Not All Lesions Need Revascularization: The Conundrum of "Completeness of Revascularization"

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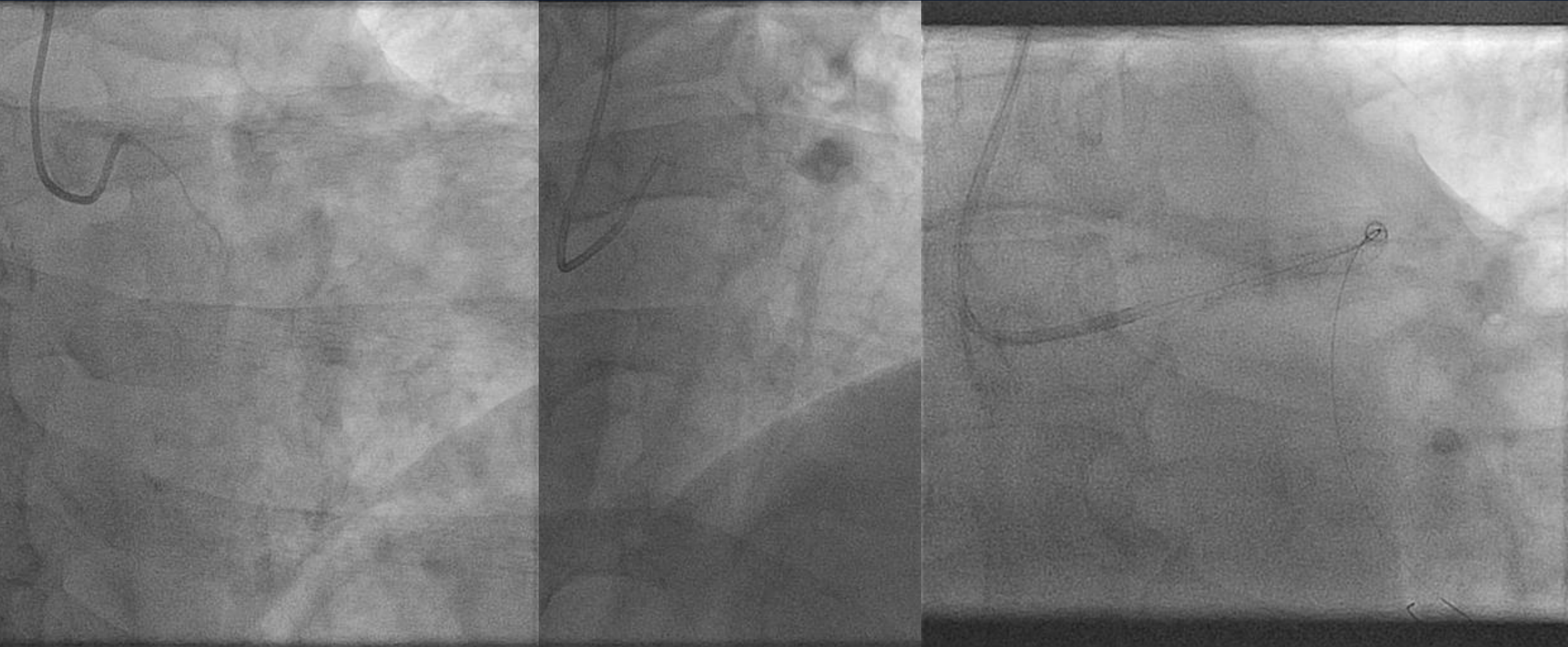
Complete or Incomplete Revascularization?



Complete Revascularization May *Not* Always Be the Best Goal for Patients

- The data for complete revascularization are not as strong as interventionalists would like to believe
  - Mostly observational data (especially for stable patients)

History of Complete Revascularization Data

- Long-term FU of early surgical series support CR at the time of CABG:
  - Reductions in angina
  - Improvements in mortality

- CR during CABG makes empiric sense:
  - Pros: Less ischemic burden with little downside (sternotomy, GA is free)
  - Cons:
    - Greater pump time
    - Greater progression of native disease?

Buda et al, J Thoracic and Cardiovasc Surgery 1981

NY State PCI Database Through the Years

Impact of Incomplete Revascularization on Outcomes

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HR 1.1

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1 IR with no

1 IR vessel i

≥2 IR, no CT

≥2 IR, ≥1 CT

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CR

IR (All)

1 IR with no

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NY State: EES vs. CABG
Impact of CR vs. ICR on Outcomes

Propensity-Matched Analysis of 18,446 pts; CR in 21%

		HR (EES vs. CABG)	p	Interaction p
Death	Complete	1.08 (0.82,1.42)	0.58	0.77
	Incomplete	1.03 (0.91,1.17)	0.63	
MI	Complete	*1.02 (0.71,1.47)*	*0.93*	*0.02*
	Incomplete	*1.66 (1.39,1.98)*	*<0.001*	
Stroke	Complete	0.43 (0.24,0.75)	0.003	0.16
	Incomplete	0.66 (0.52,0.83)	<0.001	
Rpt Revasc	Complete	*1.55 (1.26,1.90)*	*<0.001*	*<0.001*
	Incomplete	*2.59 (2.34,2.88)*	*<0.001*	

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Bangalore et al, NEJM 2015

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When does “comparative effectiveness” in fact represent “ineffective comparativeness”??

Are these really comparable?

Complete Revasc

vs.

