CTO*

## Procedural Mortality In Context

- 0.9% (95% CI 0.6-1.2%)

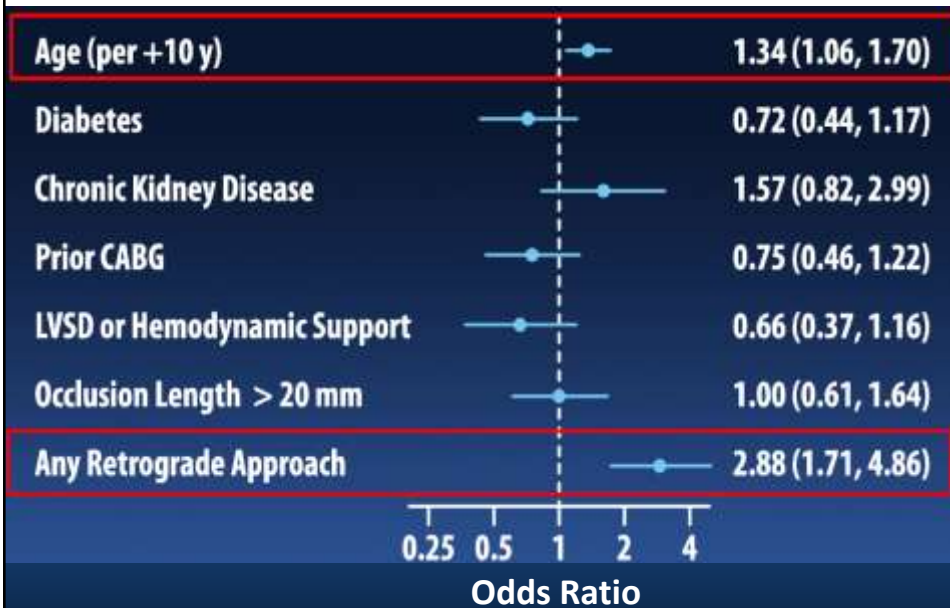
- Mortality in NCDR registry 0.65%

- Expected mortality by NCDR risk model 0.41%

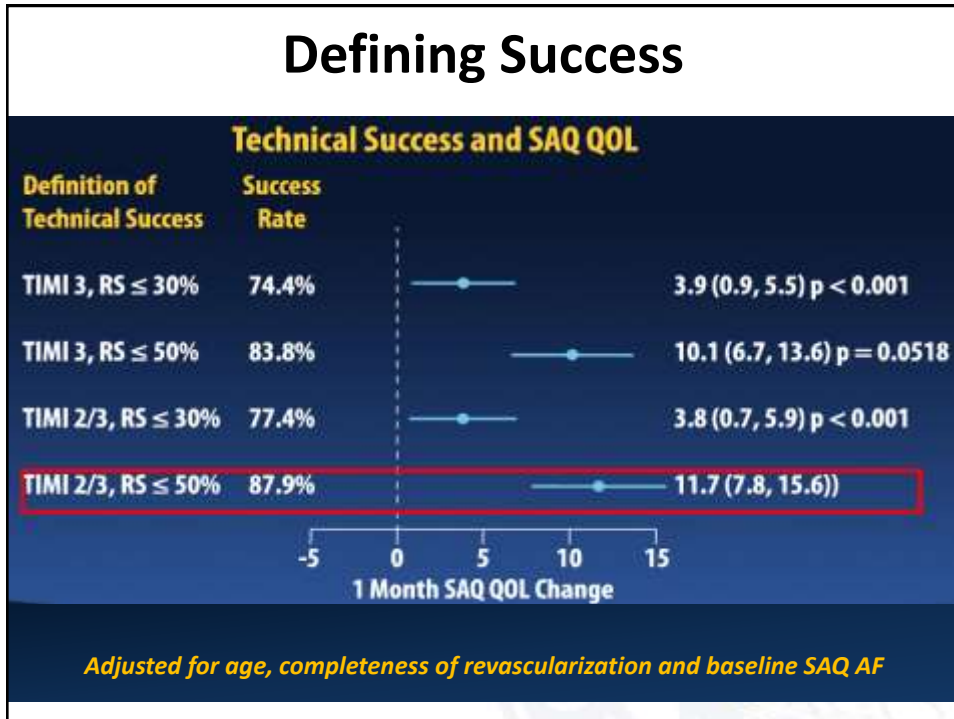
- Expected mortality of surgery from STS risk calculator 1.67%



## Predictors of MACCE



## Defining Success



## Defining Success: Sapontis and Grantham

- Traditional definitions of success are based on angiographic surrogates of durability
- These have never been correlated with patient outcomes
- Linear regression models of change in SAQ QoL at one month between success and failure using 4 definitions

## Conclusions

Dyspnea is common and resolves with CTO PCI

Depression is common, these patients respond better to CTO PCI than non depressed patients

Diabetes is common and diabetics respond as well as non diabetics despite smaller vessels

Death and MACE are associated with age and the retrograde approach, beware.

Definitions of success should be re thought



[J Am Coll Cardiol. 2016 Nov 1;68\(18\):1968-1970. doi: 10.1016/j.jacc.2016.08.034.](#)

### The Hybrid Algorithm for Treating Chronic Total Occlusions in Europe: The RECHARGE Registry.

[Maeremans J<sup>1</sup>](#), [Walsh S<sup>2</sup>](#), [Knaapen P<sup>3</sup>](#), [Spratt JC<sup>4</sup>](#), [Avran A<sup>5</sup>](#), [Hanratty CG<sup>2</sup>](#), [Faune B<sup>6</sup>](#), [Agostoni P<sup>7</sup>](#), [Bressollette E<sup>8</sup>](#), [Kavaert P<sup>4</sup>](#), [Bagnal AJ<sup>10</sup>](#), [Egred M<sup>10</sup>](#), [Smith D<sup>11</sup>](#), [Chase A<sup>11</sup>](#), [McErtegart MB<sup>12</sup>](#), [Smith WH<sup>13</sup>](#), [Harcombe A<sup>13</sup>](#), [Kelly P<sup>14</sup>](#), [Irving J<sup>15</sup>](#), [Smith EJ<sup>16</sup>](#), [Strange JW<sup>17</sup>](#), [Dens J<sup>18</sup>](#).

A total of 1,253 CTO-PCIs

Overall procedure success was 86% and major in-hospital complications occurred in 2.6%



## “And an Encore?”

- Two randomized controlled clinical trials comparing CTO PCI with medical therapy are currently under way: the **DECISION-CTO** (Drug-Eluting Stent Implantation Versus Optimal Medical Treatment in Patients with Chronic Total Occlusion; *NCT01078051*) trial and the **EURO-CTO** (European Study on the Utilization of Revascularization Versus Optimal Medical Therapy for the Treatment of Chronic Total Coronary Occlusion); *NCT01760083*) trial.
- Results of those studies are not expected to be available until 2018



# Thank You

