COMPLETE TRIAL

A randomized, comparative effectiveness study of complete versus culprit-only revascularization strategies to treat multivessel disease after early percutaneous coronary intervention for ST-segment elevation myocardial infarction

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Version Oct 23, 2019

Population Health Research Institute
HEALTH THROUGH KNOWLEDGE

Hamilton Health Sciences

McMaster University
HEALTH SCIENCES

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Disclosures

The COMPLETE Trial was funded by the Canadian Institutes of Health Research and the Population Health Research Institute with additional unrestricted grants from AstraZeneca and Boston Scientific.

Coordinated by the Population Health Research Institute in Hamilton, Canada

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Prior Trials of PCI versus Med Rx in Patients with STEMI and Multivessel Disease

Trial	Same-sitting or Staged	Sample Size
Di Mario 2004	Index	69
Politi 2009	Index or staged	149
Ghani 2012	Staged (FFR guided)	119
PRAMI 2013[1]	Index	465
Cvlprit 2014[2]	Index or staged	296
DANAMI-3 2015[3]	Staged	627
PRAGUE 13	Staged	214
Explore	Staged (CTO)	300
COMPARE-ACUTE[4]	Mainly index	885

1. Wald et al. *N Engl J Med* 2013;369:1115-23.
2. Gershlick et al. *J Am Coll Cardiol* 2015;65:963-72.
3. Engstrom et al. *Lancet* 2015;386:665-71.
4. Smits et al. *N Engl J Med* 2017;376:1234-44.

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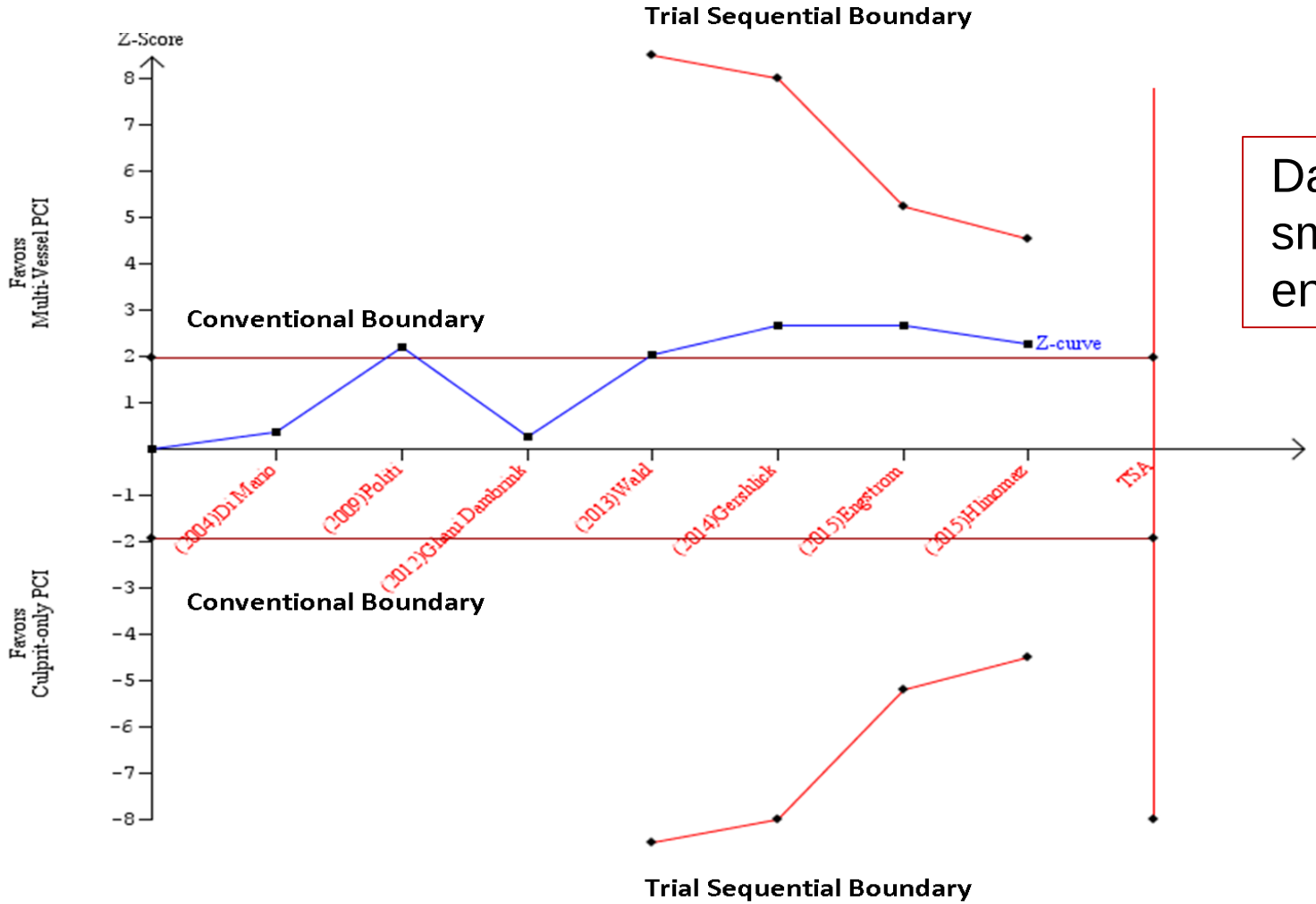
RCT Sequential Meta-Analysis: Death or MI



Data on Death/MI in smaller RCTs are encouraging, but **fragile**

Bainey et al. *Can J Cardiol* 2016;32:1542-51

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COMPARE-ACUTE: Complete vs culprit only PCI for STEMI and Multivessel disease

Table 3. Prespecified Clinical End Points at 1 Year.

End Point	Complete Revascularization (N=295)	Infarct-Artery-Only Treatment (N=590)	Hazard Ratio (95% CI)	P Value
	number (percent)			
Primary				
MACCE*	23 (7.8)	121 (20.5)	0.35 (0.22–0.55)	<0.001
Death from any cause	4 (1.4)	10 (1.7)	0.80 (0.25–2.56)	0.70
Cardiac event	3 (1.0)	6 (1.0)	1.00 (0.25–4.01)	1.00
Myocardial infarction	7 (2.4)	28 (4.7)	0.50 (0.22–1.13)	0.10
Spontaneous event	5 (1.7)	17 (2.9)	0.59 (0.22–1.59)	0.29
Periprocedural event	2 (0.7)	11 (1.9)	0.36 (0.08–1.64)	0.19
Revascularization	18 (6.1)	103 (17.5)	0.32 (0.20–0.54)	<0.001
PCI	15 (5.1)	98 (16.6)	0.37 (0.24–0.57)	<0.001
Coronary-artery bypass graft	3 (1.0)	5 (0.8)	1.20 (0.29–5.02)	0.80
Cerebrovascular event	0	4 (0.7)	NA	NA

Smits et al. *N Engl J Med* 2017;376:1234-44

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Background

- Patients undergoing primary PCI to the culprit lesion for STEMI are often found to have multivessel CAD, with 1 or more angiographically significant non-culprit lesions.

- There is uncertainty on how best to manage these non-culprit lesions:
  - *Routinely revascularize them with PCI?*
  - *Manage them conservatively with guideline-directed medical therapy alone?*

- Prior RCT's have shown non-culprit lesion PCI reduces revascularization but none were powered to detect moderate reductions in hard clinical outcomes such as CV death or MI. [1-4]

- Meta-analyses have suggested a possible reduction in CV death or MI, but this result is fragile and no single RCT has been adequately powered to confirm this.[5]

The COMPLETE trial was designed to address this evidence gap.

1. Wald et al. *N Engl J Med* 2013;369:1115-23.
2. Gershlick et al. *J Am Coll Cardiol* 2015;65:963-72.
3. Engstrom et al. *Lancet* 2015;386:665-71.
4. Smits et al. *N Engl J Med* 2017;376:1234-44.
5. Bainey et al. *Can J Cardiol* 2016;32:1542-51.

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Primary Objective

In patients presenting with STEMI and multi-vessel coronary artery disease who have undergone culprit-lesion PCI, the objective is:

To determine whether a strategy of routine, staged non-culprit lesion PCI with the goal of complete revascularization is superior to a strategy of culprit lesion-only PCI in reducing the composite of CV death or new MI.

