Lesson Learned from the OPEN CTO Trial

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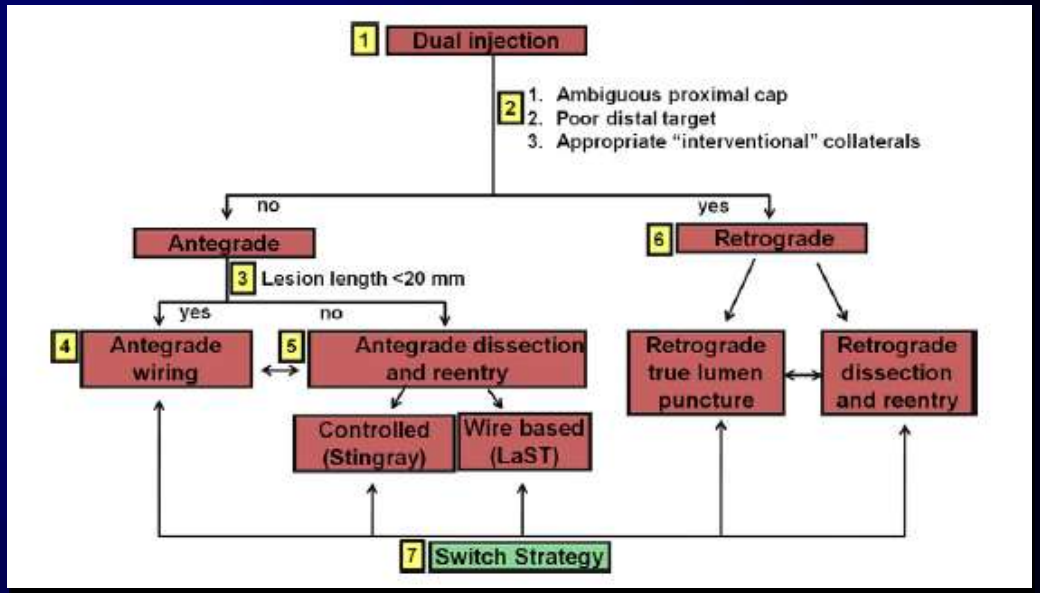
Disclosure Statement of Financial Interest

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
• Consulting Fees/Honoraria	• BSCI, ABT, Asahi-Intecc, Vascular Solutions, St Jude (Abbott)
• Major Stock Shareholder/Equity	• Corindus, Insysiv Inc.
• Royalty Income	• None
• Ownership/Founder	• CTOfundamentals.org
• Intellectual Property Rights	• None
• Employment/Director	• Corindus Vascular Robotics

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

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

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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

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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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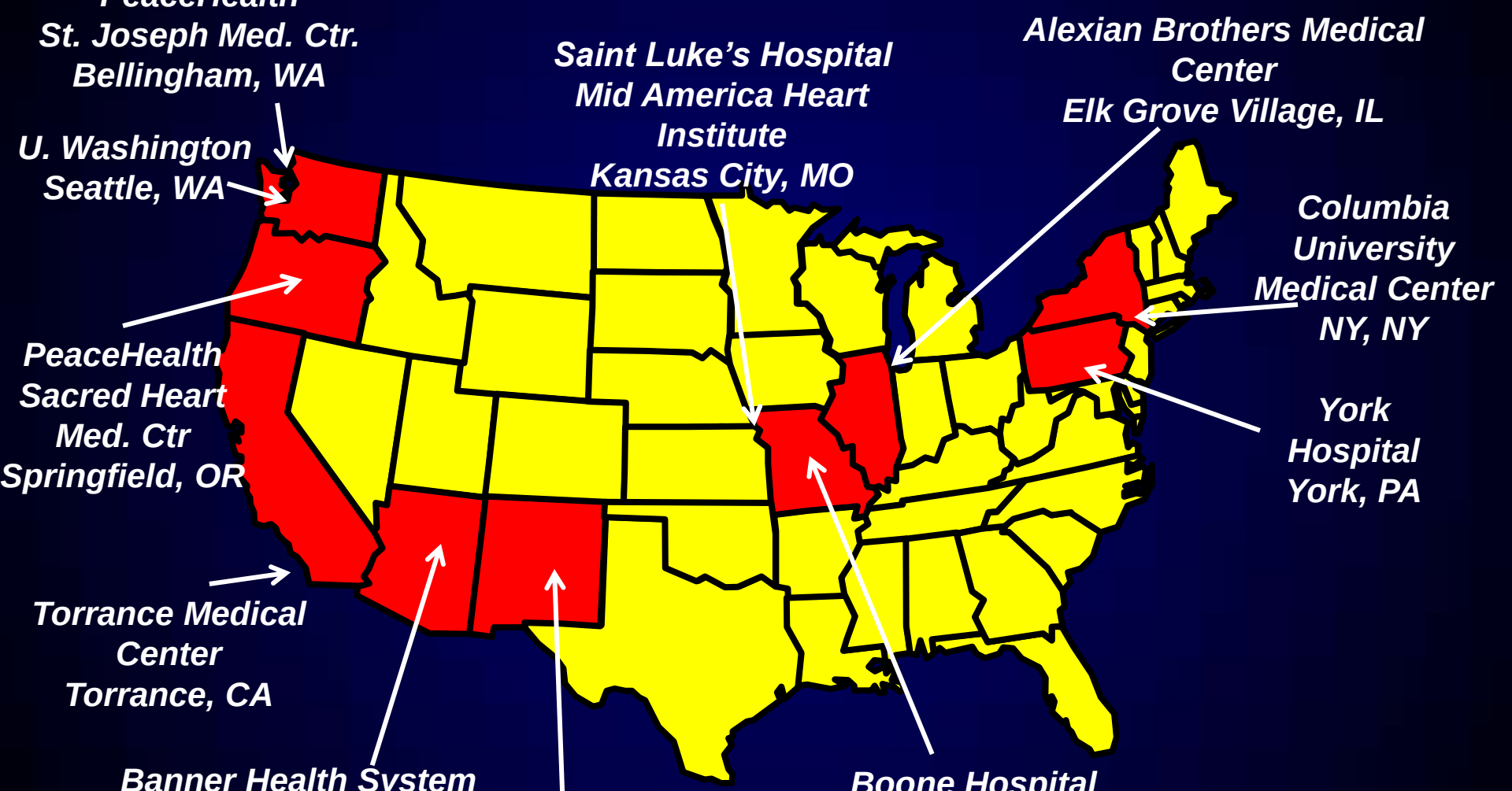
OPEN CTO Sites



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

Audit Results

Table 1 The NCDR audit results

	Total in NCDR ($n=1096$) [n (%)]	Enrolled ($n=987$) [n (%)]	Not enrolled ($n=109$) [n (%)]	P-value
Patient characteristics				
Age (years)	65.3±10.3	65.3±10.3	65.2±10.4	0.893
Male	883 (80.6)	797 (80.7)	86 (78.9)	0.643
Race White	988 (90.1)	903 (91.5)	85 (78.0)	<0.001
Hispanic origin	40 (3.7)	31 (3.2)	9 (8.4)	0.012
Smoker	188 (17.2)	167 (16.9)	21 (19.3)	0.537
Hypertension	975 (89.0)	884 (89.6)	91 (83.5)	0.054
Dyslipidemia	1030 (94.1)	928 (94.1)	102 (93.6)	0.820
Previous MI	535 (48.8)	479 (48.5)	56 (51.4)	0.572
Previous CHF	242 (22.1)	215 (21.8)	27 (24.8)	0.475
Previous PCI	728 (66.4)	657 (66.6)	71 (65.1)	0.764
Previous CABG	389 (35.5)	358 (36.3)	31 (28.4)	0.103
CKD stage 4	27 (2.5)	25 (2.5)	2 (1.8)	1.000
Diabetes	442 (40.3)	403 (40.8)	39 (35.8)	0.307
Chronic lung disease	144 (13.1)	131 (13.3)	13 (11.9)	0.693
Procedural outcomes				
Technical success by NCDR definition	981 (89.5)	888 (90.0)	93 (85.3)	0.132