Culprit-Only

Images c/o M. Mack

RCT of CR vs. ICR for MVD PCI

Single-center study in Netherlands; 4.6 year follow-up

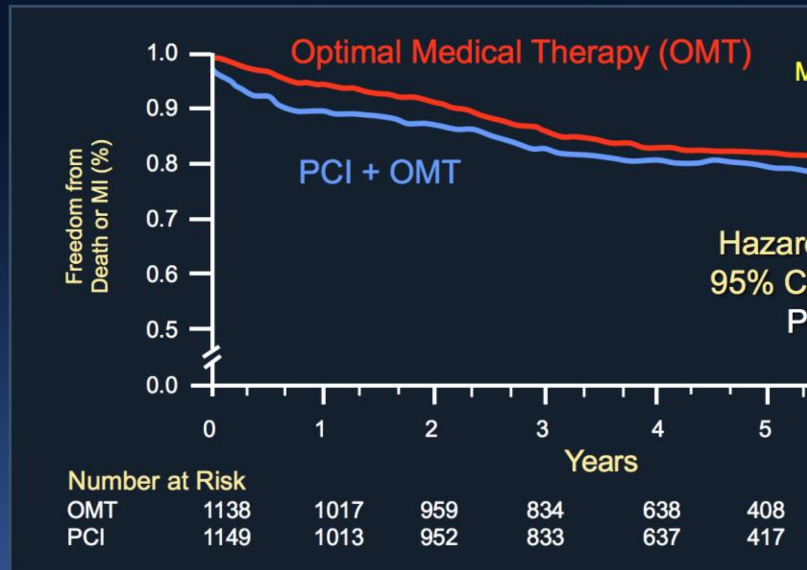
6% 3VD; "non-culprit" LAD 36%

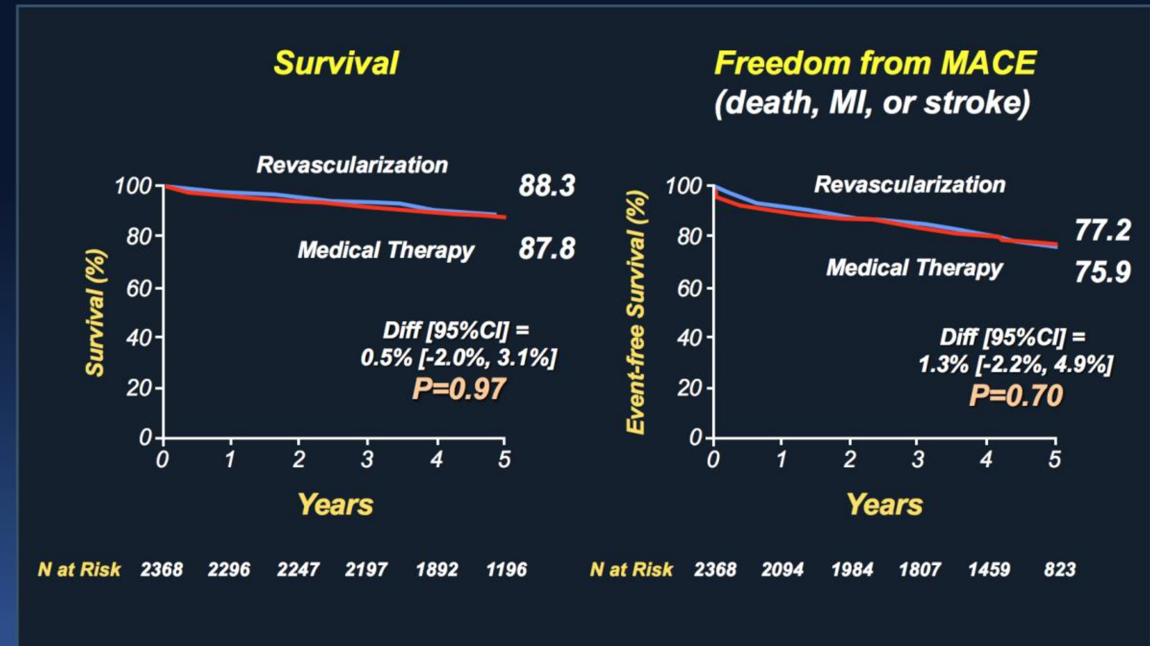
	"Culprit" Only n=109	Complete n=104	p
Overall MACE	40.4%	34.6%	0.40
Cardiac Death	0.9%	3.8%	0.21
MI	7.3%	10.6%	0.48
Repeat PCI	31.2%*	21.2%	0.06

*21% of PCIs were of previously untreated disease

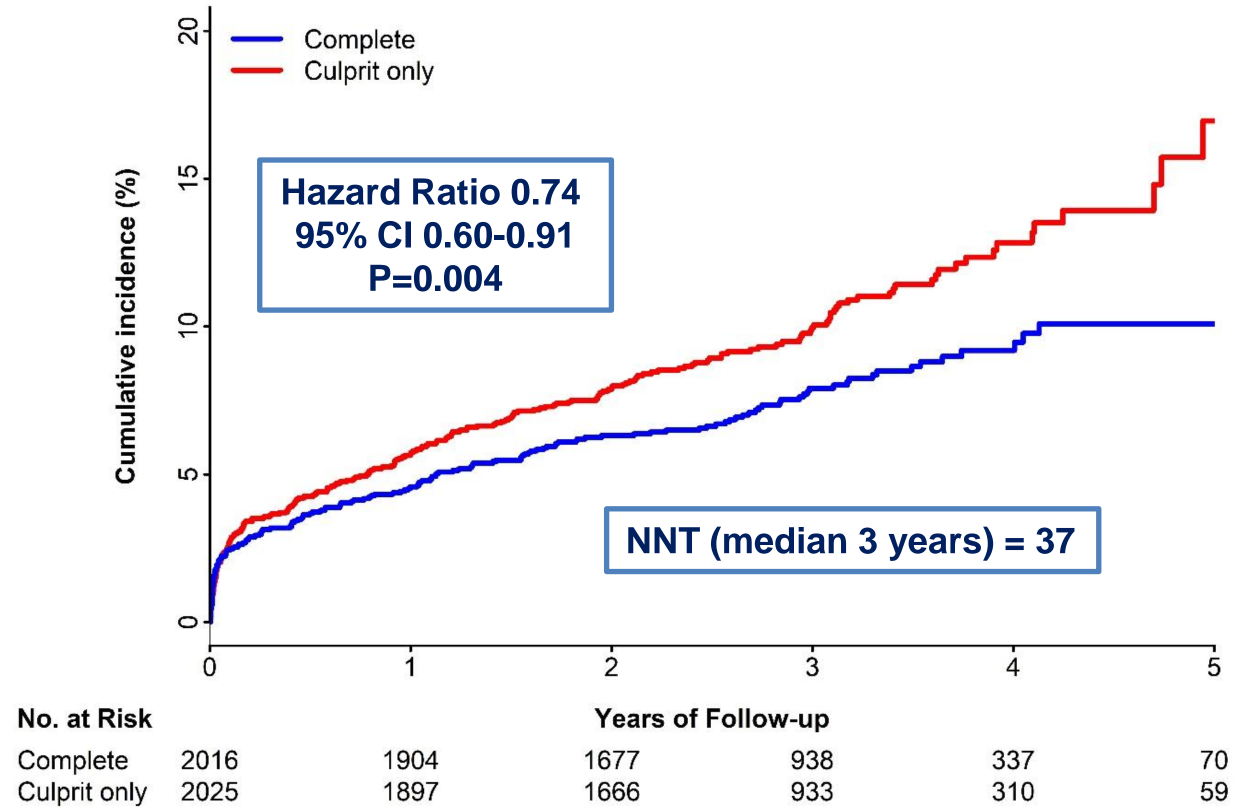
Ijsselmuiden et al, Am Heart J 2004

And What About These Trials of the Ultimate Form of Incomplete Revascularization (Medical Therapy)?

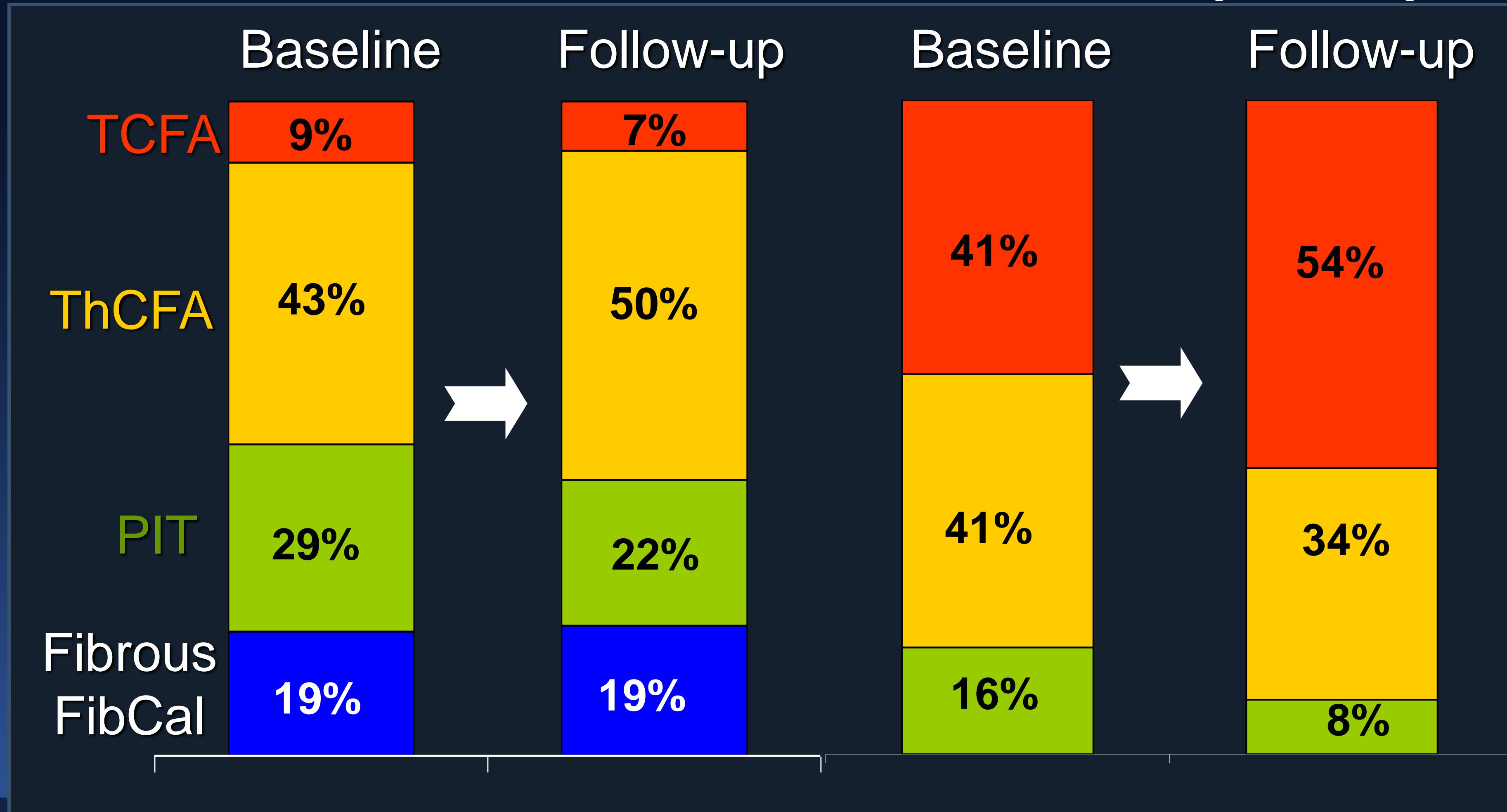




First Co-Primary Outcome: CV Death or New MI



Differences in Temporal Changes of Non-Culprit Lesions



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TCFA, thin-cap fibroatheroma; ThCFA, thick-cap fibroatheroma; PIT, pathological intimal thickening; FibCal, fibrocalcific