COMPLETE Trial Design

STEMI WITH MULTIVESSEL CAD AND SUCCESSFUL PCI TO THE CULPRIT LESION
MVD defined as at least one additional non-culprit lesion ≥ 2.5 mm diameter
and ≥70% stenosis or 50-69% with FFR ≤0.80

Exclusion Criteria: Intent to revascularize NCL, planned surgical revascularization, prior CABG

RANDOMIZATION
Stratified for intended timing of NCL PCI:
During initial hospitalization or after discharge (max 45 d)

Actual Time to study NCL PCI in Complete Group (median)
During initial hospitalization: 1 day (IQR 1-3)
After hospital discharge: 23 days (IQR 12.5-33.5)

COMPLETE REVASCULARIZATION
Routine staged PCI* of all suitable non-culprit lesions
with the goal of complete revascularization
N=2016

CULPRIT-LESION-ONLY REVASCULARIZATION
No further revascularization of non-culprit lesions,
guideline-directed medical therapy alone
N=2025

*Everolimus-eluting stents strongly recommended

Guideline-Directed Medical Therapy
ASA, P2Y12 inhibitor (Ticagrelor strongly recommended), Statin, BB, ACE/ARB + Risk Factor Modification

MEDIAN FOLLOW-UP: 3 YEARS

CO-PRIMARY OUTCOMES: 1. Composite of CV death or new MI
2. Composite of CV death, new MI or IDR

KEY SECONDARY OUTCOME: CV death, new MI, IDR, unstable angina, NYHA class IV heart failure

Mehta SR et al. *Am Heart J* 2019; 215:157-166.

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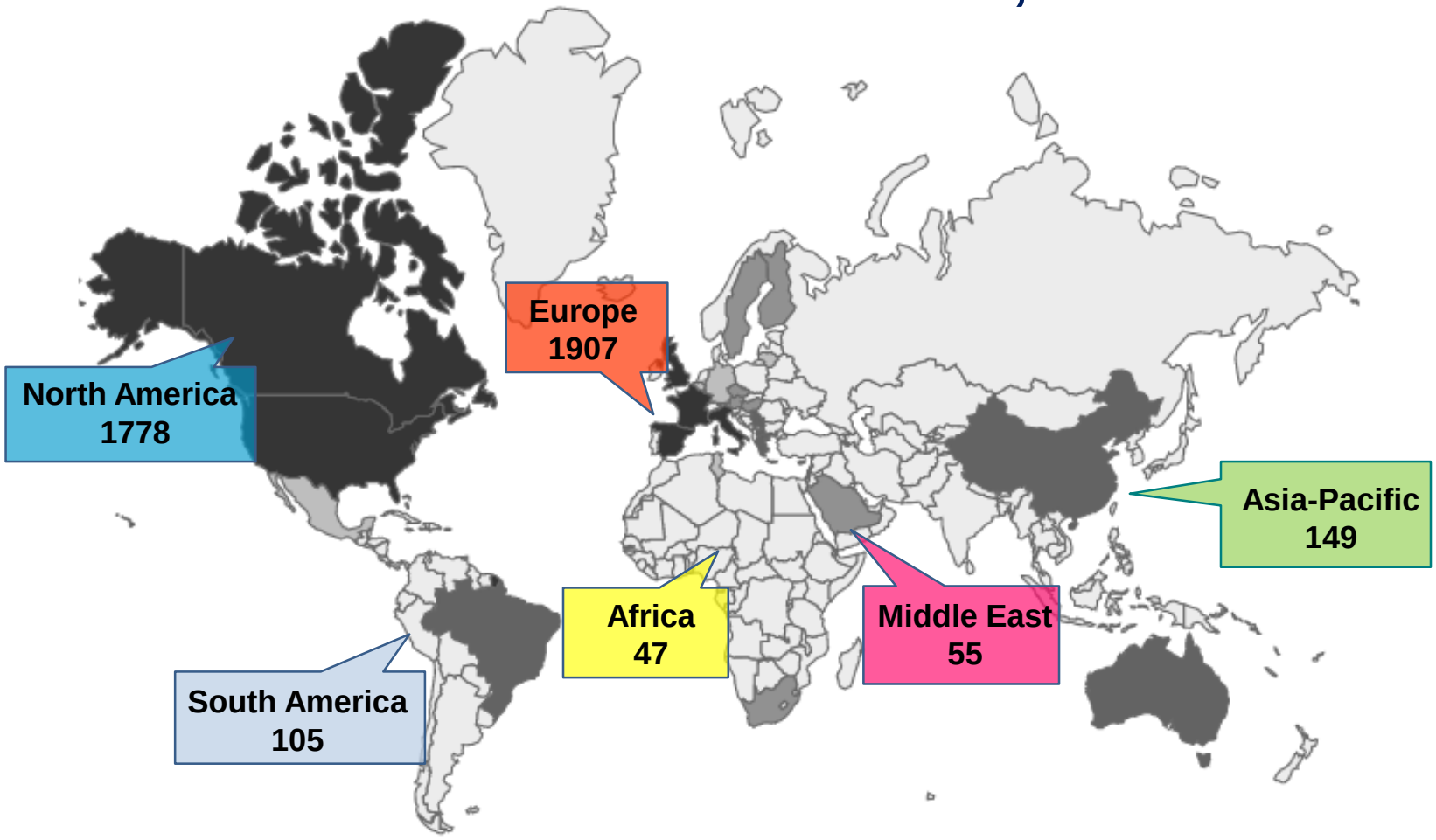
Global Recruitment

140 centers, 31 countries



Australia	*Lithuania*
Austria	*Macedonia*
Belgium	*Mexico*
Brazil	*Poland*
Canada	*Portugal*
China	*Romania*
Colombia	*Saudi Arabia*
Czech Republic	*Serbia*
Finland	*South Africa*
France	*Spain*
Germany	*Sweden*
Greece	*Switzerland*
Hungary	*Tunisia*
Israel	*United Kingdom*
Italy	*USA*
Kuwait	

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Study Power and Follow-up

- **Study Power:** 80% power for CVD/MI and 89% power for CVD/MI/IDR to detect a 22% HRR.

  To preserve the overall type I error rate of 5% for the testing of both co-primary outcomes, the first co-primary outcome was tested at a P value of 0.045 and the second at a P value of 0.0119*

- **Recruitment Period:** February 1, 2013 – March 6, 2017

- **Angiographic Core Lab:** Central review of all coronary angiograms in the trial

- **Analysis:** Intention-to-treat, Cox proportional hazards model, stratified by intended timing of revascularization, stratified log rank test

- **Follow-up (vital status):** 99.1% in *Complete* group and 99.3% *Culprit-Lesion-only* group

- **Crossover in first 45 days:** From *Complete Revasc* to *Culprit-Lesion-only* = 3.9%
  From *Culprit-Lesion-only* to *Complete Revasc* = 4.7%

*Mehta SR et al. *Am Heart J* 2019; 215:157-166.

The NEW ENGLAND JOURNAL of MEDICINE

ORIGINAL ARTICLE

Complete Revascularization with Multivessel PCI for Myocardial Infarction

Shamir R. Mehta, M.D., David A. Wood, M.D., Robert F. Storey, M.D., Roxana Mehran, M.D., Kevin R. Bainey, M.D., Helen Nguyen, B.Sc., Brandi Meeks, M.Sc., Giuseppe Di Pasquale, M.D., Jose López-Sendón, M.D., David P. Faxon, M.D., Laura Mauri, M.D., Sunil V. Rao, M.D., Laurent Feldman, M.D., P. Gabriel Steg, M.D., Álvaro Avezum, M.D., Tej Sheth, M.D., Natalia Pinilla-Echeverri, M.D., Raul Moreno, M.D., Gianluca Campo, M.D., Benjamin Wrigley, M.D., Sasko Kedev, M.D., Andrew Sutton, M.D., Richard Oliver, M.D., Josep Rodés-Cabau, M.D., Goran Stanković, M.D., Robert Welsh, M.D., Shahar Lavi, M.D., Warren J. Cantor, M.D., Jia Wang, M.Sc., Juliet Nakamya, Ph.D., Shrikant I. Bangdiwala, Ph.D., and John A. Cairns, M.D., for the COMPLETE Trial Steering Committee and Investigators*