Sapontis et al CAD 2017

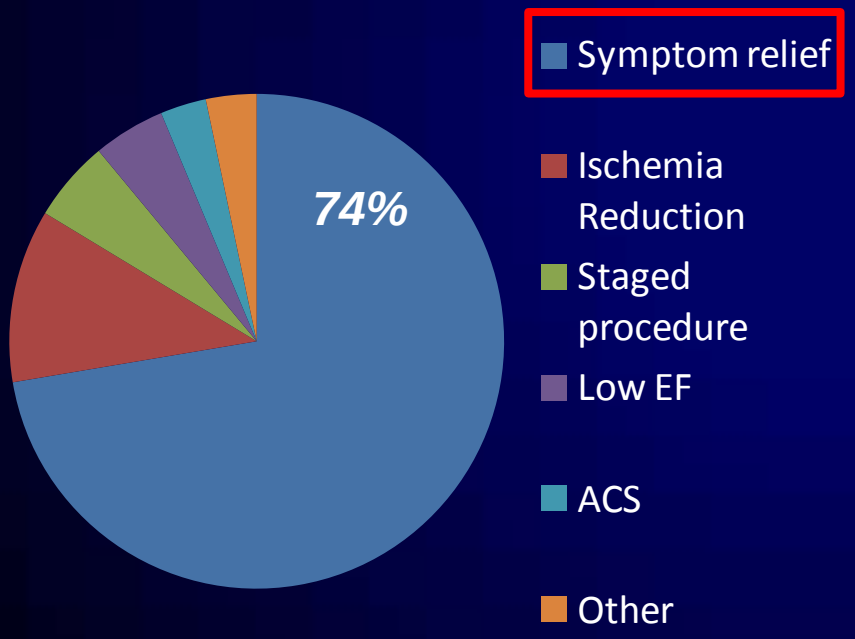
Baseline Patient and Lesion Characteristics in OPEN CTO

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

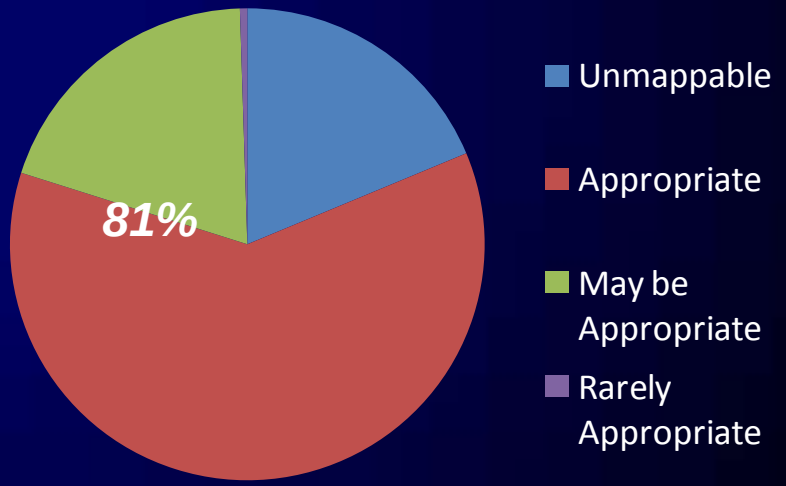
Angiographic Characteristic	
CTO only (%)	86.2
Complete Revasc (%)	82.3
Target Vessel RCA (%)	60.5
LAD (%)	19.6
LCX (%)	13.3
Occlusion Length (mm)	29.9 ± 24.3
Length>20 mm (%)	54.8
Total lesion length (mm)	63.4 ± 28.6
JCTO score <3 (%)	81.2
JCTO score ≥3 (%)	19.7

Indications and Appropriateness

Primary Indication



Appropriateness



Procedural Results in OPEN CTO

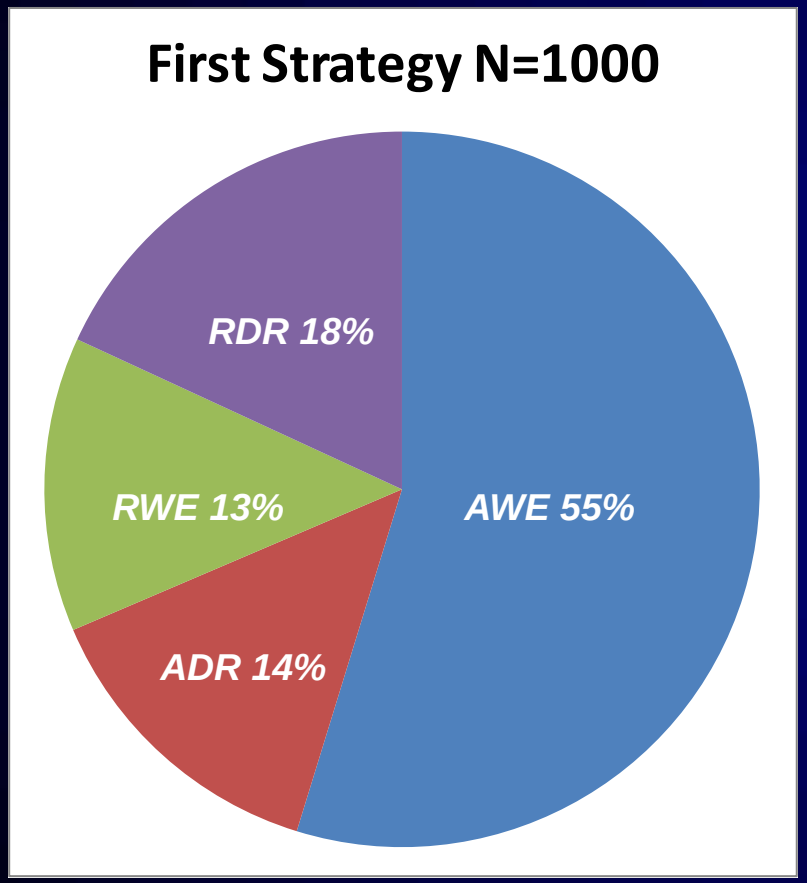
89% operator reported
86% core lab adjudicated