Zhao Z et al. J Am Coll Cardiol Img. 2013;6:86-95

Columbia University Medical Center
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The University Hospital of Columbia and Cornell

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  - There may be an optimal revascularization “threshold”

Definitions of Incompleteness of Revascularization

- **Anatomic:**
  - Residual stenosis 50% or 70%
  - Vessel diameter >1.5 mm, >2.5 mm
  - SYNTAX segments

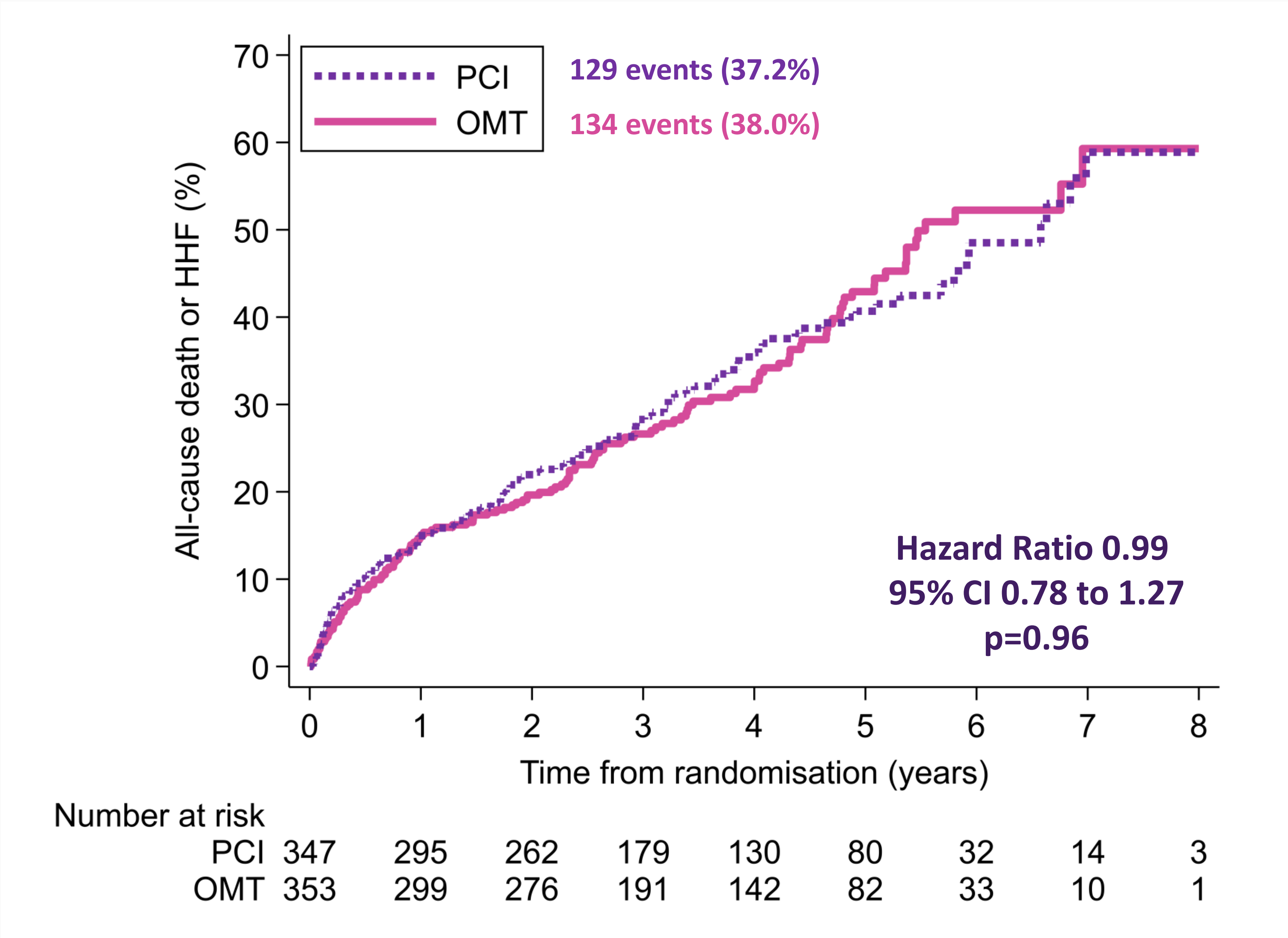
Jeopardy or SYNTAX Score

- **Functional / Physiologic**
  - Non-invasively assessed viable and ischemic segments
  - FFR <0.75 or <0.8

Extent of Ischemia or Functional SYNTAX Score

REVIVED

Primary Outcome



Perera et al, NEJM 2022

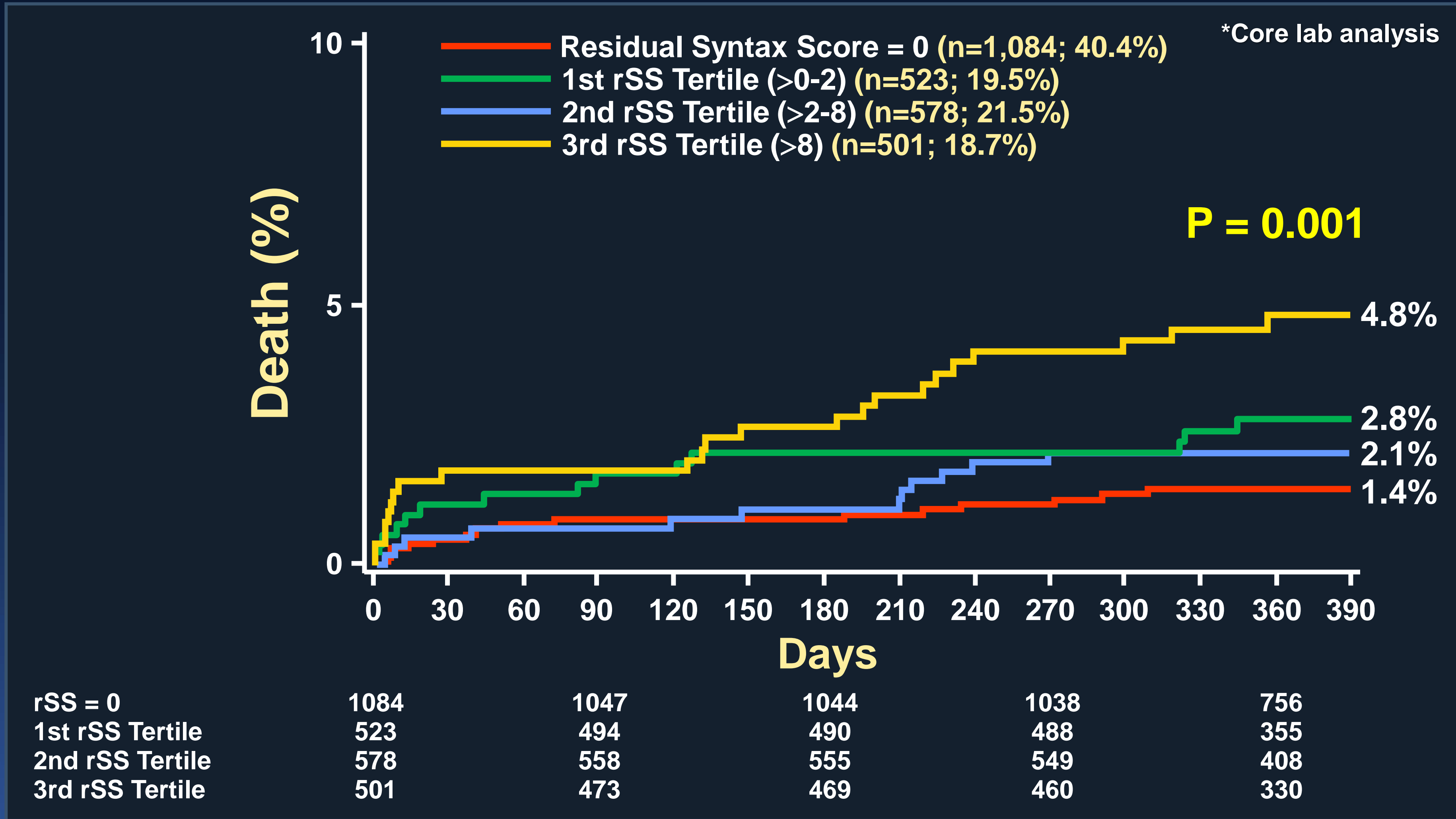
	PCI (N = 347)	OMT (N = 353)
Age – yrs	70.0 ± 9.0	68.8 ± 9.1
Male sex – no. (%)	302 (87)	312 (88)
Hypertension – no. (%)	184 (53)	207 (59)
Diabetes – no. (%)	136 (39)	153 (43)
Left ventricular ejection fraction - %	27.0 ± 6.6	27.0 ± 6.9
Viability assessment – no. (%)		
Cardiac MRI	246 (71)	247 (70)
Stress echocardiography	91 (26)	93 (26)
SPECT/PET	14 (4)	17 (5)
Coronary artery disease characteristics		
Median BCIS jeopardy score (IQR)	10 (8 to 12)	10 (8 to 12)
Left main coronary artery disease – no. (%)	50 (14)	45 (13)
3-vessel coronary artery disease – no. (%)	133 (38)	148 (42)
2-vessel coronary artery disease – no. (%)	178 (51)	166 (47)