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Baseline Characteristics

	Complete N=2016	Culprit-only N=2025
Age (yrs)	61.6	62.4
Gender (% male)	80.5	79.1
Diabetes (%)	19.1	19.9
Chronic renal insuff. (%)	2.0	2.3
Prior MI (%)	7.3	7.6
Current smoker (%)	40.6	38.9
Hypertension (%)	48.7	50.7
Dyslipidemia (%)	37.9	39.4
Prior PCI (%)	7.0	7.0
Prior stroke (%)	3.2	3.1
Hemoglobin A1C	6.3	6.3
LDL (mmol/L)	3.1	3.1
Creatinine (µmol/L)	84.7	85.2

	Complete N=2016	Culprit-only N=2025
Sx onset to Culprit PCI (%)		
<6 hours	69.4	67.1
6~12 hours	16.1	17.7
>12 hours	14.5	15.3
Discharge Meds (%)		
ASA	99.8	99.5
P2Y12 Inhibitor	99.4	99.7
Ticagrelor	64.4	63.3
Prasugrel	9.6	8.3
Clopidogrel	25.6	28.2
Beta blocker	88.1	89.1
ACEi/ARB	85.5	84.6
Statin	98.2	97.2

Mehta SR et al. *N Engl J Med* 2019; 381:1411-1421

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Procedural Characteristics

	Complete N=2016	Culprit-only N=2025
Index PCI for STEMI		
Primary	**91.9%**	**93.1%**
Pharmaco-invasive	**3.2%**	**3.0%**
Rescue	**4.9%**	**3.9%**
Radial access	**80.8%**	**80.7%**
Residual diseased vessels		
1	**76.1%**	**77.1%**
≥2	**23.9%**	**22.9%**
NCL location		
Left main	**0.4%**	**0.1%**
LAD	**38.0%**	**41.2%**
Proximal LAD	**9.8%**	**10.4%**
Mid LAD	**21.7%**	**23.7%**
Circumflex	**36.4%**	**35.6%**
RCA	**25.3%**	**23.2%**

	Complete N=2016	Culprit-only N=2025
NCL diameter	**2.8 mm**	**2.9 mm**
Mean NCL stenosis (visual)	**79.3%**	**78.7%**
NCL stenosis (visual)		
50-69% and FFR<0.80	**0.8%**	**0.6%**
70-79%	**41.3%**	**45.1%**
80-89%	**33.5%**	**32.6%**
90-99%	**22.3%**	**19.7%**
100%	**2.1%**	**2.0%**
SYNTAX score (Core Lab)		
Baseline	**16.3**	**16.0**
Culprit lesion specific	**8.8**	**8.6**
Non-culprit lesion specific	**4.5**	**4.5**
Residual (after index PCI)	**7.2**	**7.0**

Mehta SR et al. *N Engl J Med* 2019; 381:1411-1421

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Procedural Characteristics

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Mid LAD	21.7%	23.7%
Circumflex	36.4%	35.6%
RCA	25.3%	23.2%

Complete revascularization was achieved in 90.1% after NCL PCI (SYNTAX score = 0)

	Complete N=2016	Culprit-only N=2025
NCL diameter	2.8 mm	2.9 mm
Mean NCL stenosis (visual)	79.3%	78.7%
		0.6%
		45.1%
80-89%	33.5%	32.6%
90-99%	22.3%	19.7%
100%	2.1%	2.0%
SYNTAX score (Core Lab)		
Baseline	16.3	16.0
Culprit lesion specific	8.8	8.6
Non-culprit lesion specific	4.5	4.5
Residual (after index PCI)	7.2	7.0

Mehta SR et al. *N Engl J Med* 2019; 381:1411-1421

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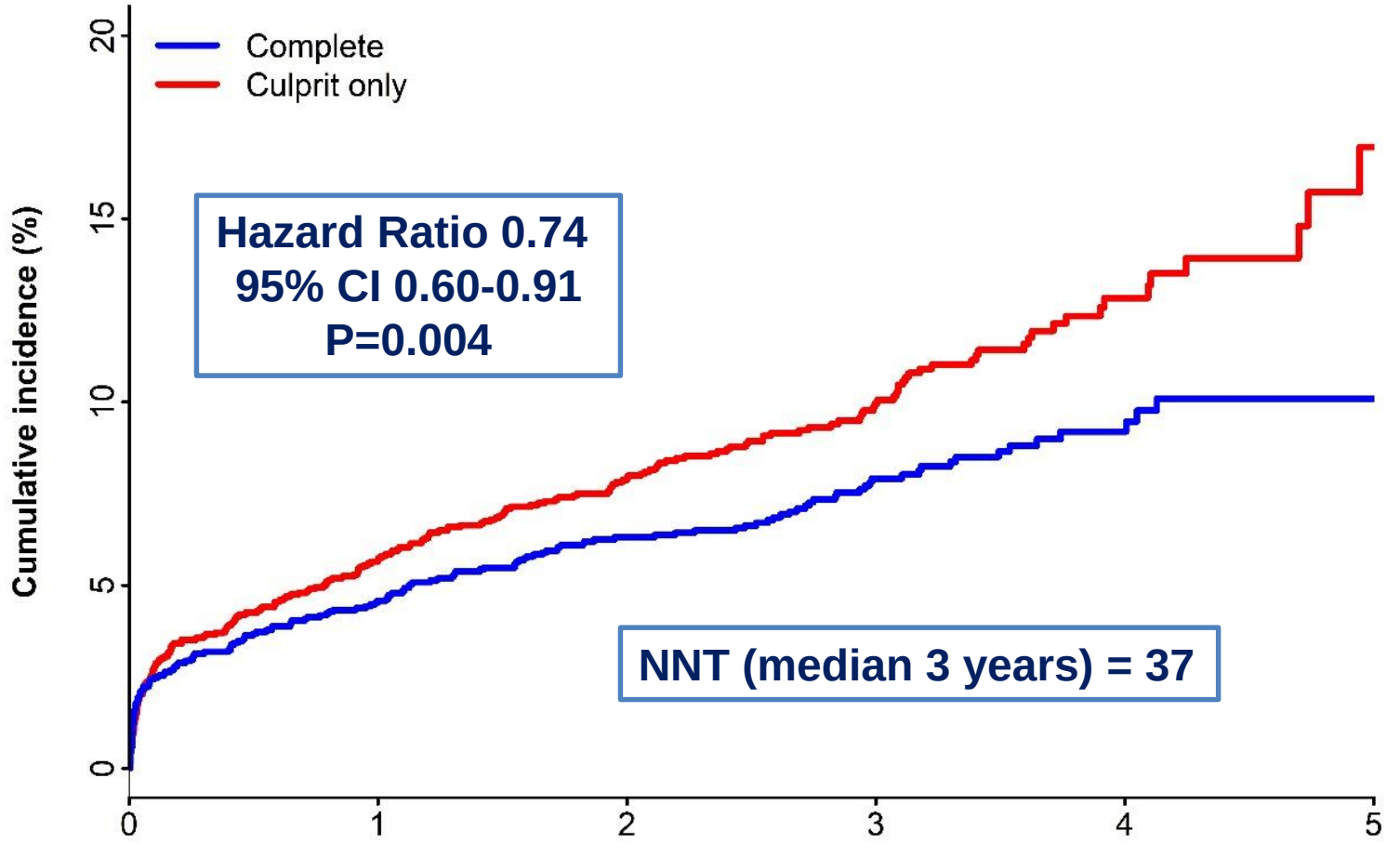
First Co-Primary Outcome: CV Death or New MI



No. at Risk						
Complete	2016	1904	1677	938	337	70
Culprit only	2025	1897	1666	933	310	59