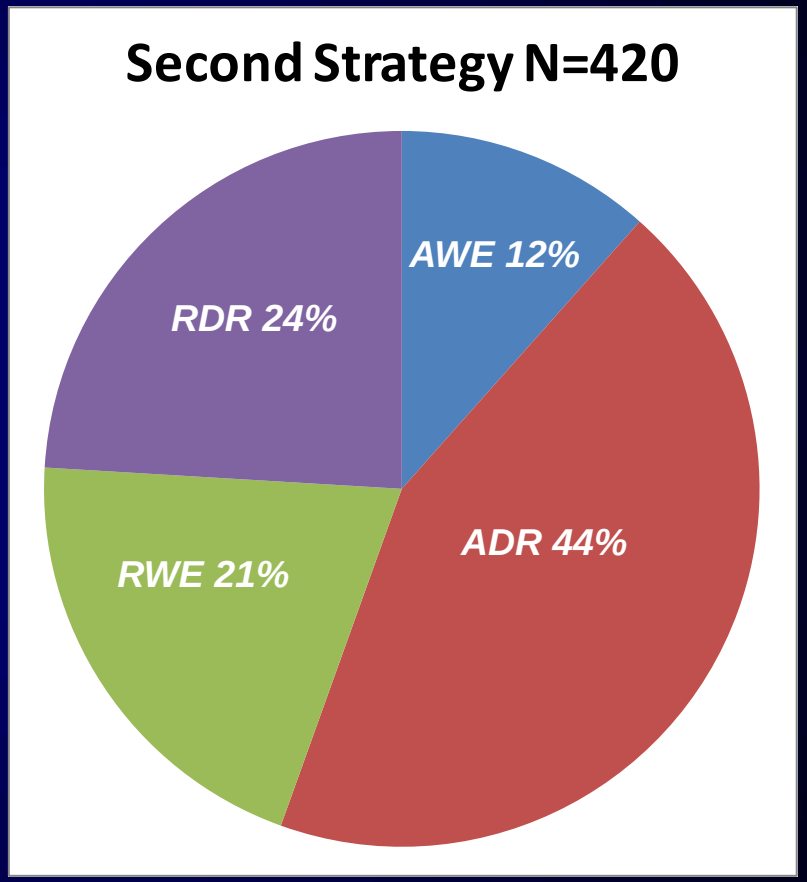
119 ± 72 min

2.5 ± 1.9 Gy

265 ± 194 ml

Hybrid Algorithm Use





Success rate 58%

Success rate 55%

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

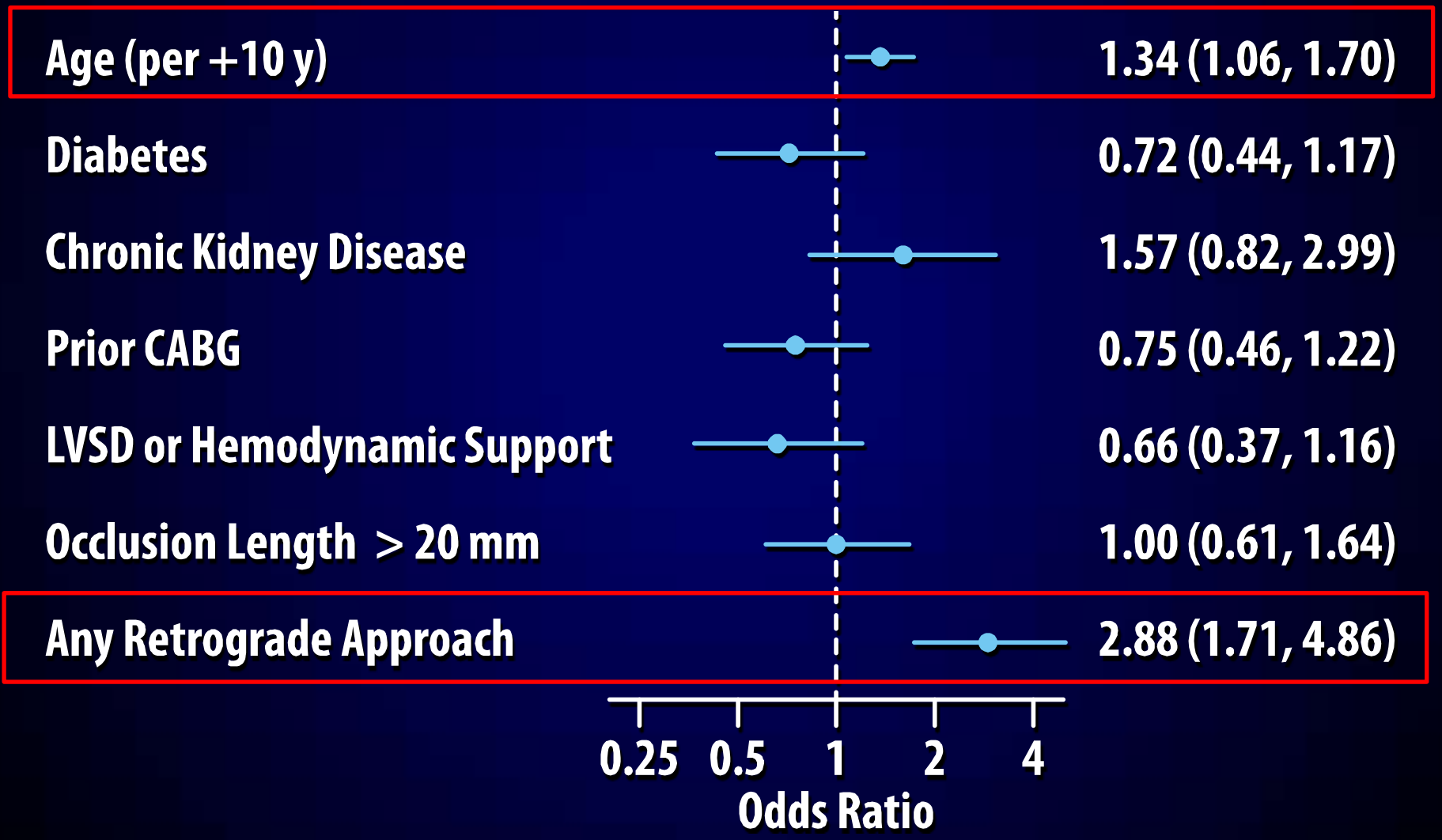
5/9 deaths associated with perforation were in post CABG patients

Unpublished Data from OPEN CTO

Procedural Mortality In Context

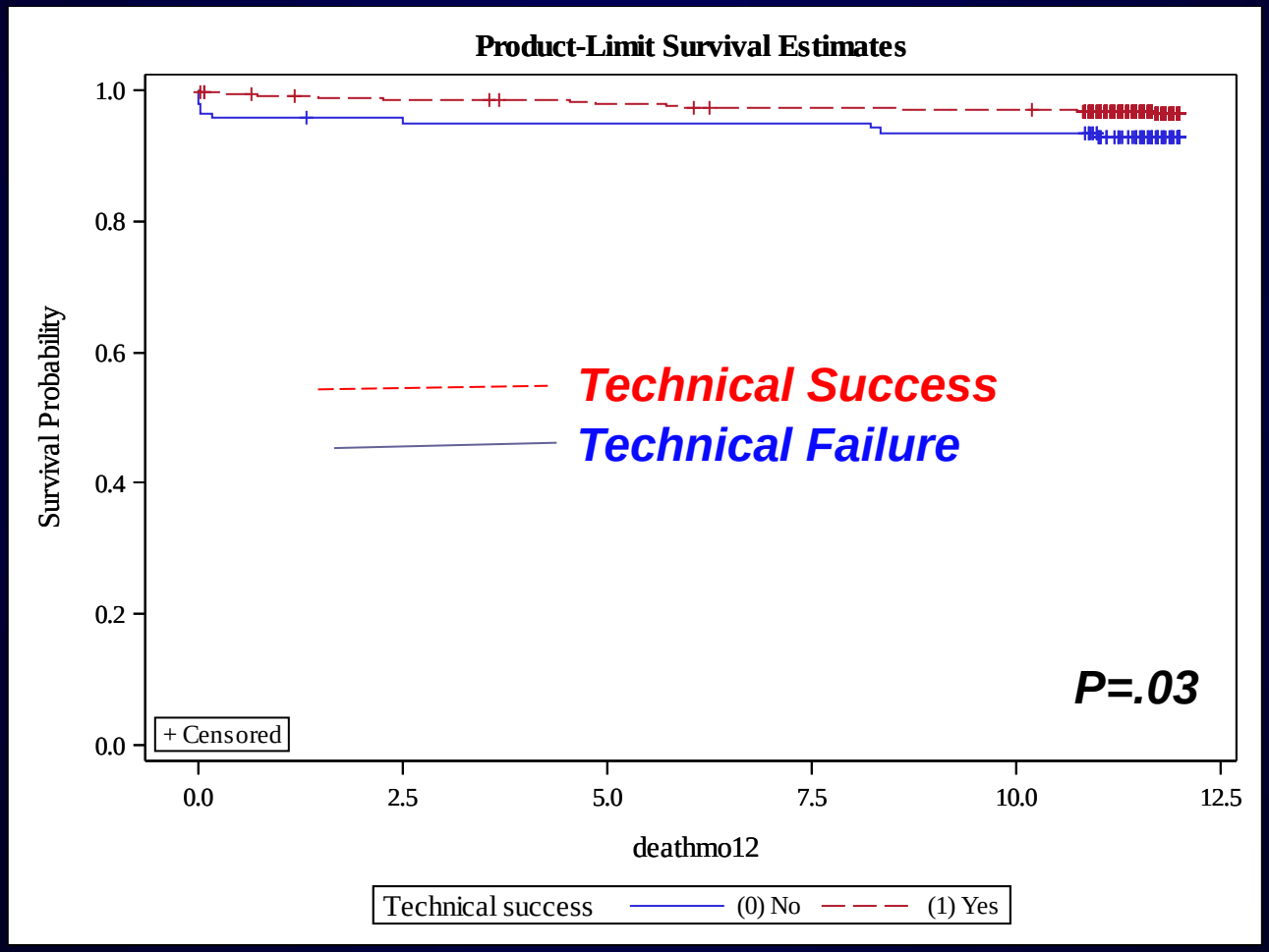
- 0.9% (95% CI 0.6-1.2%)
  - Mortality in NCDR registry 0.65%
  - Expected mortality by NCDR risk model 0.41%
  - Expected mortality of surgery from STS risk calculator 1.67%
  - Mortality associated with SVG PCI 1.1%