Median of 2 lesions and vessels treated per patient

Completeness of revascularization reported in 71% (anatomically)!!

Perera et al, NEJM 2022

Residual SYNTAX Score: SS Calculated* pre and post PCI in 2,686 pts from ACUITY



Généreux P et al. *J Am Coll Cardiol.* 2012;59:2165-74

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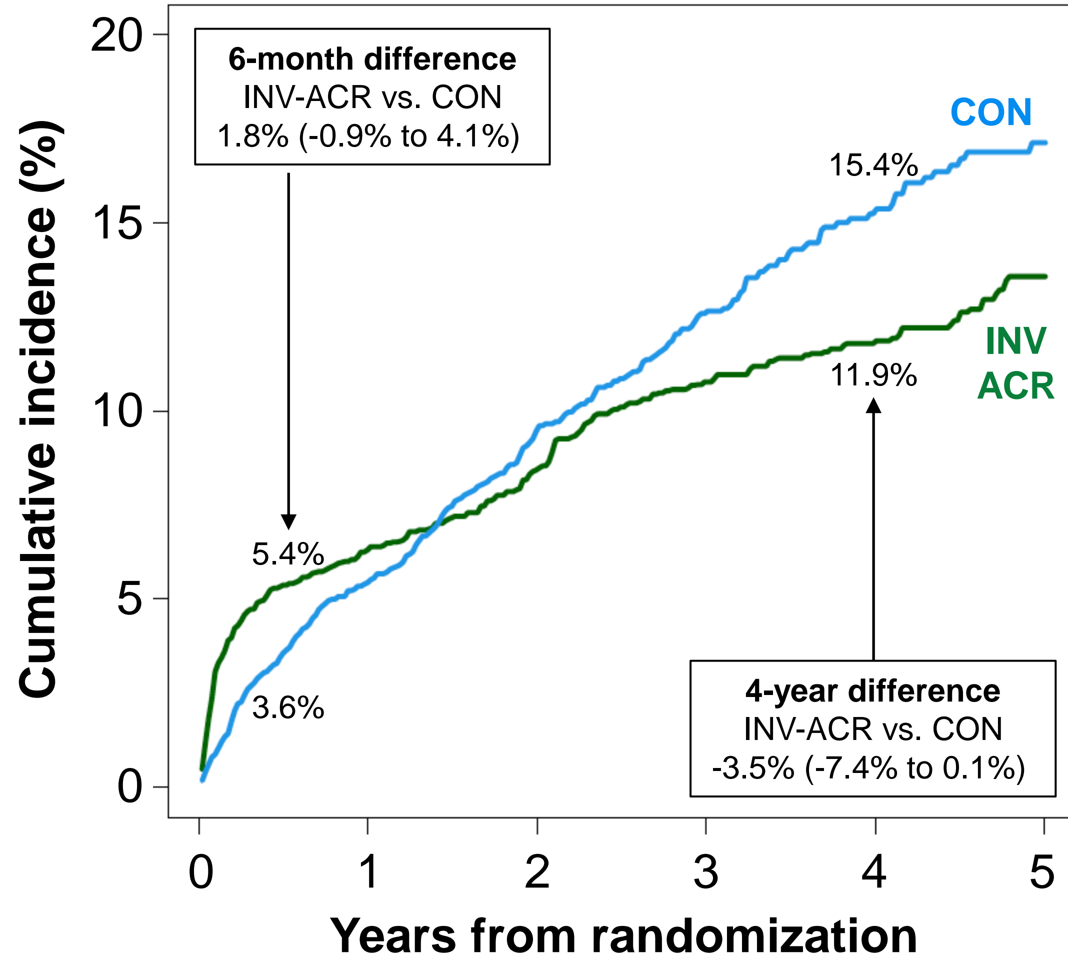
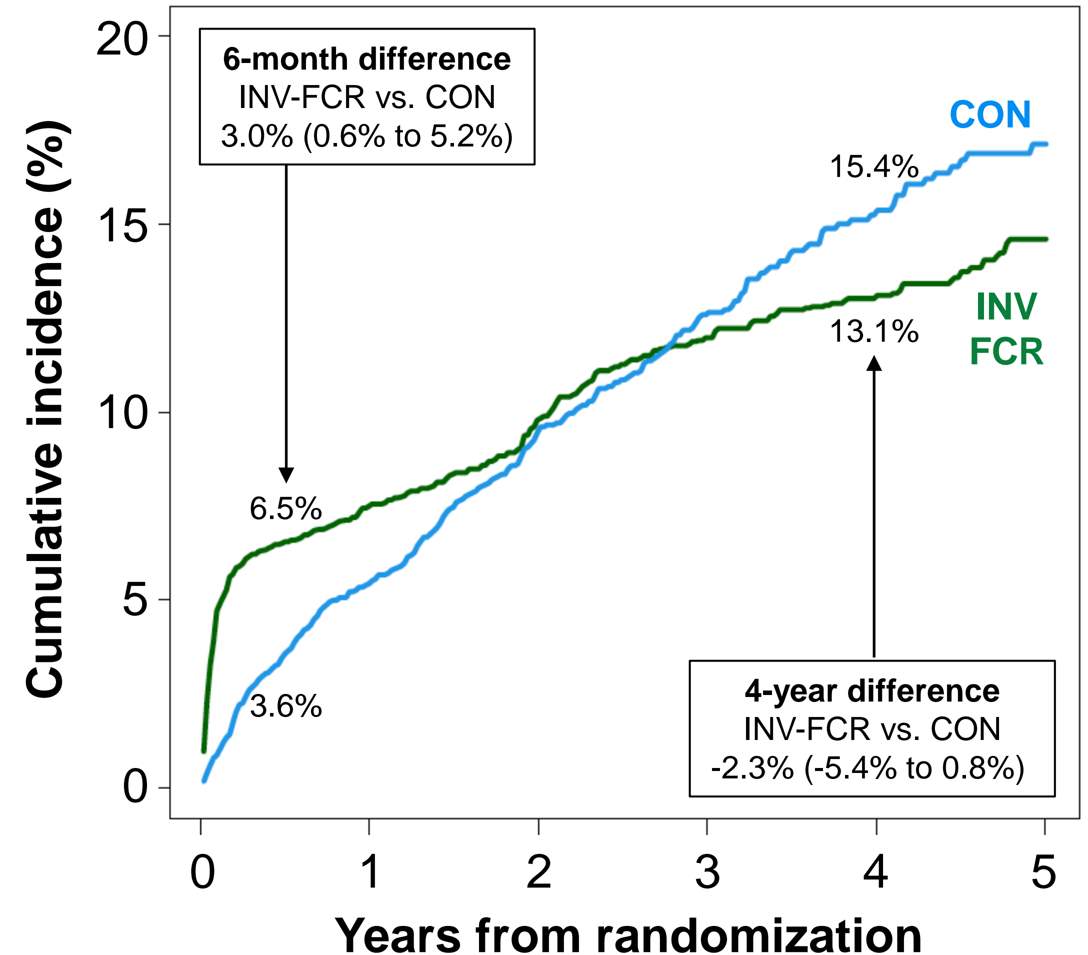
ISCHEMIA: INV-CR versus CON: Primary endpoint