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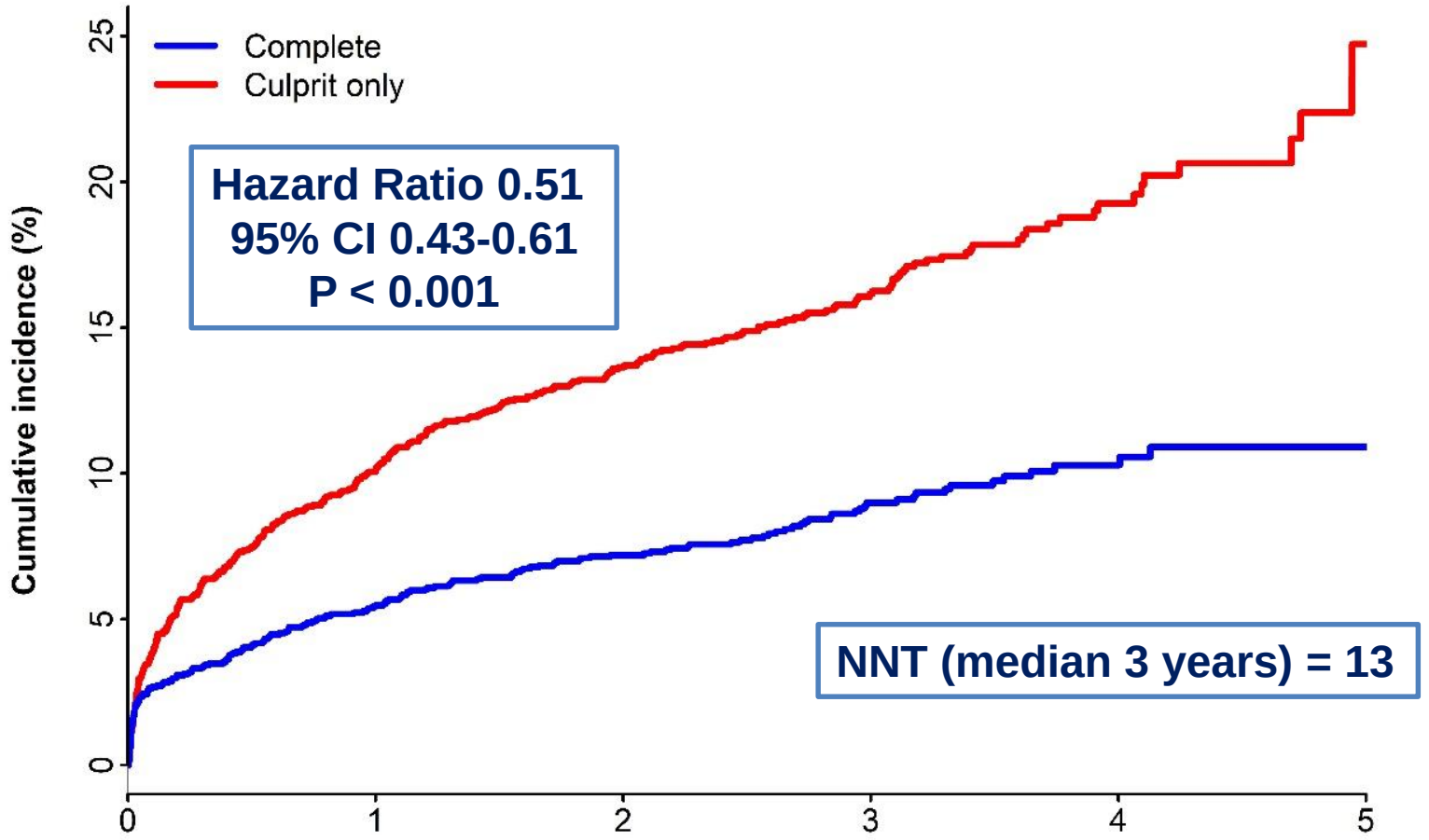
2nd Co-Primary Outcome: CV Death, New MI, or IDR



No. at Risk						
Complete	2016	1886	1659	925	329	66
Culprit only	2025	1808	1559	865	294	57

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Efficacy Outcomes

	Complete Revasc. N=2016		Culprit Lesion Only N=2025		HR (95% CI)	P value
	N (%)	%/year	N (%)	%/year		
Co-Primary Outcomes						
CV death or MI	**158 (7.8)**	**2.7**	**213 (10.5)**	**3.7**	**0.74 (0.60-0.91)**	**0.004**
CV death, MI or IDR	**179 (8.9)**	**3.1**	**339 (16.7)**	**6.2**	**0.51 (0.43-0.61)**	**<0.001**
Key Secondary Outcome						
CV death, MI, IDR, unstable angina or class IV HF	272 (13.5)	4.9	426 (21.0)	8.1	0.62 (0.53-0.72)	<0.001
Other Secondary Outcomes						
MI	109 (5.4)	1.9	160 (7.9)	2.8	0.68 (0.53-0.86)	0.002
IDR	29 (1.4)	0.5	160 (7.9)	2.8	0.18 (0.12-0.26)	<0.001
Unstable Angina	70 (3.5)	1.2	130 (6.4)	2.2	0.53 (0.40-0.71)	<0.001
CV death	59 (2.9)	1.0	64 (3.2)	1.0	0.93 (0.65-1.32)	0.68
All-cause Death	96 (4.8)	1.6	106 (5.2)	1.7	0.91 (0.69-1.20)	0.51

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Sub-types of MI

	Complete Revasc. N=2016		Culprit Lesion Only N=2025		HR (95% CI)
	N (%)	%/year	N (%)	%/year	
Subtype of MI					
NSTEMI	66 (3.27)	1.11	105 (5.19)	1.78	0.63 (0.46-0.85)
STEMI	43 (2.13)	0.72	53 (2.62)	0.88	0.81 (0.54-1.22)
Universal MI Definition					
Type 1	63 (3.13)	1.05	128 (6.32)	2.17	0.49 (0.36-0.66)
Type 2	16 (0.79)	0.26	13 (0.64)	0.21	1.24 (0.60-2.58)
Type 3	4 (0.20)	0.07	1 (0.05)	0.02	4.04 (0.45-36.17)
Type 4a	16 (0.79)	0.27	8 (0.40)	0.13	2.01 (0.86-4.70)
Type 4b	8 (0.40)	0.13	13 (0.64)	0.21	0.62 (0.26-1.49)
Type 5	1 (0.05)	0.02	1 (0.05)	0.02	1.00 (0.06-15.92)

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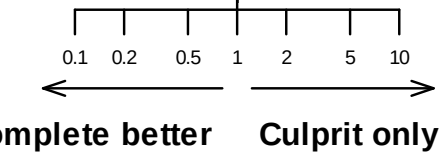
Timing of Non-Culprit Lesion PCI: During or After Index Hospitalization

Actual Median Time to study NCL PCI in Complete Group

During initial hospitalization: **1 day** (IQR 1-3); **After Hospital Discharge: 23 days** (IQR 12.5-33.5)

CV death or New MI

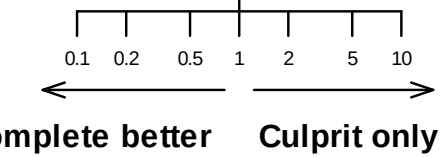
	Complete	Culprit Only	HR (95% CI)	Interaction P
	no. of events/total no. (%/yr)			
Intent to perform non-culprit lesion PCI				0.62
During initial hospitalization	101/1353 (2.7)	130/1349 (3.5)	0.77 (0.59-1.00)	
After initial hospitalization	57/663 (2.7)	83/676 (3.9)	0.69 (0.49-0.97)	



Complete better **Culprit only better**

CV death, New MI, or IDR

	Complete	Culprit Only	HR (95% CI)	Interaction P
	no. of events/total no. (%/yr)			
Intent to perform non-culprit lesion PCI				0.27
During initial hospitalization	113/1353 (3.0)	227/1349 (6.6)	0.47 (0.38-0.59)	
After initial hospitalization	66/663 (3.1)	112/676 (5.4)	0.59 (0.43-0.79)	



Complete better **Culprit only better**

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Timing Analysis: Baseline Characteristics

Characteristic	Intended timing of complete revascularization		P value
	Index hospitalization (N=2702)	After discharge (N=1339)	
Actual complete revascularization	1353 (50.1)	663 (49.5)	
Age – year	62.2±10.7	61.7±10.7	0.18
Gender (male)	2151 (79.6)	1074 (80.2)	0.65
Diabetes	552 (20.4)	235 (17.6)	0.03
Chronic renal insufficiency	61/2586 (2.4)	20/1201 (1.7)	0.17
Prior stroke	88 (3.3)	38 (2.8)	0.47
Body mass index (BMI) – kg/m^2	28.3±5.6	28.3±5.0	0.97
Prior myocardial infarction	188 (7.0)	114 (8.5)	0.08
Prior PCI	184 (6.8)	99 (7.4)	0.49
Time from symptom onset to primary PCI • **<6 hours** • **6-12 hours** • **>12 hours**	 1821/2678(68.0) 468/2678(17.5) 389/2678(14.5)	 903/1316 (68.6) 208/1316 (15.8) 205/1316 (15.6)	0.34
Killip class ≥2	293/2674 (11.0)	137/1317 (10.4)	0.59