Predictors of MACCE



12 Month Mortality

Success vs Failure



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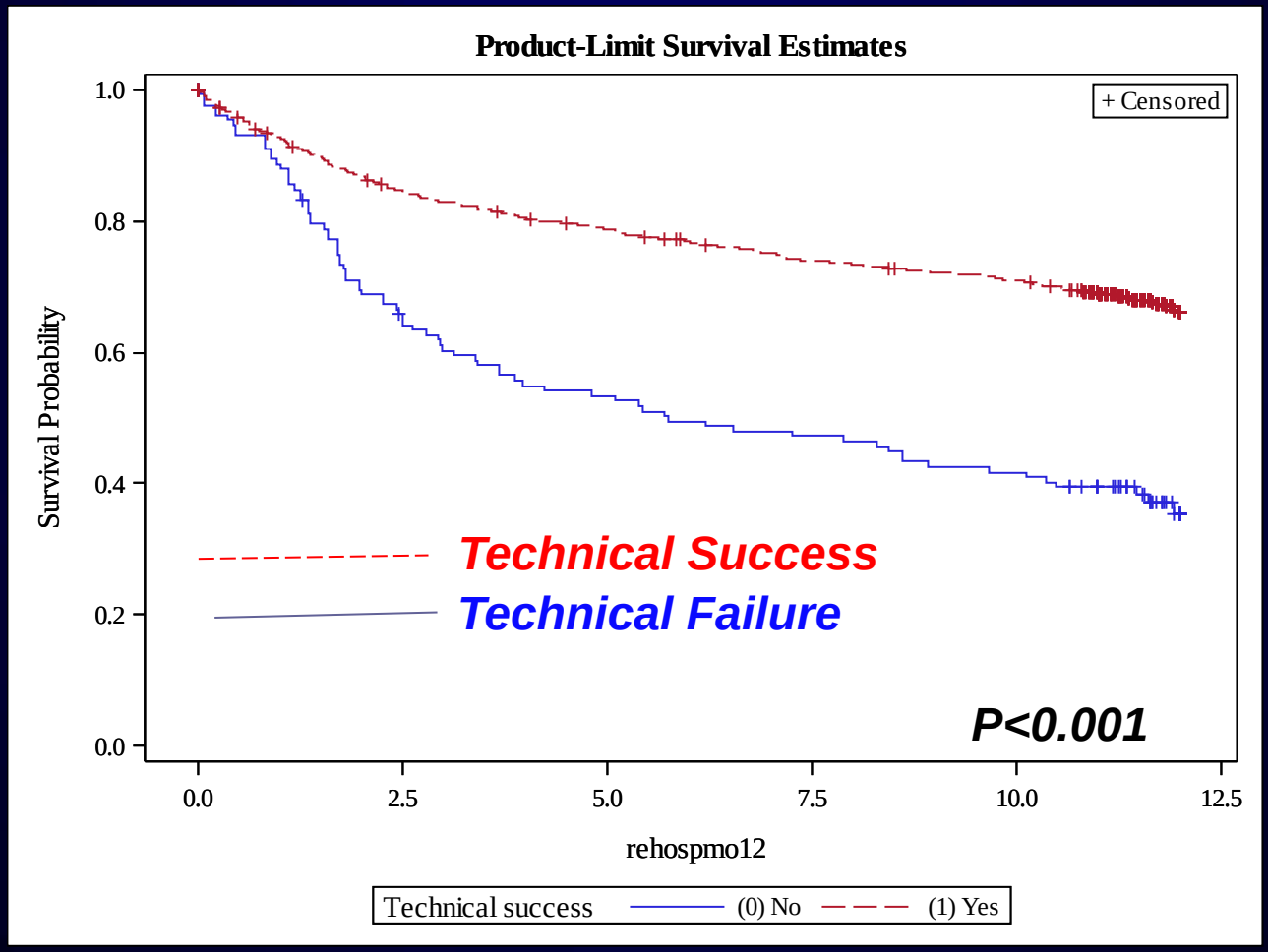
12 Month all Cause Rehospitalization



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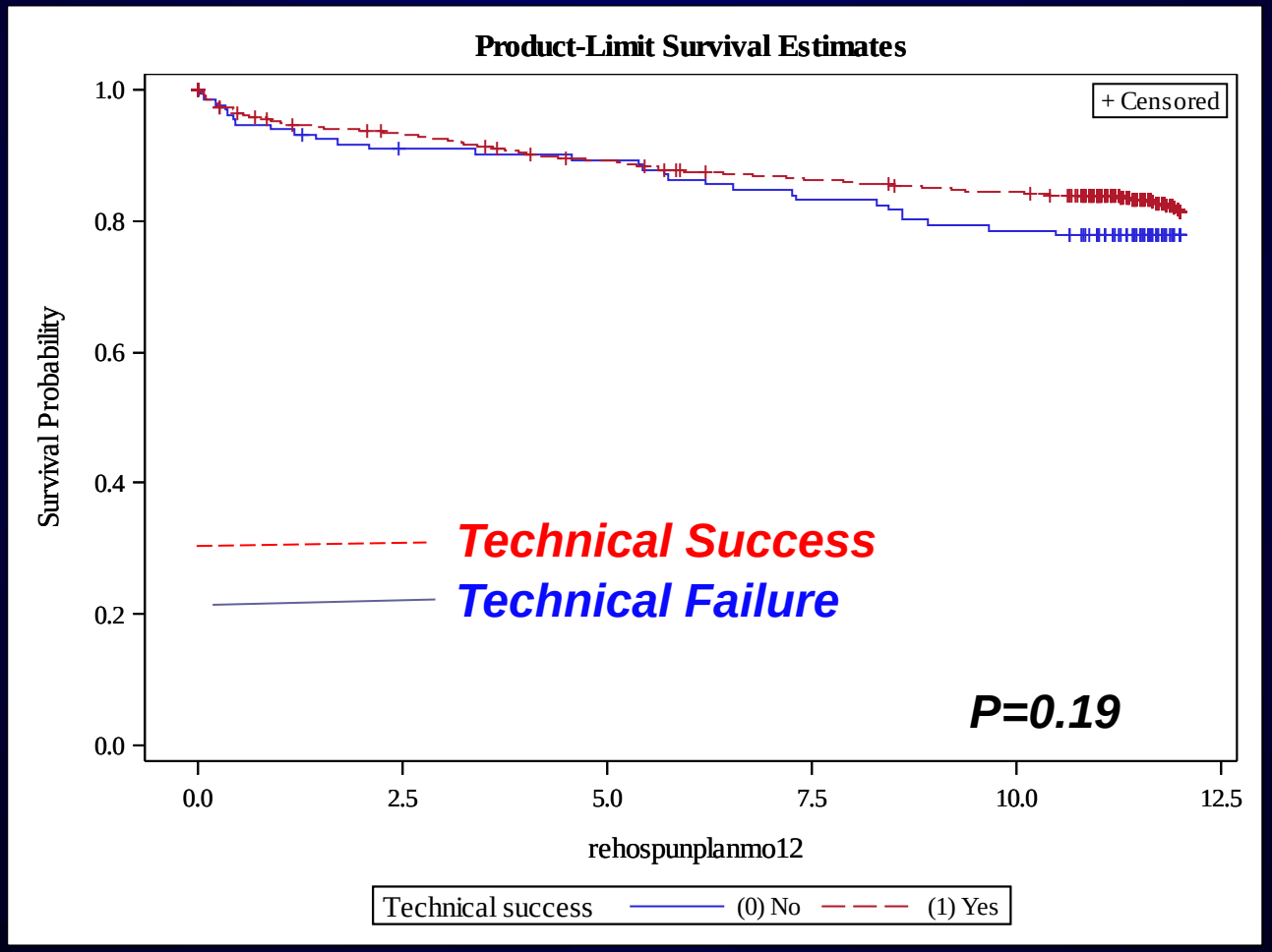
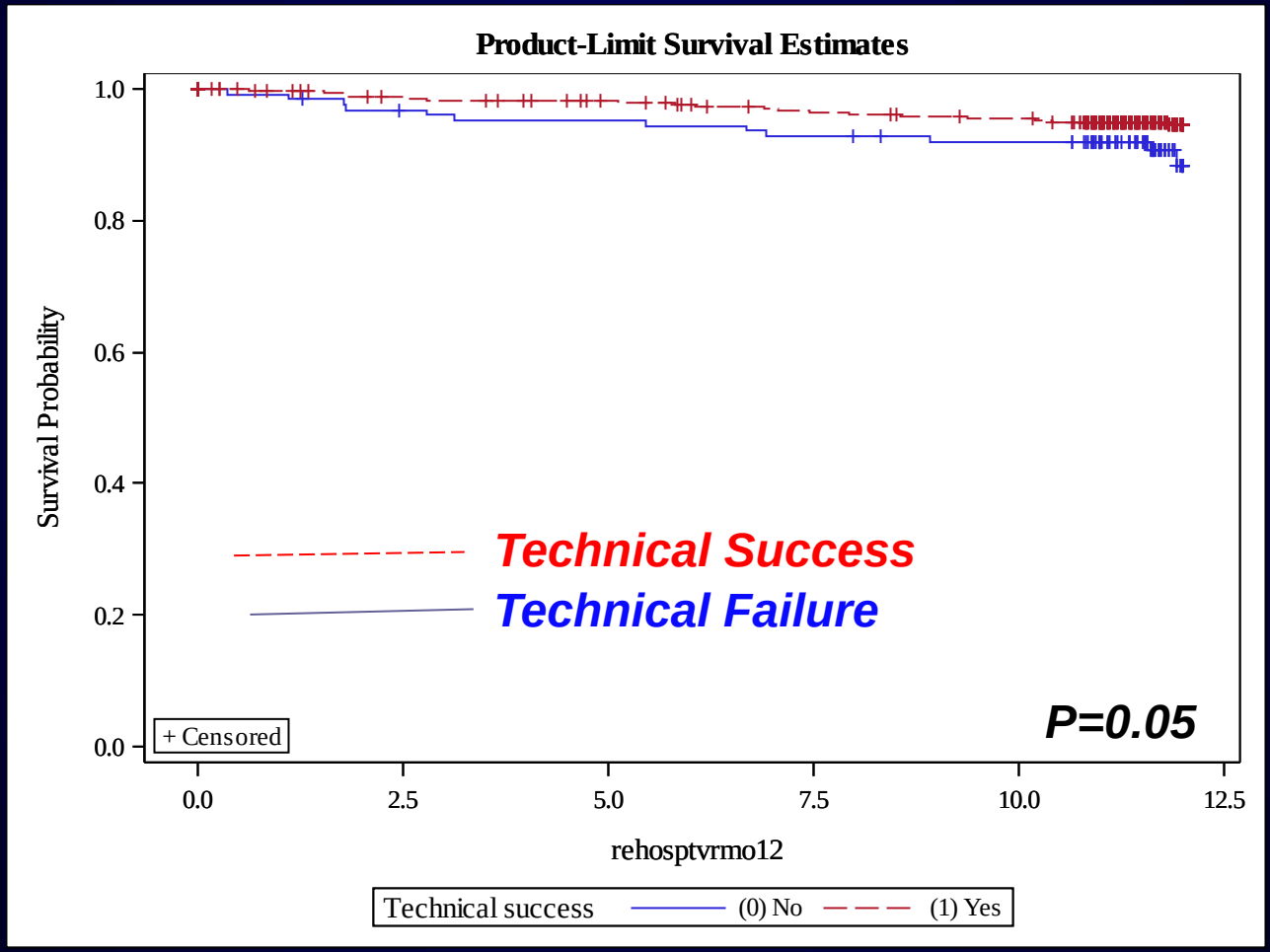
12 Month all Cause Unplanned Rehospitalization