INV IPW-adjusted, marginal structural model using natural splines

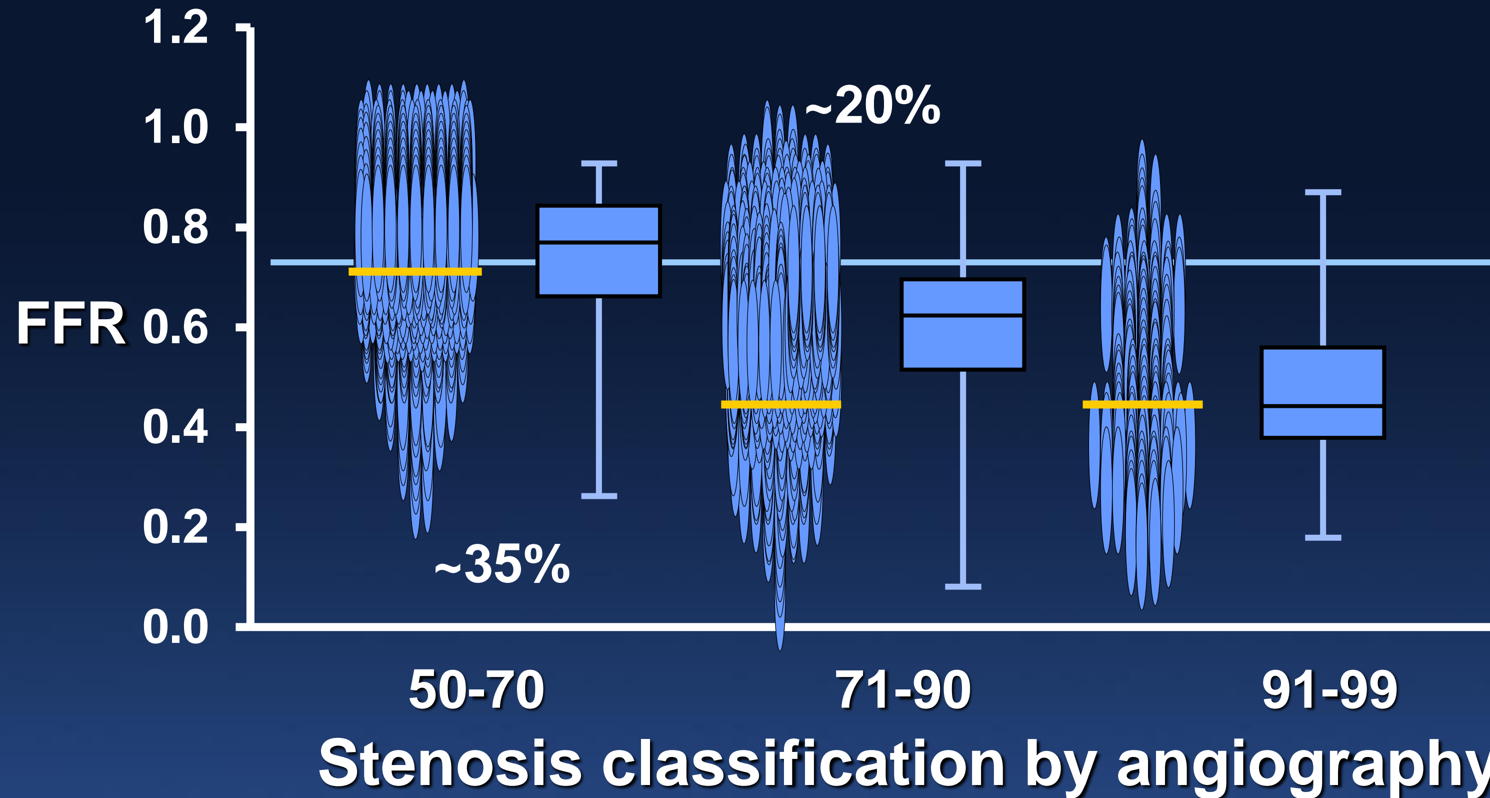
Anatomic CR achieved



Functional CR achieved



Angiographic vs. Functional Severity of Coronary Stenosis

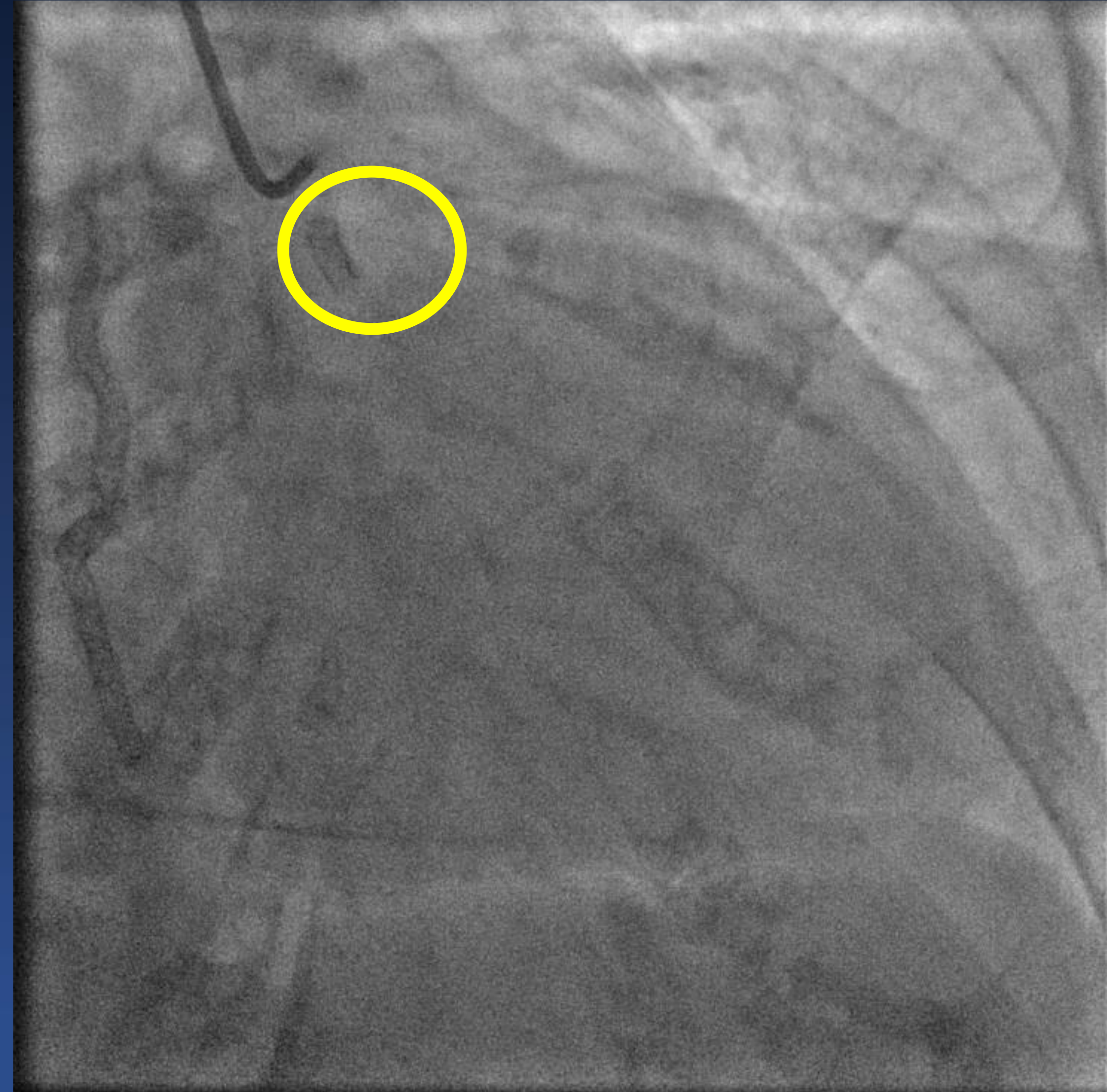


Of 509 pts with angiographically-defined MVD, 46% had "functional MVD"