Wood DA et al. *J Am Coll Cardiol* 2019; 74, 22

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Timing Analysis: Procedural Characteristics

Characteristic	Intended timing of complete revascularization Index hospitalization (N=2702)	After discharge (N=1339)	P-value
SYNTAX score			
• Baseline (including STEMI culprit)	16.1±6.8	16.4±6.6	0.12
• Residual (after index PCI)	7.1±4.8	7.2±4.8	0.48
• Lesion specific (STEMI culprit)	8.6±5.3	8.9±5.3	0.04
• Lesion specific (Non-culprit)	4.5±2.7	4.7±2.7	0.04
• Post NCL lesion PCI=0 (Complete revascularization achieved)	1095/1200 (91.3)	525/598 (87.8)	0.02
Non-culprit lesions location			
• Left main	7/3543 (0.2)	6/1812 (0.3)	0.77
• Left anterior descending	1379/3543 (38.9)	738/1812 (40.7)	0.20
• Circumflex	1293/3543 (36.5)	633/1812 (34.9)	0.26
• Right coronary artery	864/3543 (24.4)	435/1812 (24.0)	0.83
Non-culprit lesion diameter stenosis			0.12
• 50-69%	28/3468 (0.8)	9/1720 (0.5)	
• 70-79%	1435/3468 (41.4)	805/1720 (46.8)	
• 80-89%	1214/3468 (35.0)	500/1720 (29.1)	
• 90-99%	734/3468 (21.2)	357/1720 (20.8)	
• 100%	57/3468 (1.6)	49/1720 (2.8)	
Index procedure for STEMI			
• Primary PCI	2479 (91.7)	1259 (94.0)	0.01
• Pharmaco-invasive PCI	87 (3.2)	38 (2.8)	0.51
• Rescue PCI	136 (5.0)	42 (3.1)	0.006
Radial access	2143 (79.3)	1120 (83.6)	0.001
Thrombus aspiration	609/2573 (23.7)	323/1166 (27.7)	0.008

Wood DA et al. *J Am Coll Cardiol* 2019; 74, 22

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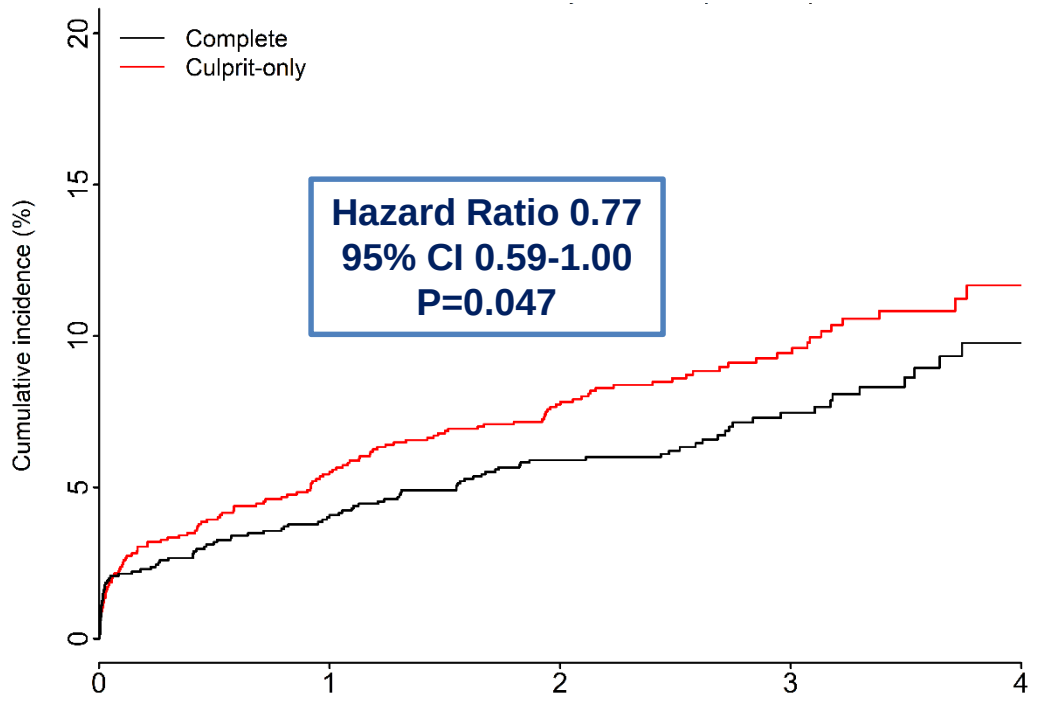
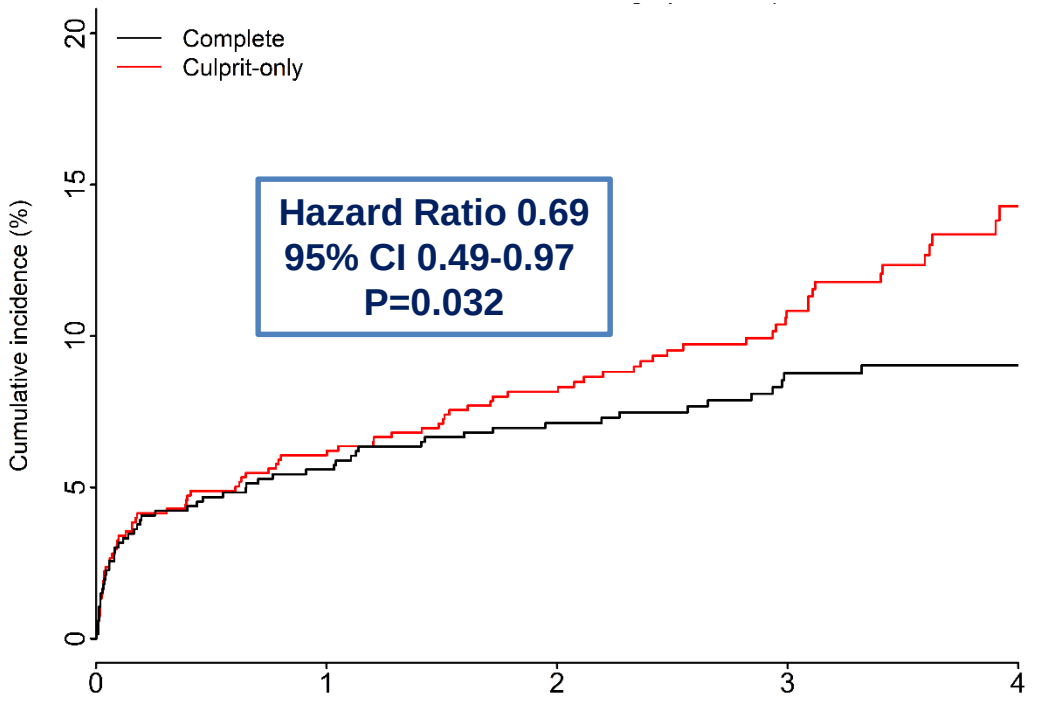
Timing Analysis: First Co-Primary Outcome CV Death or new MI

Index Hospitalization



No. at Risk					
Complete	1353	1282	1104	539	151
Culprit-only	1349	1262	1092	540	143