12 Month TVR


Product-Limit Survival Estimates
Survival Probability
1.0
0.8
0.6
0.4
0.2
0.0
Technical Success
Technical Failure
P=0.05
+ Censored
0.0
2.5
5.0
7.5
10.0
12.5
rehosptvrmo12
Technical success
(0) No
(1) Yes

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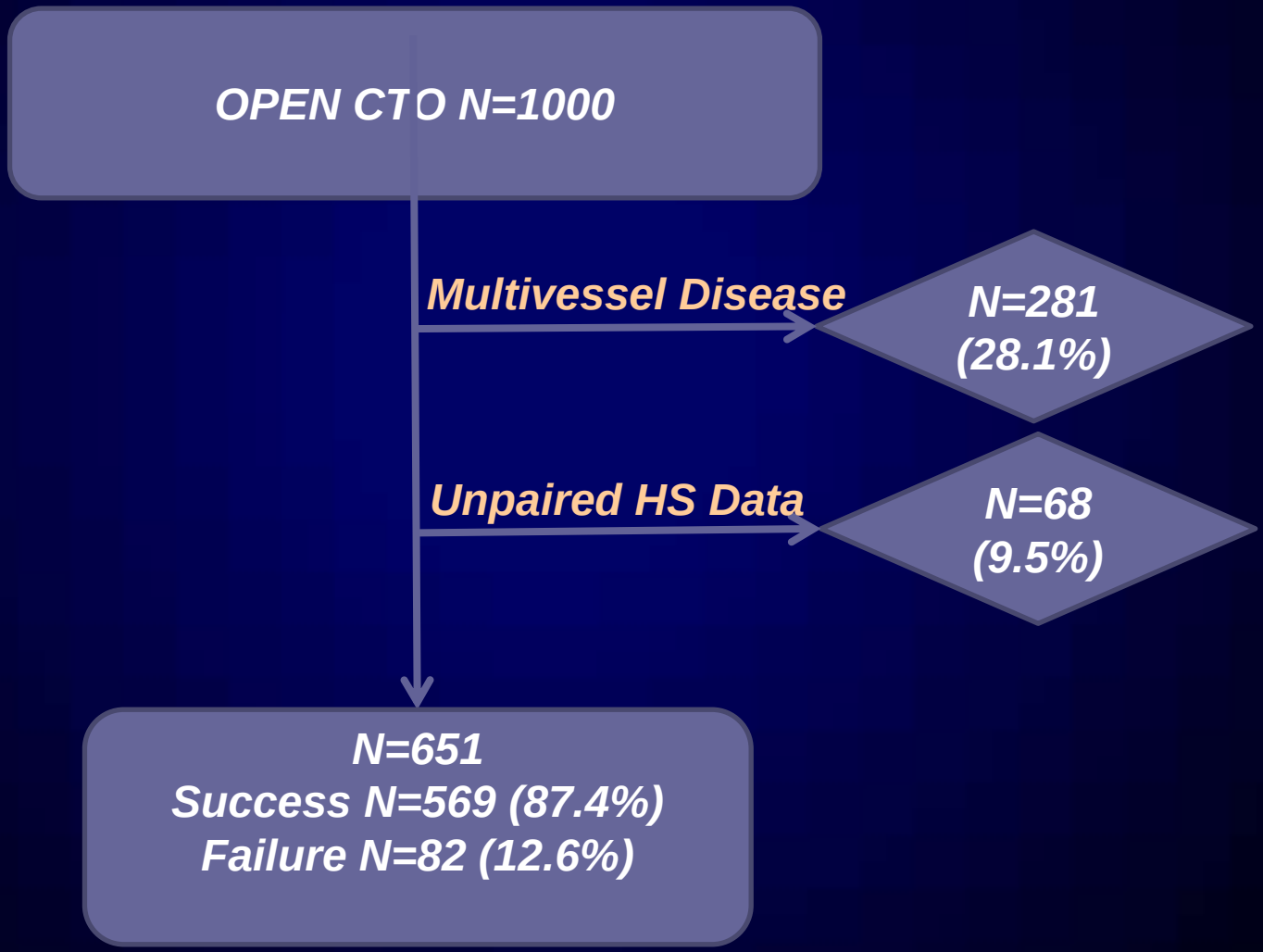
Outcomes After Single Vessel CTO PCI