Tonino et al, JACC 2010

An Interesting Case

- Frail 72F with HTN, IDDM, HLD
  - Exertional angina
- Multiple prior PCIs including:
  - PCI to LCx with DES in 2005
  - Multiple PCIs to RCA over the years with known occlusion & left-right collaterals
- Most recent cath: proximal LCX lesion (proximal to stent) thought to be difficult to treat
  - Persistent symptoms despite OMT
  - Referred for 2nd opinion



Diagnostic Angiography

What Was Done (Conventional Physiology/PCI)

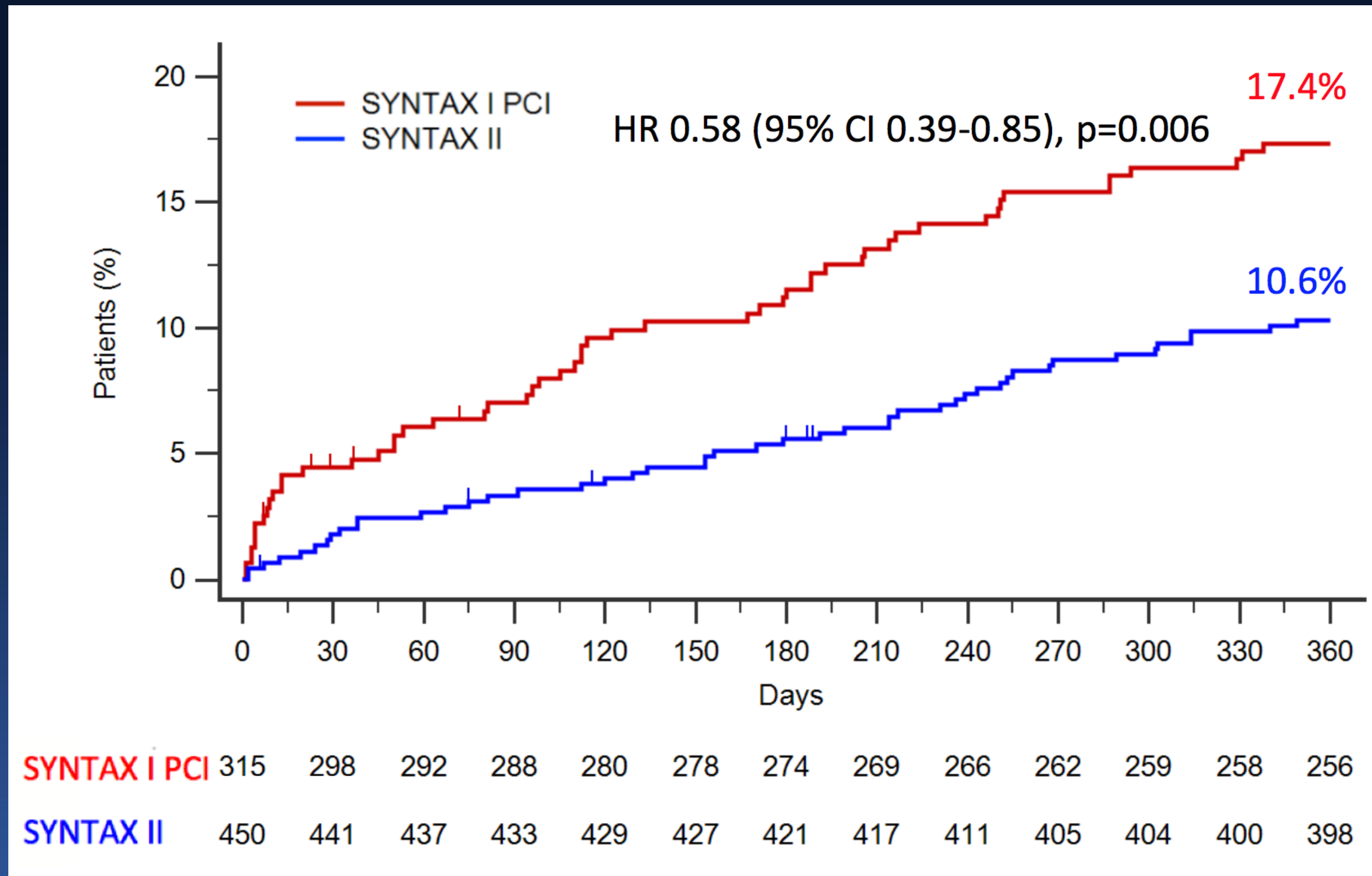
FFR of LAD

iFR=0.91
FFR=0.82
FFRangio=0.82

PCI of LCX

SYNTAX II: MACCE

SYNTAX II Score guidance for Heart Team, Physiology (75%), IVUS (84%), CTO Success 87%, Newer generation BP-DES (Synergy)



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Escaned J et al, ESC 2017

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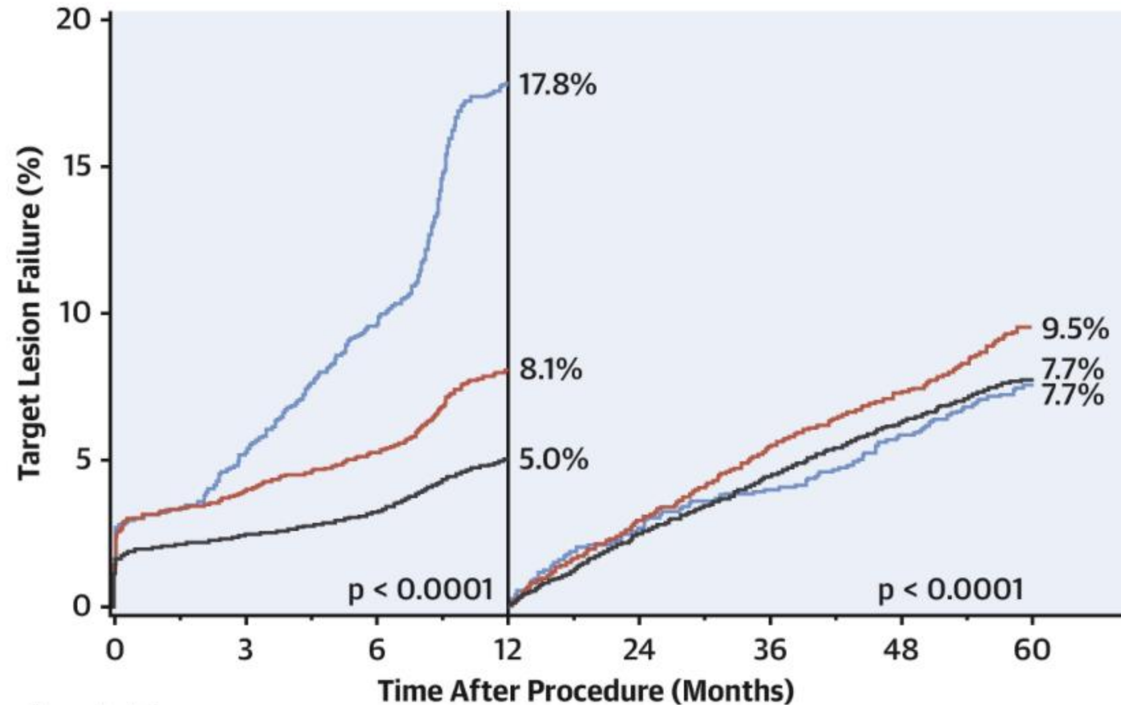
- What is the role for thoughtful interventional medicine?
  - e.g. staging