After Discharge



No. at Risk					
Complete	663	622	573	399	186
Culprit-only	676	635	574	393	167

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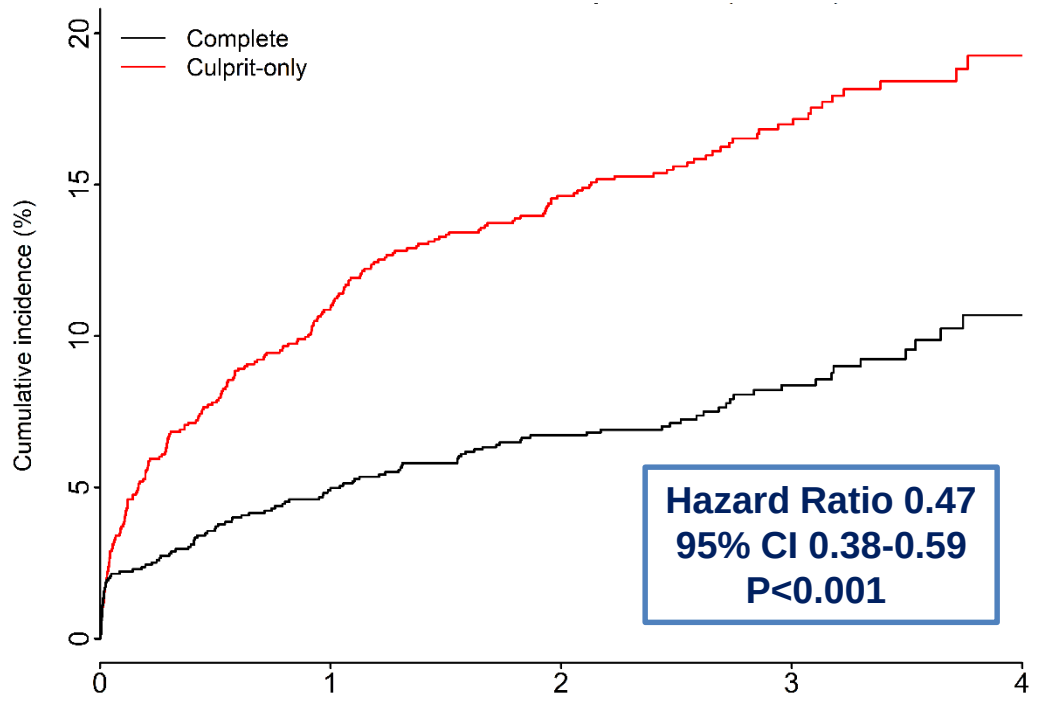
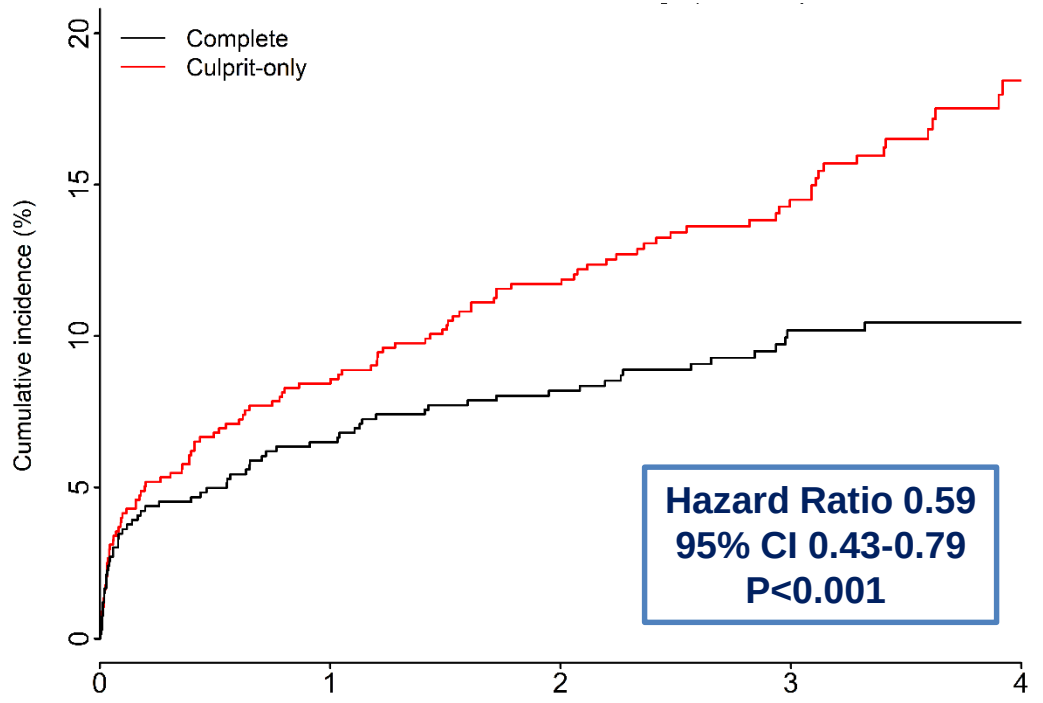
Timing Analysis: Second Co-Primary Outcome CV death, MI or IDR

Index Hospitalization



No. at Risk					
Complete	1353	1270	1093	533	149
Culprit-only	1349	1189	1008	489	132

After Discharge



No. at Risk					
Complete	663	616	566	392	180
Culprit-only	676	619	551	376	162

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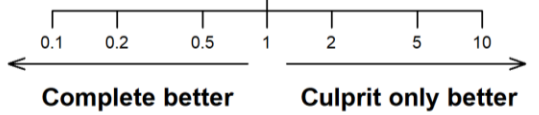
COMPLETE TRIAL

Timing Analysis: Efficacy Outcomes According to Timing of NCL PCI

Subgroup	Complete	Culprit only	HR (95% CI)	P value for Interaction
	no. of events/total no. (% per person-yr)			
Co-Primary outcomes				
Cardiovascular death or MI				0.62
Index hospitalization	101/1353 (2.7)	130/1349 (3.5)	0.77 (0.59-1.00)	
After discharge	57/663 (2.7)	83/676 (3.9)	0.69 (0.49-0.97)	
Cardiovascular death, MI or IDR				0.27
Index hospitalization	113/1353 (3.0)	227/1349 (6.6)	0.47 (0.38-0.59)	
After discharge	66/663 (3.1)	112/676 (5.4)	0.59 (0.43-0.79)	
Key secondary outcomes				
CV death, MI, IDR, unstable angina or class IV HF				0.23
Index hospitalization	175/1353 (4.9)	288/1349 (8.7)	0.58 (0.48-0.69)	
After discharge	97/663 (4.8)	138/676 (7.0)	0.70 (0.54-0.91)	
Other secondary outcomes				
MI				0.59
Index hospitalization	65/1353 (1.7)	100/1349 (2.7)	0.64 (0.47-0.88)	
After discharge	44/663 (2.1)	60/676 (2.8)	0.74 (0.50-1.09)	
IDR				0.042
Index hospitalization	15/1353 (0.4)	113/1349 (3.1)	0.13 (0.07-0.22)	
After discharge	14/663 (0.6)	47/676 (2.2)	0.30 (0.16-0.54)	
Unstable angina				0.14
Index hospitalization	43/1353 (1.1)	92/1349 (2.5)	0.46 (0.32-0.66)	
After discharge	27/663 (1.3)	38/676 (1.8)	0.72 (0.44-1.18)	



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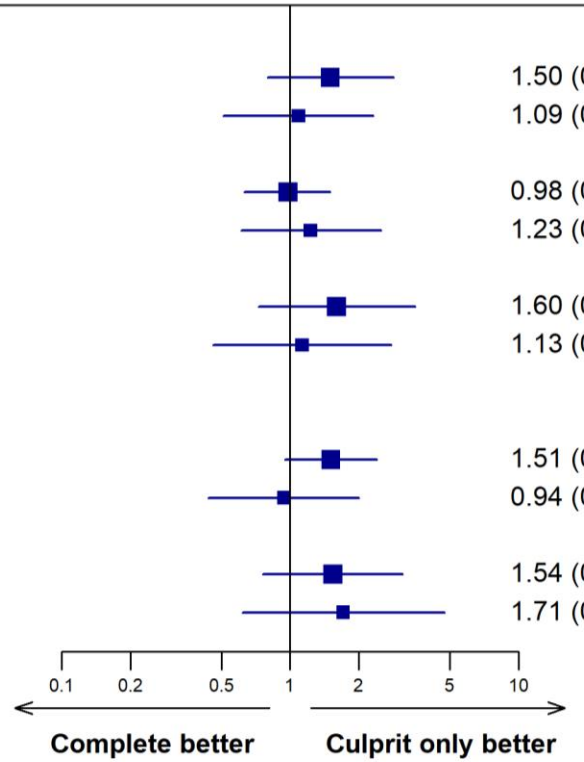
COMPLETE TRIAL