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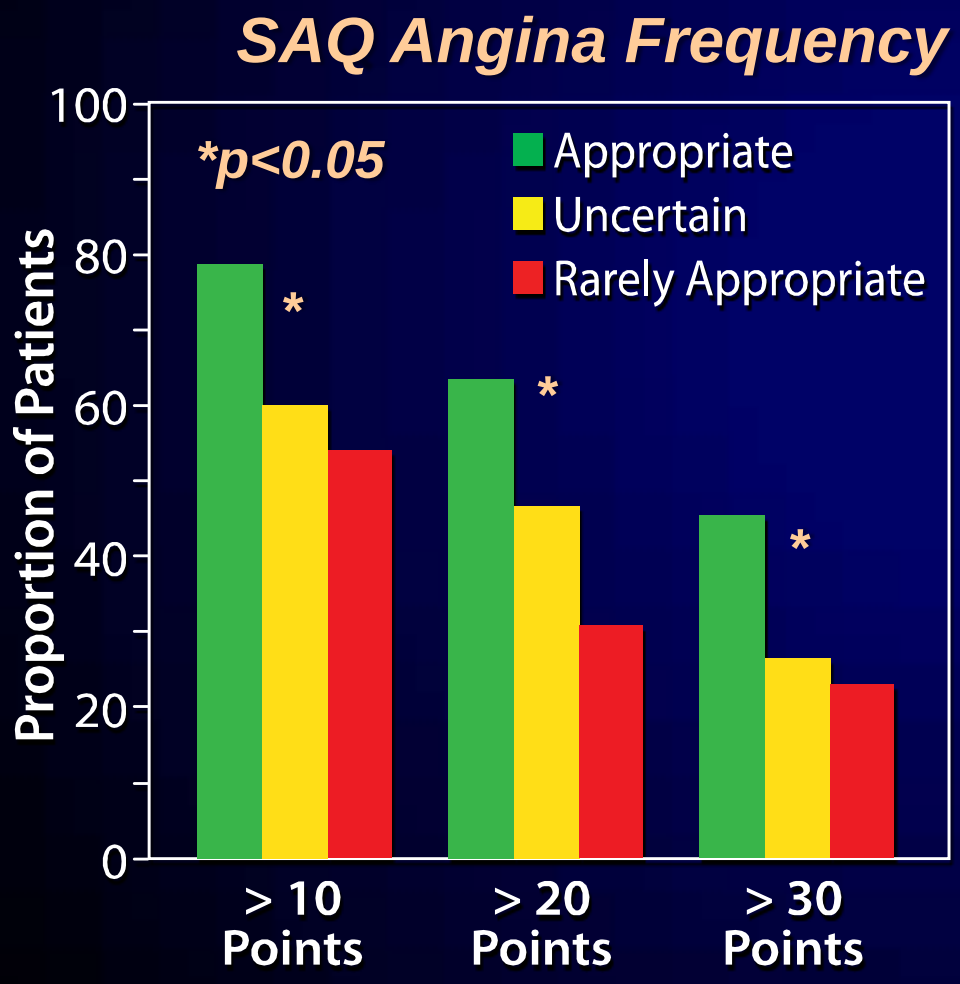
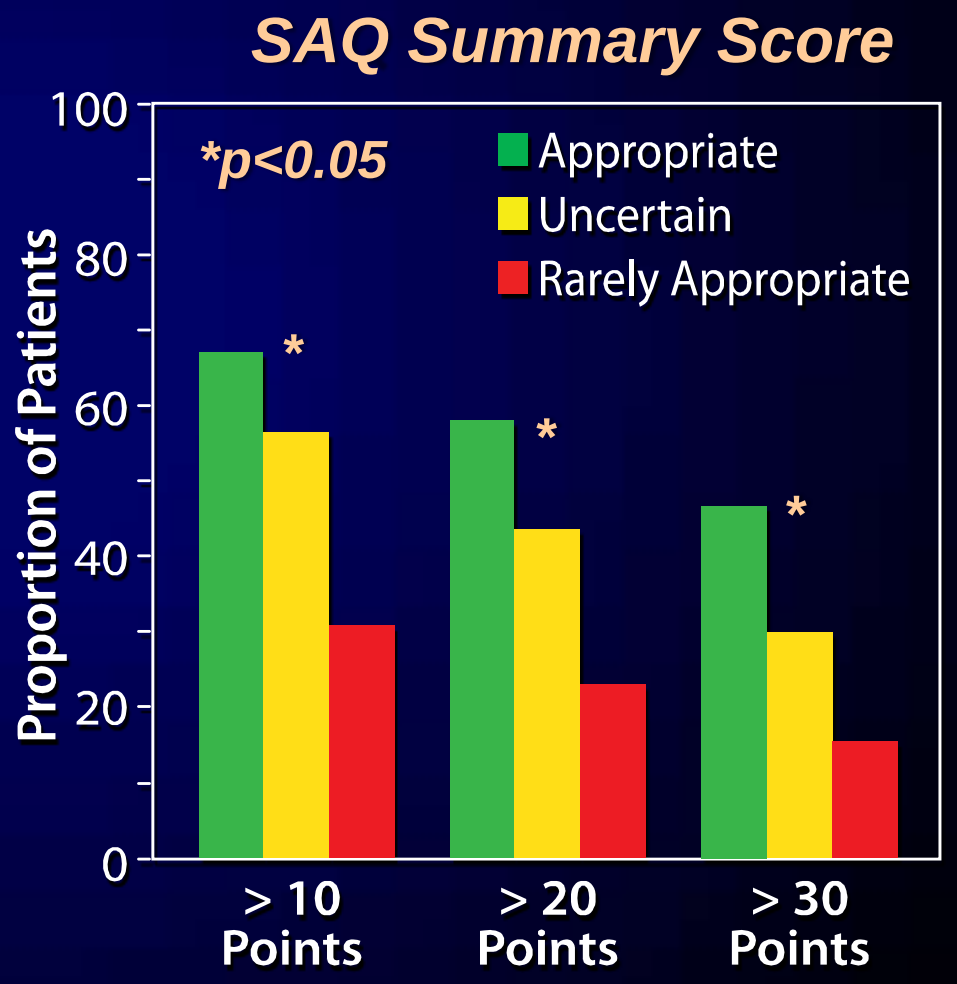
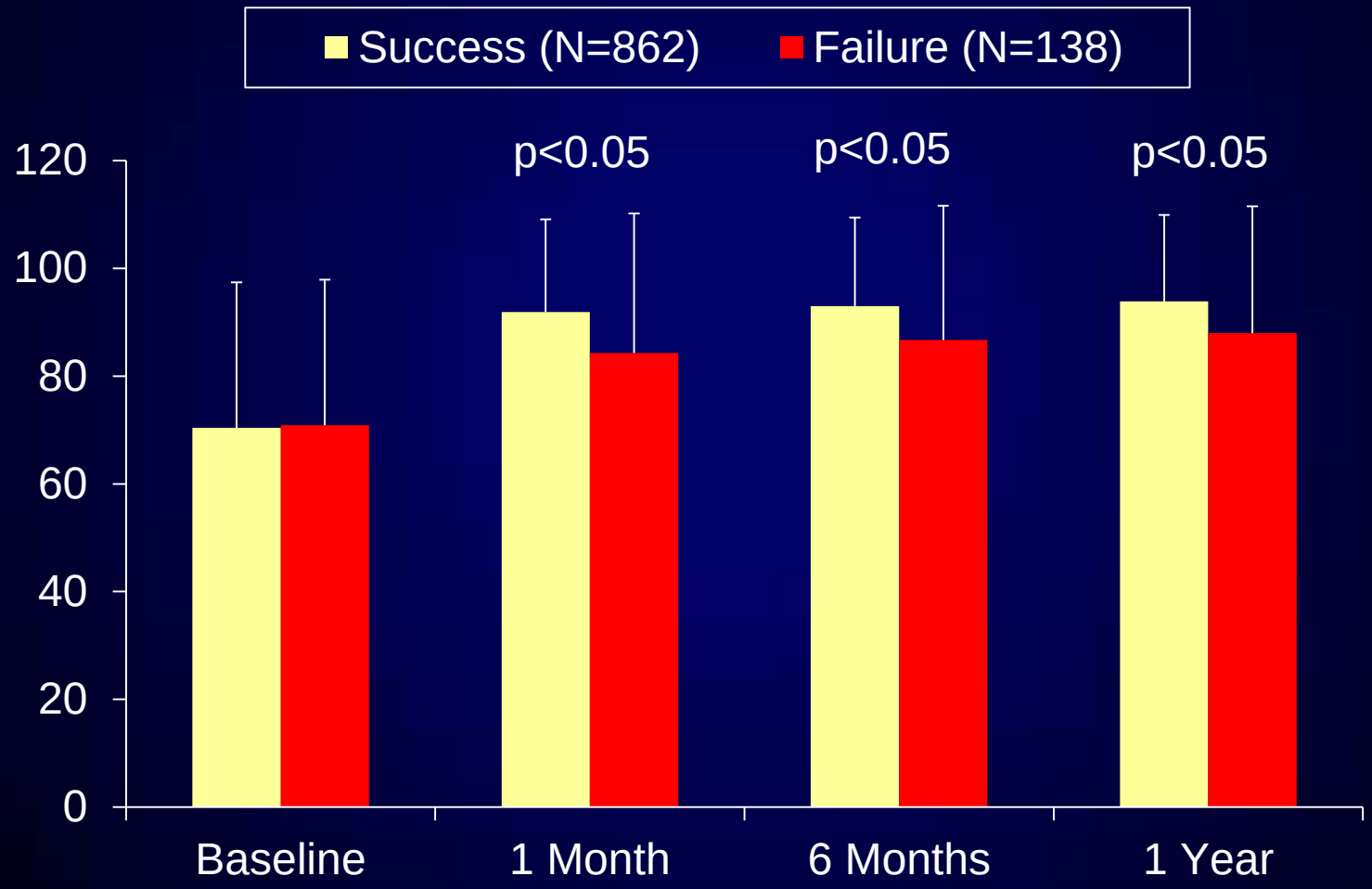
Appropriateness and Outcomes