Late Events following Stent Implantation



IPD Pooled Analysis of 19 stent trials

Very late events (beyond a year) were similar between BMS and 2nd generation DES

Approximately 1-2%/year

Madhavan et al, JACC 2020

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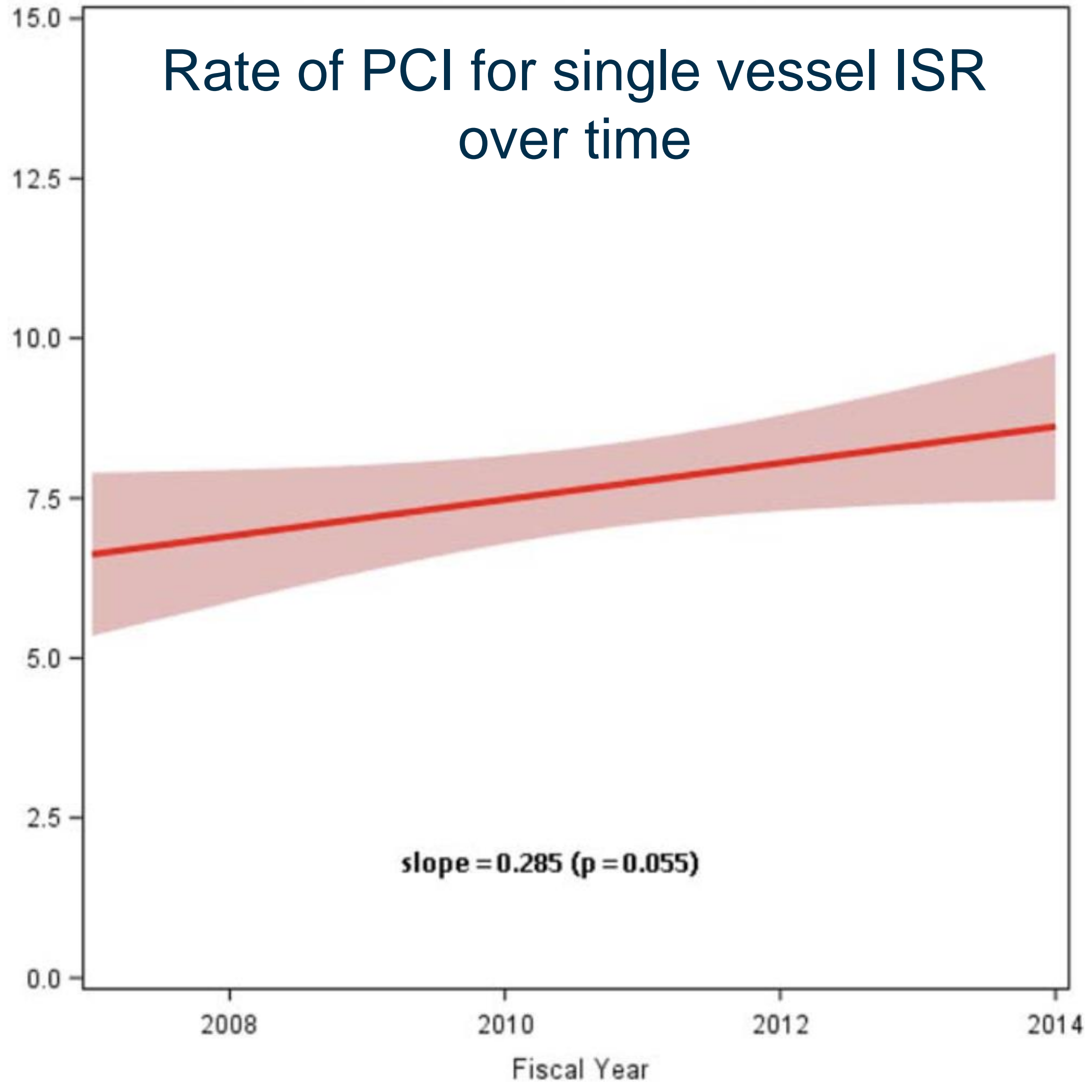
In-Stent Restenosis in the VA-CART Program



65,443 pts underwent PCI from 2006-2014

6,872 (10.5%) were treated for in-stent restenosis

Waldo et al, CCI 2018

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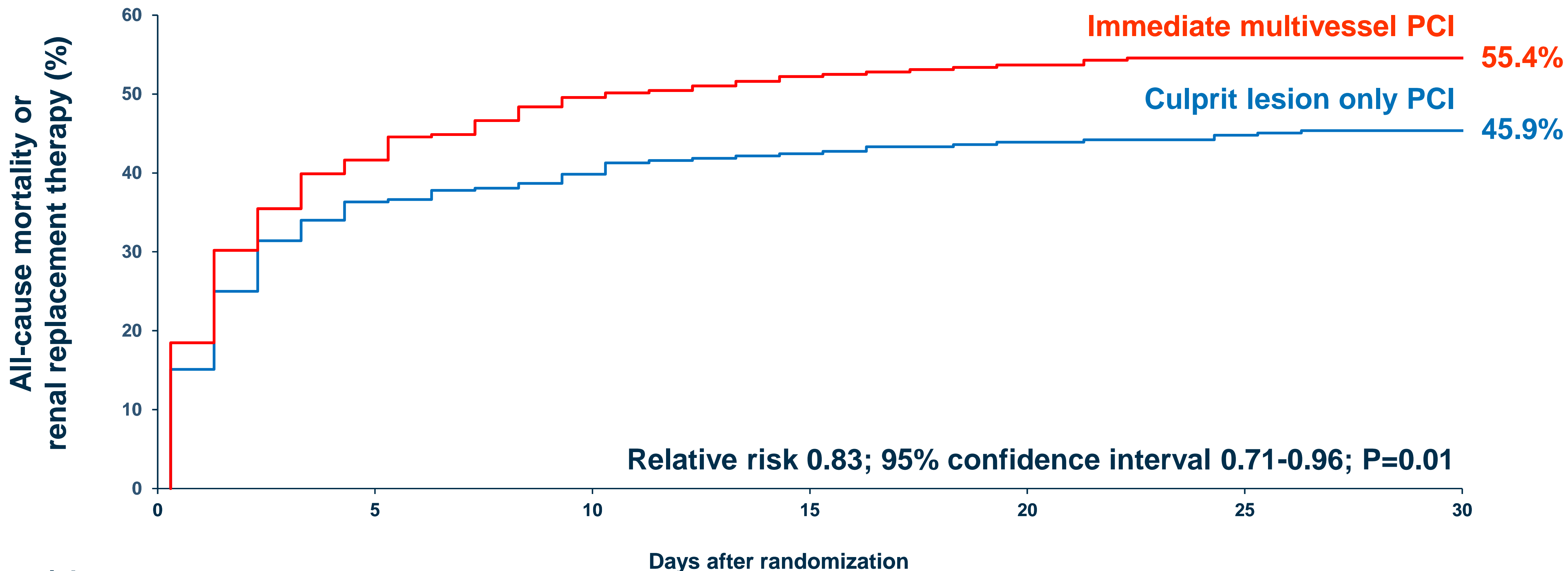
HERZZENTRUM

Primary Study Endpoint

All-Cause Mortality or Renal Replacement Therapy

CULPRIT-SHOCK



Number at risk:

	0	5	10	15	20	25	30
Culprit lesion only PCI	344	219	207	198	192	189	184
Immediate multivessel PCI	341	199	172	162	156	153	152

Potential Advantages of Staging Procedures

- Better stabilization of the patient
  - Prevention of CIN
  - Less hemodynamic perturbation
  - Mitigate other circumstances (e.g. bleeding risk)
- Consideration of alternatives (e.g. medical therapy alone)
- Operator issues including fatigue / decision-making / shortcuts
- Cath lab throughput