Timing Analysis: Safety Outcomes According to Timing of NCL PCI

Subgroup	Complete	Culprit only	HR (95% CI)	P value for Interaction
	no. of events/total no. (% per person-yr)			
Stroke				0.52
Index hospitalization	24/1353 (0.6)	16/1349 (0.4)	1.50 (0.80-2.83)	
After discharge	14/663 (0.6)	13/676 (0.6)	1.09 (0.51-2.31)	
NYHA class IV HF				0.58
Index hospitalization	41/1353 (1.1)	42/1349 (1.1)	0.98 (0.63-1.50)	
After discharge	17/663 (0.8)	14/676 (0.6)	1.23 (0.61-2.50)	
Stent thrombosis				0.56
Index hospitalization	16/1353 (0.4)	10/1349 (0.3)	1.60 (0.73-3.53)	
After discharge	10/663 (0.5)	9/676 (0.4)	1.13 (0.46-2.77)	
Safety outcomes				
Major bleeding				0.3
Index hospitalization	45/1353 (1.2)	30/1349 (0.8)	1.51 (0.95-2.39)	
After discharge	13/663 (0.6)	14/676 (0.6)	0.94 (0.44-2.00)	
Contrast associated acute kidney injury				0.87
Index hospitalization	20/1353 (1.5)	13/1349 (1.0)	1.54 (0.76-3.11)	
After discharge	10/663 (1.5)	6/676 (0.9)	1.71 (0.62-4.73)	



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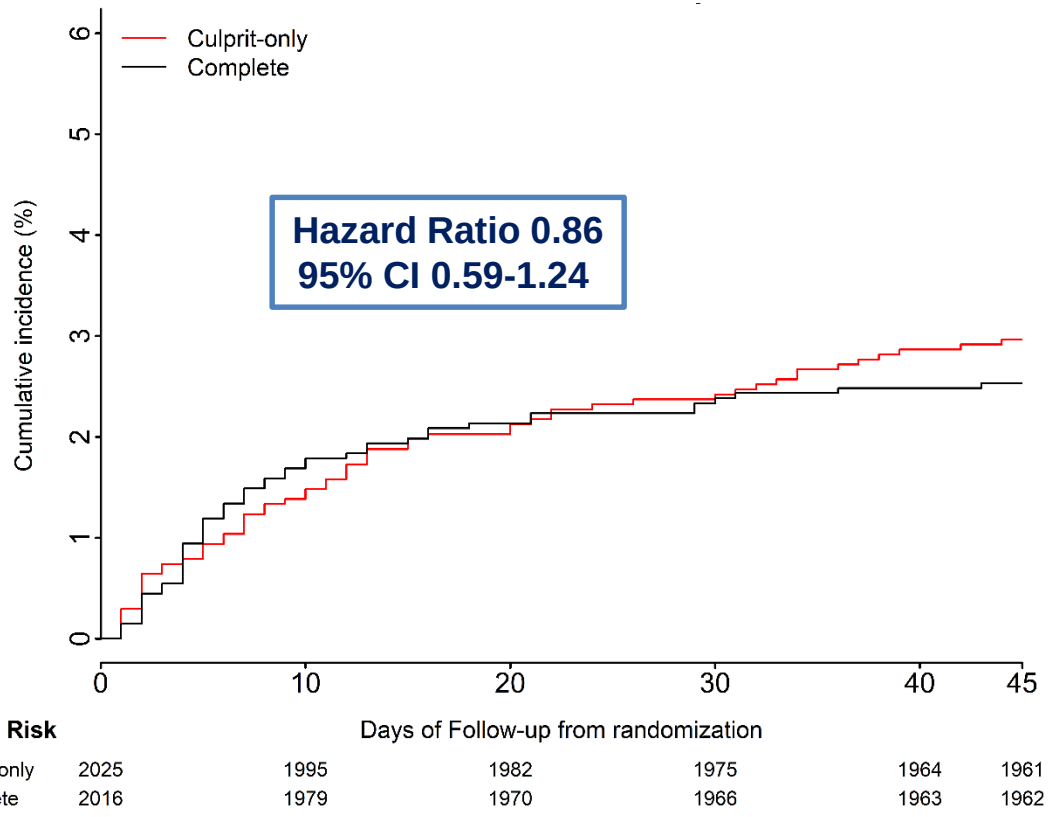
COMPLETE TRIAL

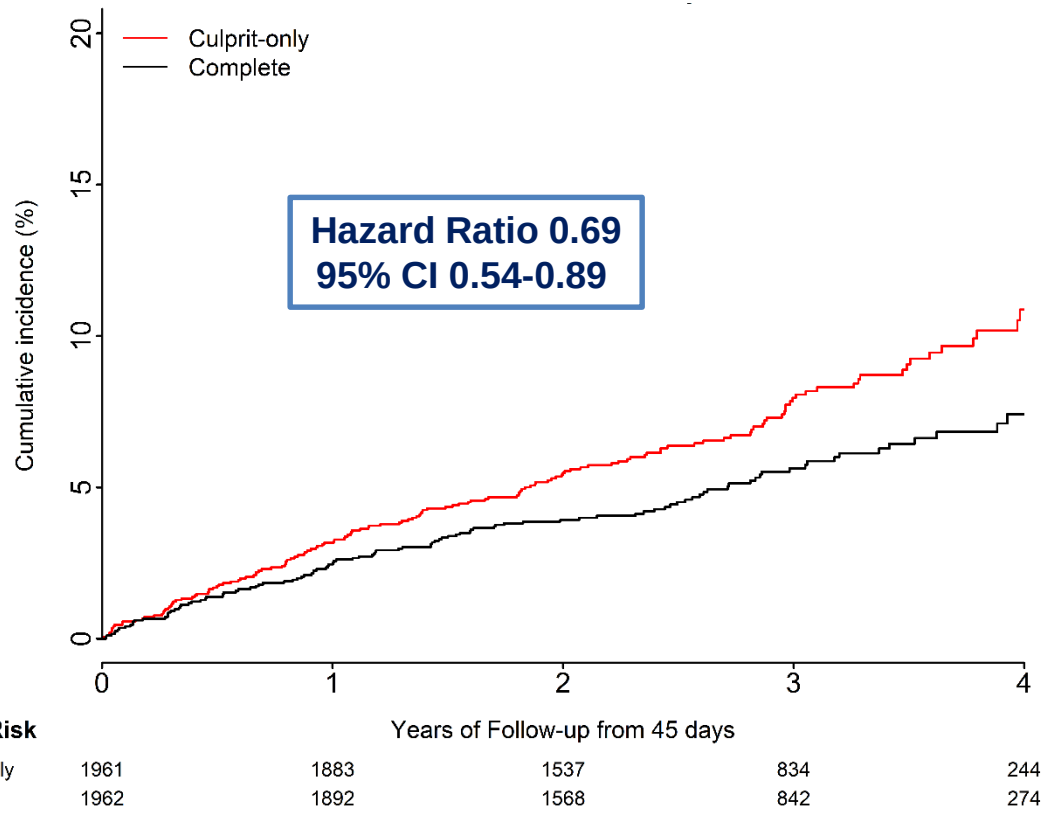
Landmark Analysis Before and After 45 days
CV Death or New MI

Randomization to 45 Days



No. at Risk						
Culprit-only	2025	1995	1982	1975	1964	1961
Complete	2016	1979	1970	1966	1963	1962

>45 days to Study End



No. at Risk					
Culprit-only	1961	1883	1537	834	244
Complete	1962	1892	1568	842	274