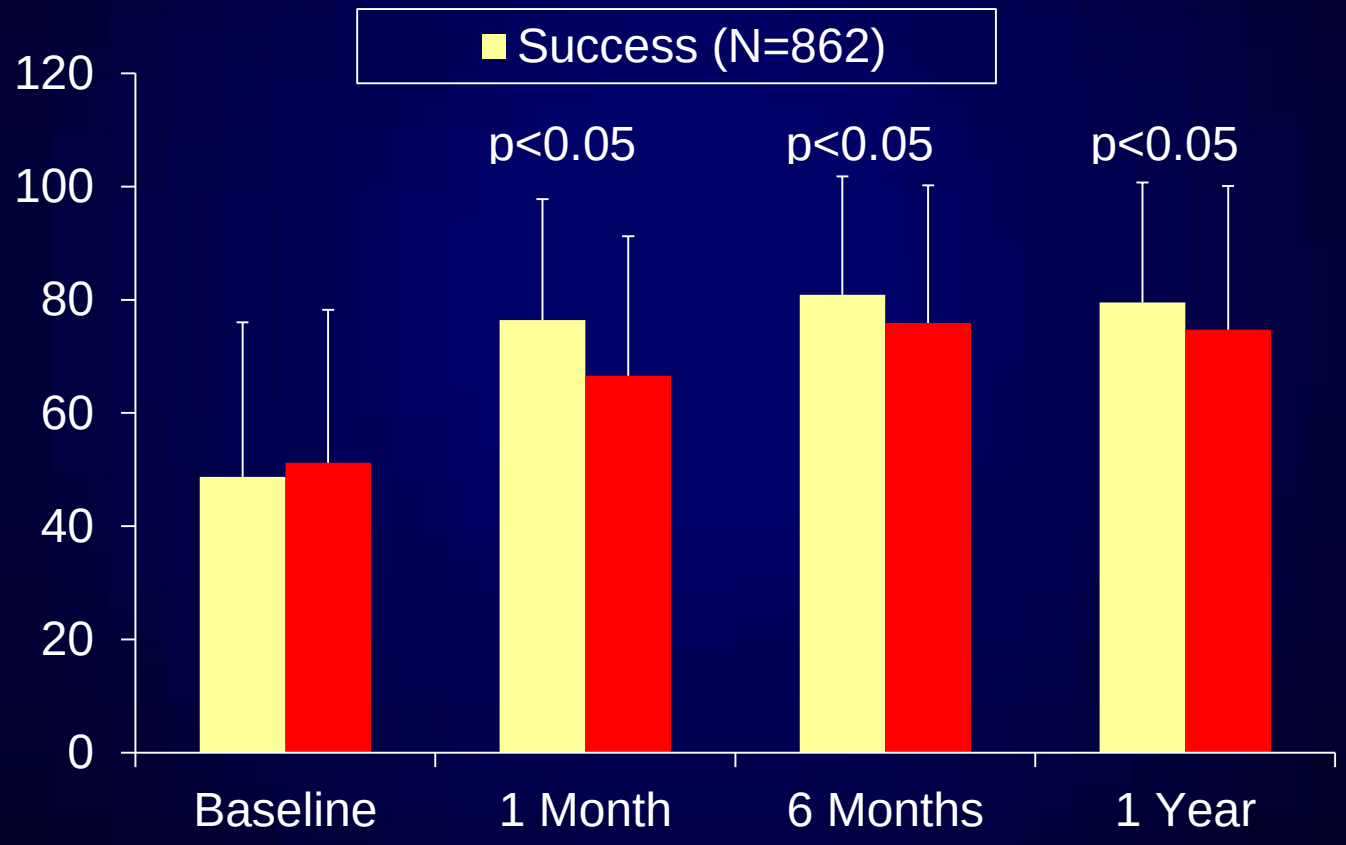




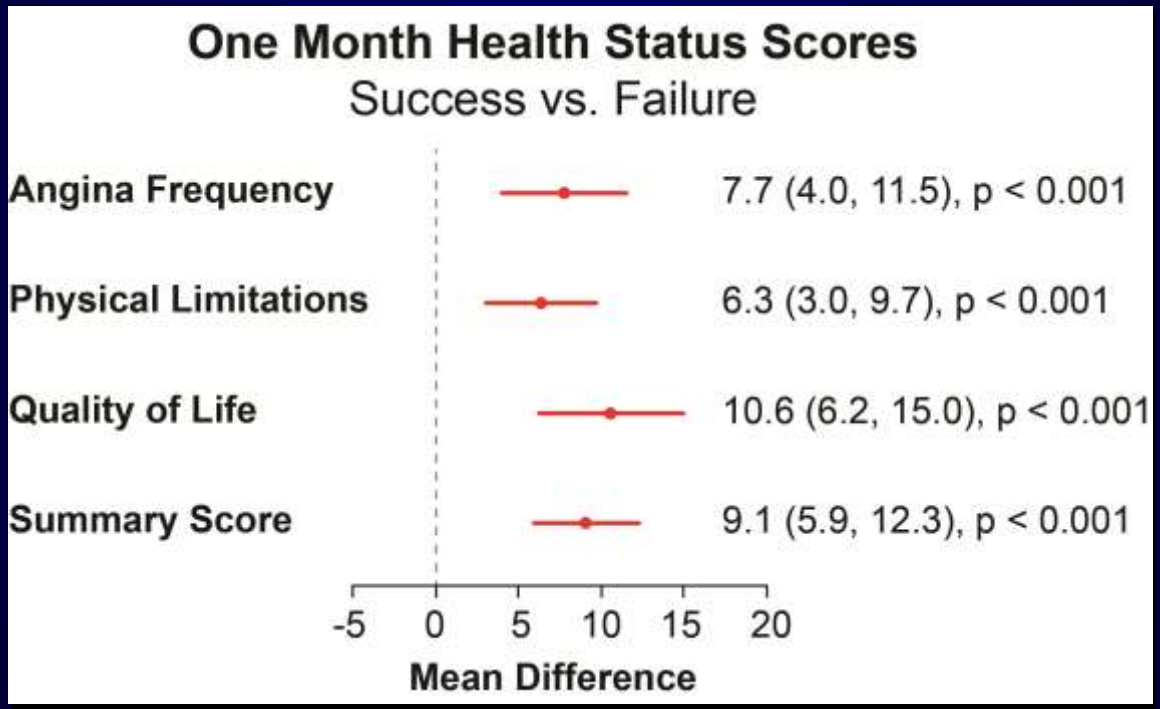
SAQ AF


Success (N=862)
Failure (N=138)
p<0.05
p<0.05
p<0.05
120
100
80
60
40
20
0
Baseline
1 Month
6 Months
1 Year

SAQ QoL


Success (N=862)
120
100
80
60
40
20
0
p<0.05
p<0.05
p<0.05
Baseline
1 Month
6 Months
1 Year