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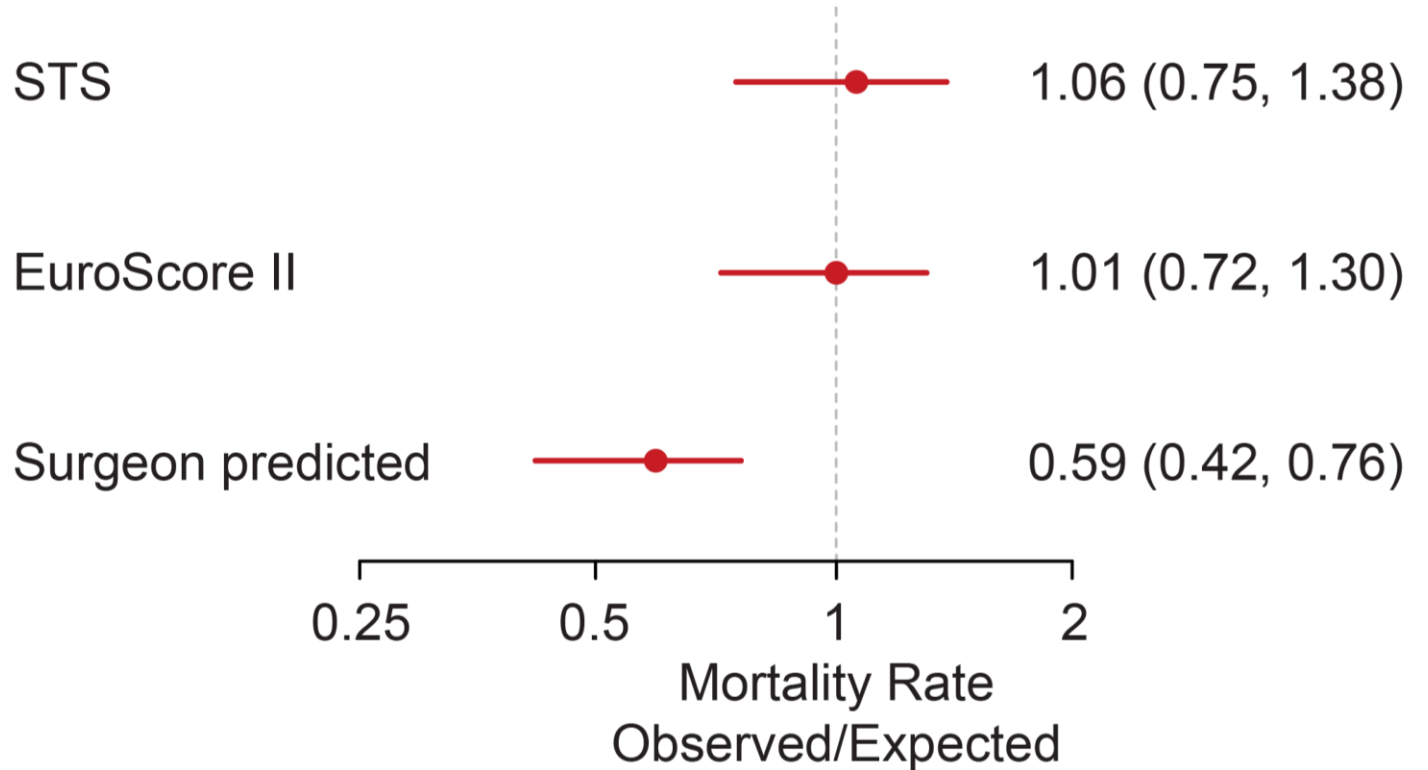
- *Primum non nocere* (a.k.a. CHIP patients are sick)

OPTIMUM

30-day/In-hospital Mortality and Observed/Expected Estimates

	N= 726
Death, 30 Days	5.6%
In-hospital	3.0%
Post-discharge	2.6%
Death, 6 Months	12.3%



100% 30-day follow-up regarding survival status; confidence intervals calculated using bootstrap samples

Kandzari and Salisbury, TCT 2021

OPEN CTO Registry

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

Overall success: 89%

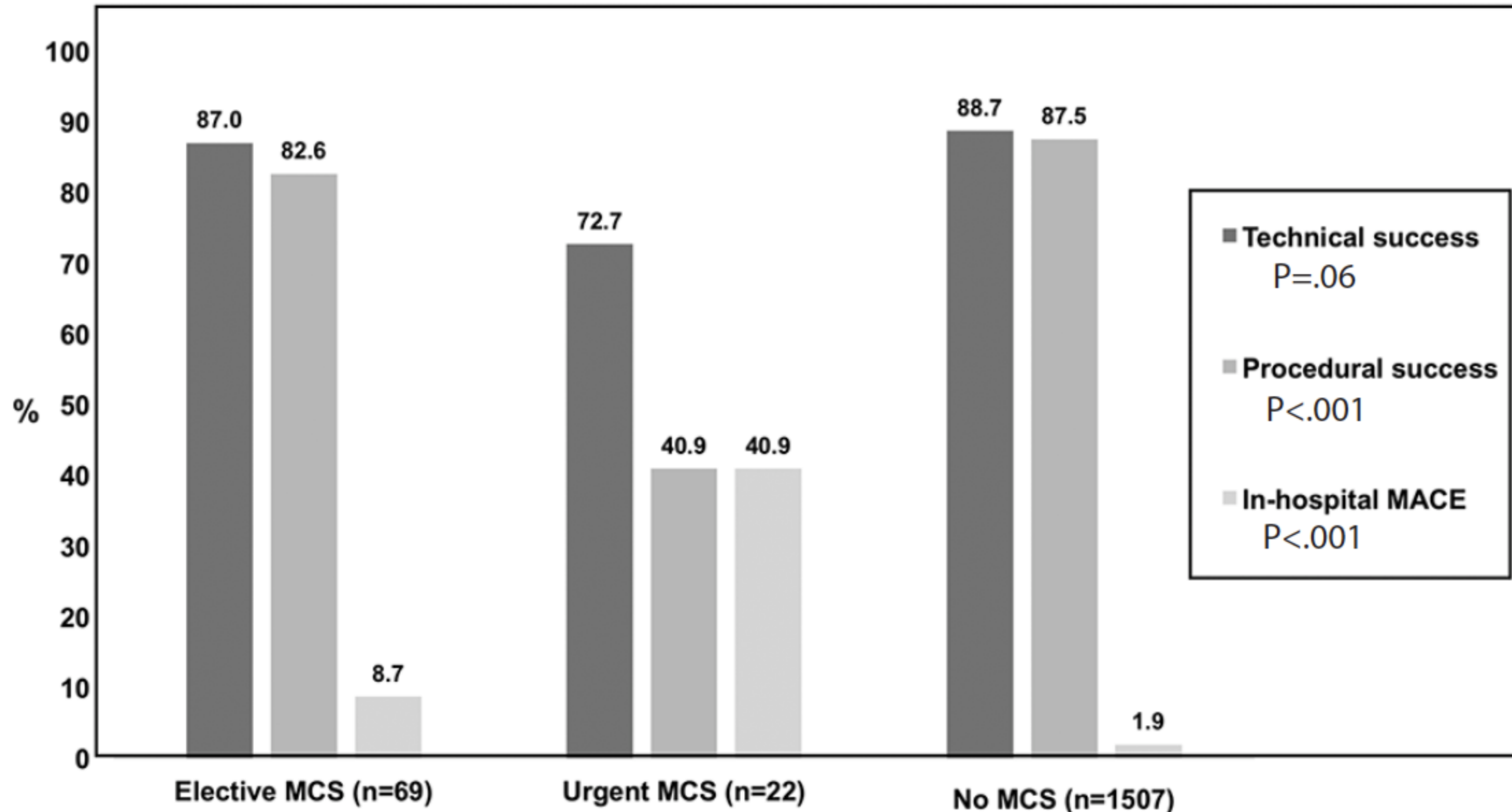
Success of 1st approach: 58%

In Hospital	Frequency
Death	0.9%
MI	2.4%
Emergent surgery	0.6%
Perforation	6.0%
Clinical perforation	4.9% (82%)
Bleeding Access	4.0%
Radiation injury	0.1%

30 Day	Frequency
Death	1.3%
Rehospitalization	14.7%
Unplanned	12.1%
Revascularization	2.6%
Planned	2.6%
PCI	2.3%
CABG	0.3%
Skin change	3.1%

MCS in CTO PCI: PROGRESS-CTO Registry

1,598 CTO PCI procedures from 12 high-volume centers
MCS device (62% Impella) used electively in 69 cases (4%) and urgently in 22 cases (1%)



Elective MCS associated with higher in-hospital MACE (8.7% vs. 2.5%) & bleeding (7.3% vs. 1.0%)

Conclusions: Completeness of Revascularization

- Ability to perform CR of viable and ischemic territories should influence choice of revascularization strategy for complex / multivessel disease
- We run the risk of pushing too hard on the PCI front especially with operators who might not be able to safely and reliably perform complete revascularization!
- It's very important to consider risk/benefit of all procedures
  - Don't use this as an excuse not to perform indicated procedures
  - But not all lesions need to be revascularized