Adjusted Between Group Differences in Early HS Response to CTO PCI



Sapontis et al TCT 2016, Accepted JACC: CI

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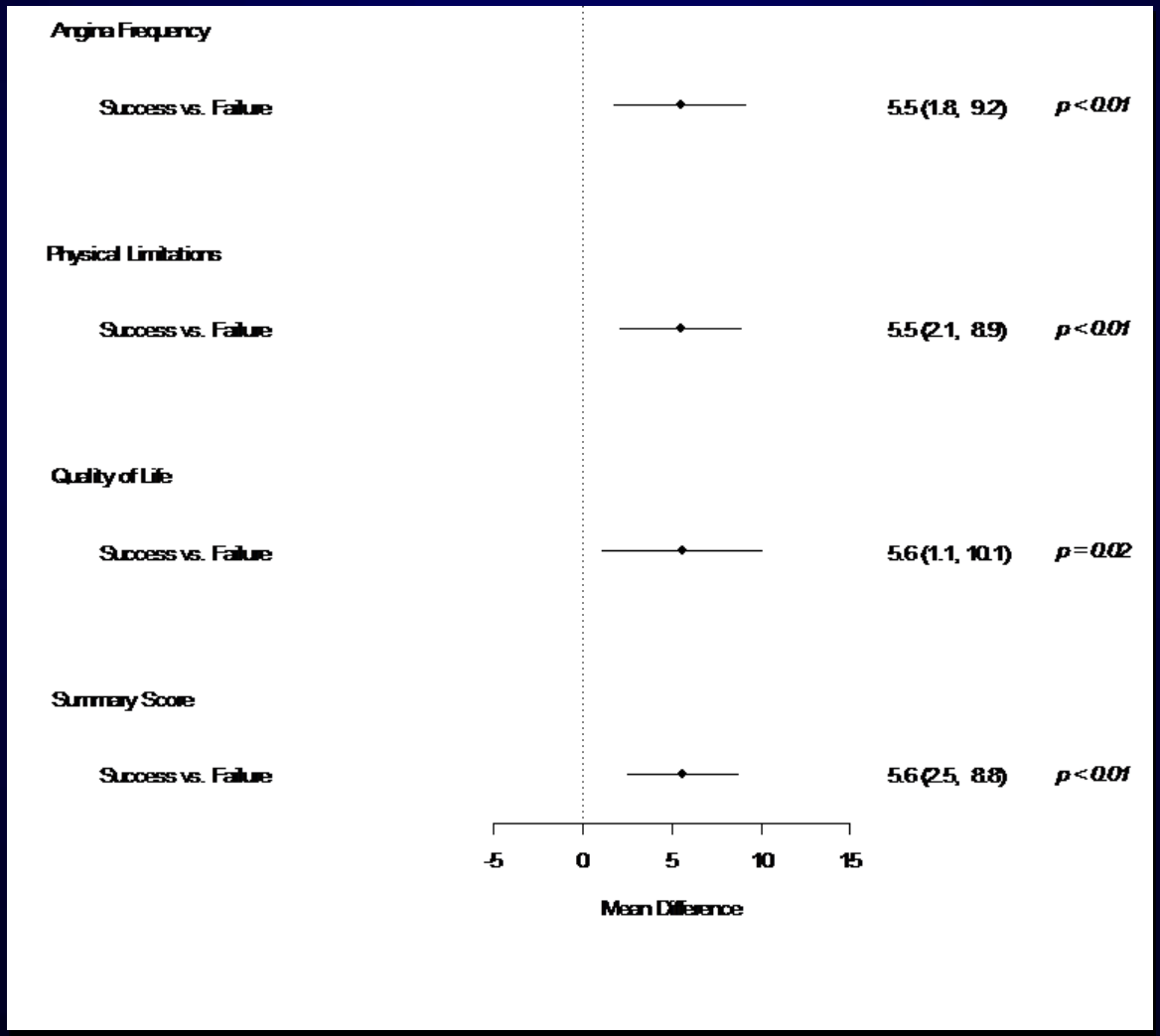
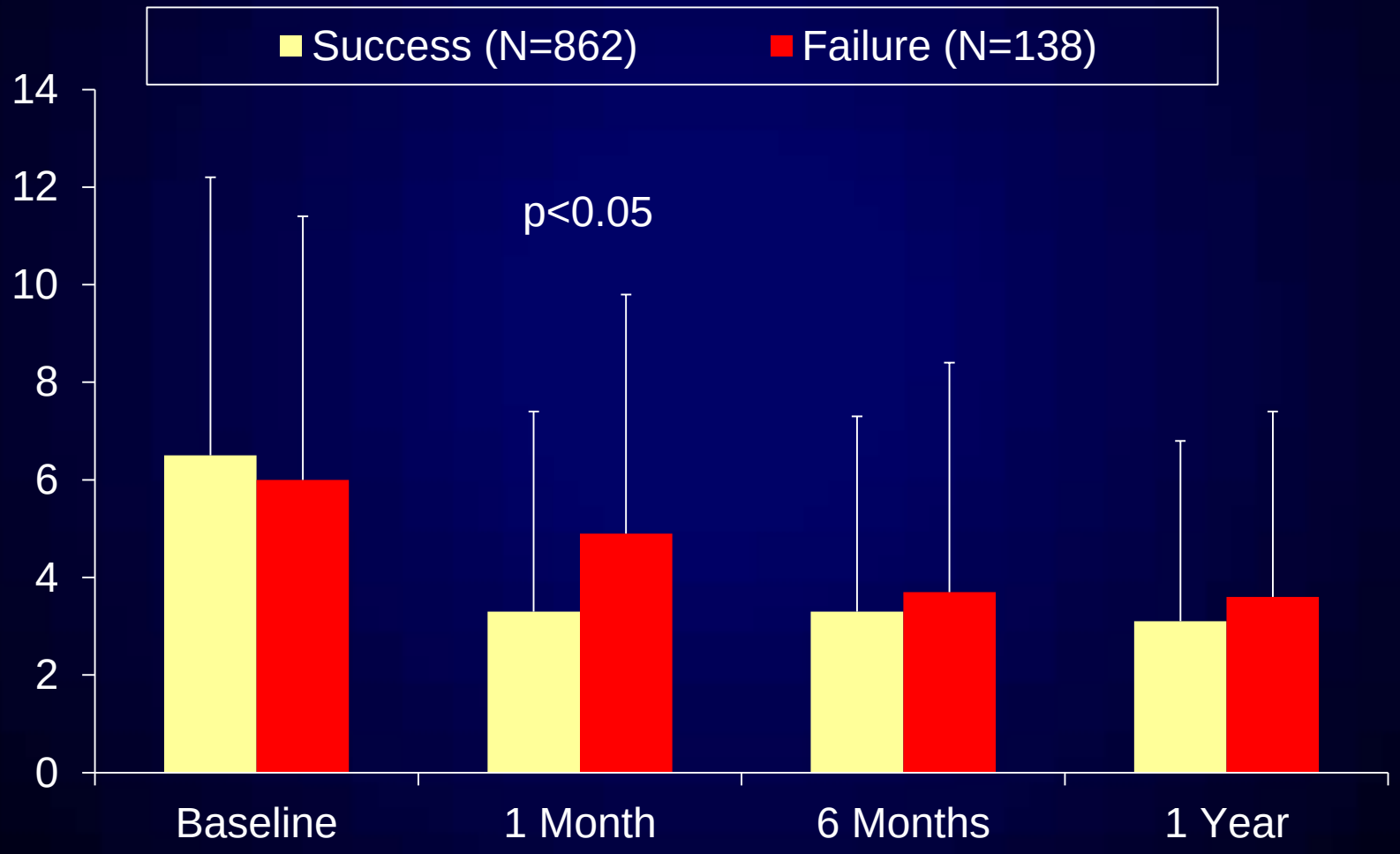
One Year Health Status Changes



Rose Dyspnea Score



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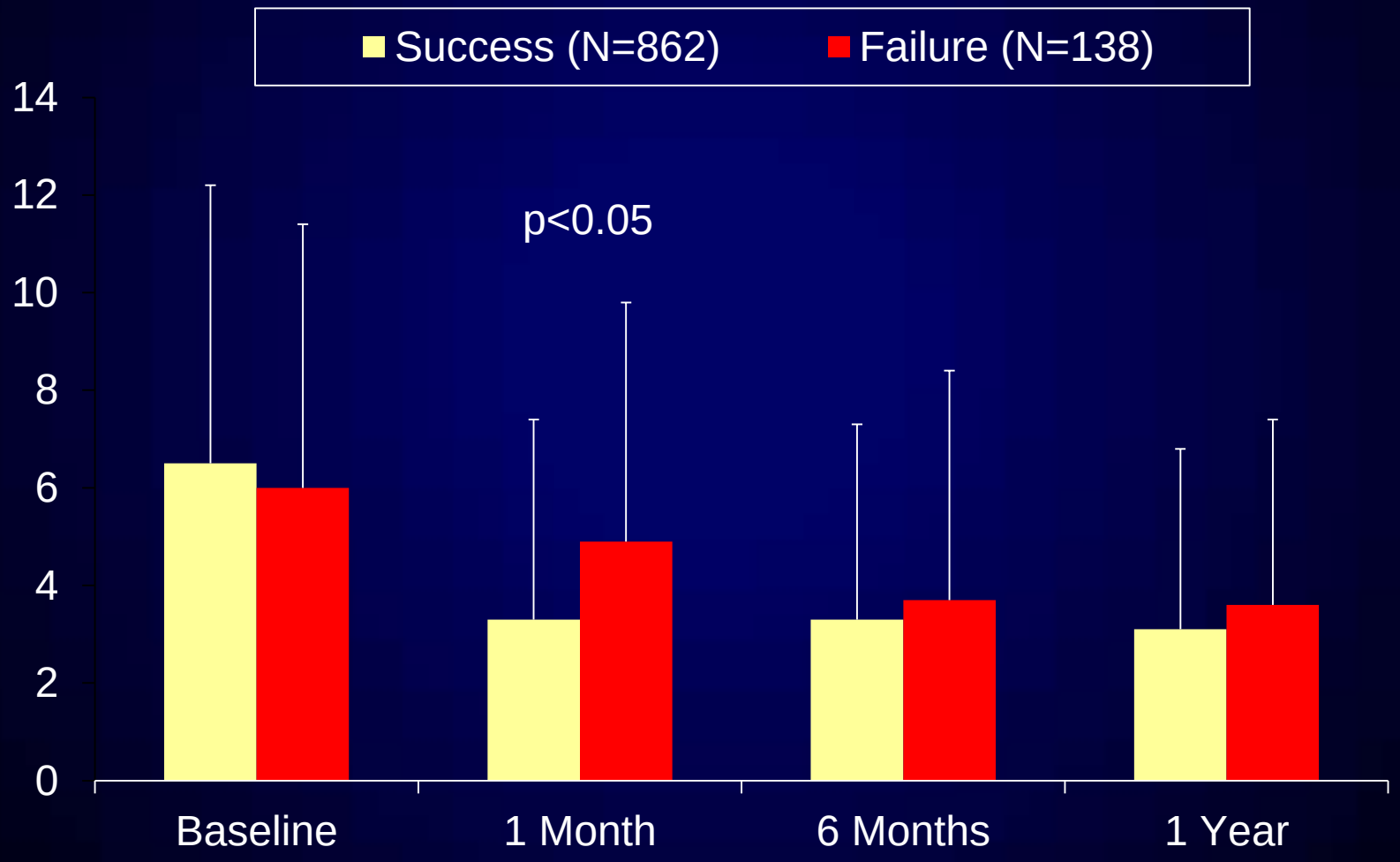
PHQ-8 Scores



Conclusions

- The early health status benefits of CTO PCI success vs failure are attenuated over time
- Primarily due to catch up among initially failed procedures
- Mechanisms might include reattempts, facilitated recanalization, med changes, accommodation, regression to the mean, or placebo effect
- Patients with appropriate indications gain the most in QoL, but rarely appropriate may benefit
- Clinical event rates (death, MI, TVR, rehospitalization) are similar among success and failed groups