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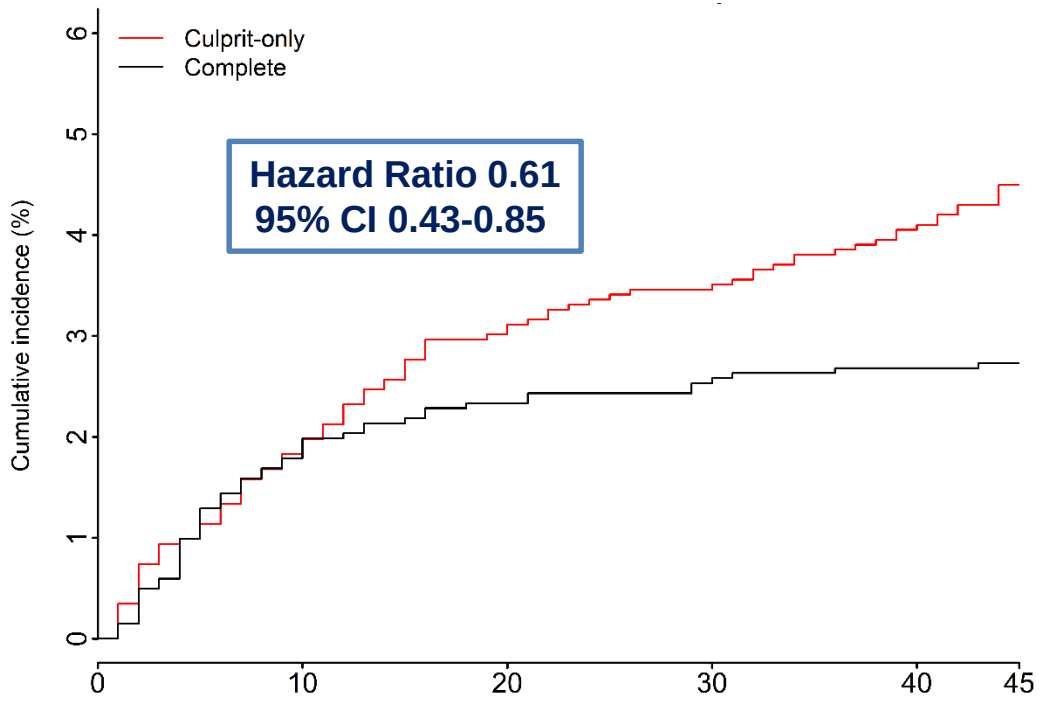
COMPLETE TRIAL

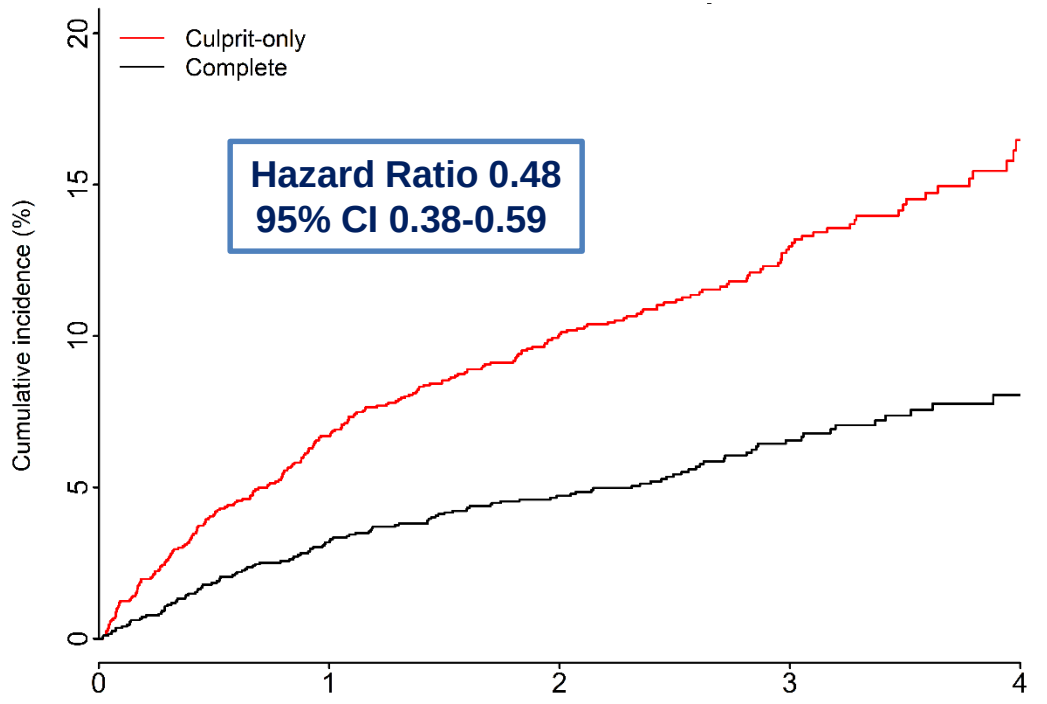
Landmark Analysis Before and After 45 days
CV Death, new MI or IDR

Randomization to 45 Days



No. at Risk						
Culprit-only	2025	1986	1962	1953	1940	1930
Complete	2016	1977	1966	1962	1959	1958

>45 days to Study End



No. at Risk					
Culprit-only	1930	1786	1438	774	230
Complete	1958	1874	1550	829	267

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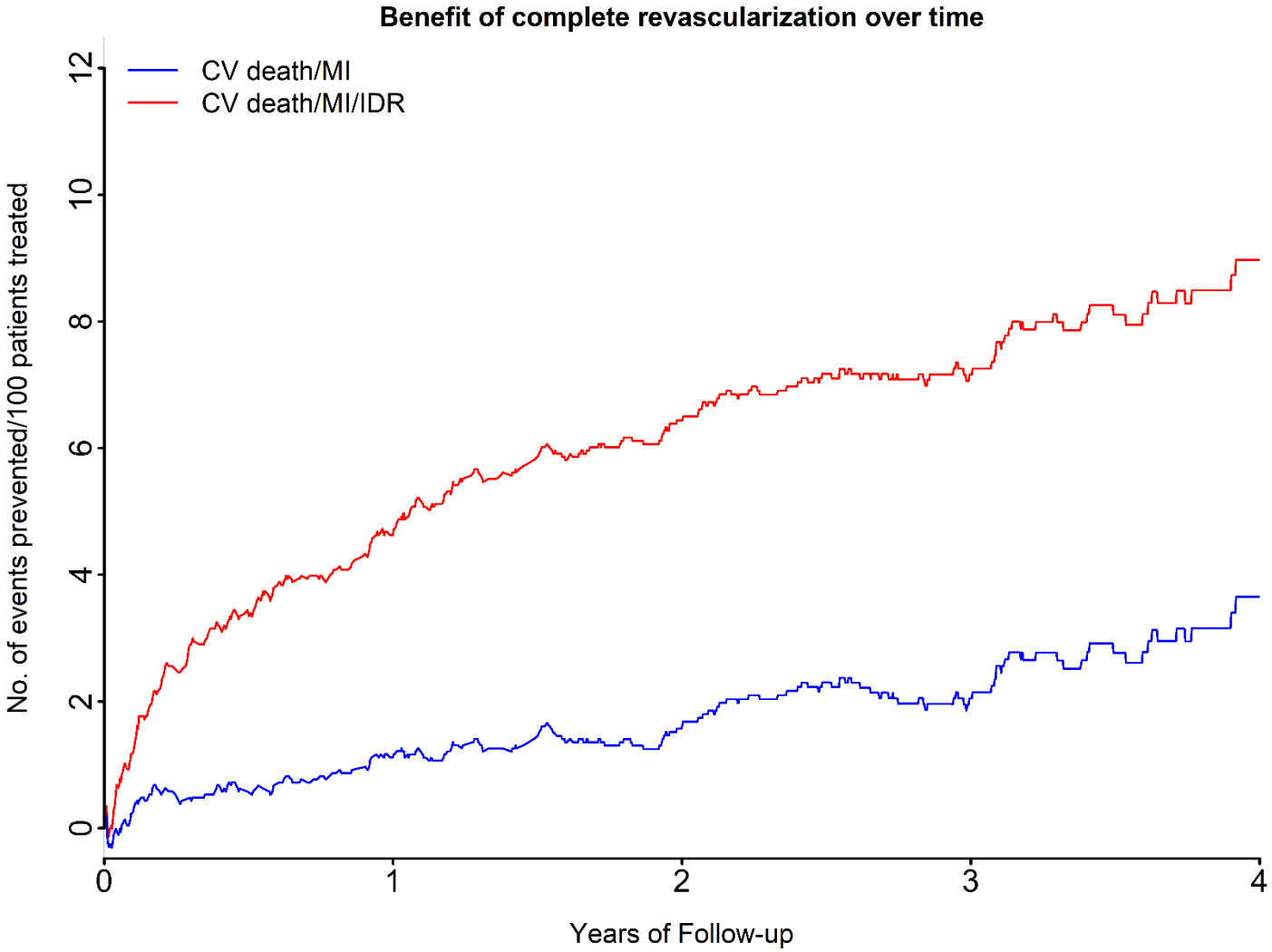
COMPLETE TRIAL

Absolute Difference in Events Prevented over Time



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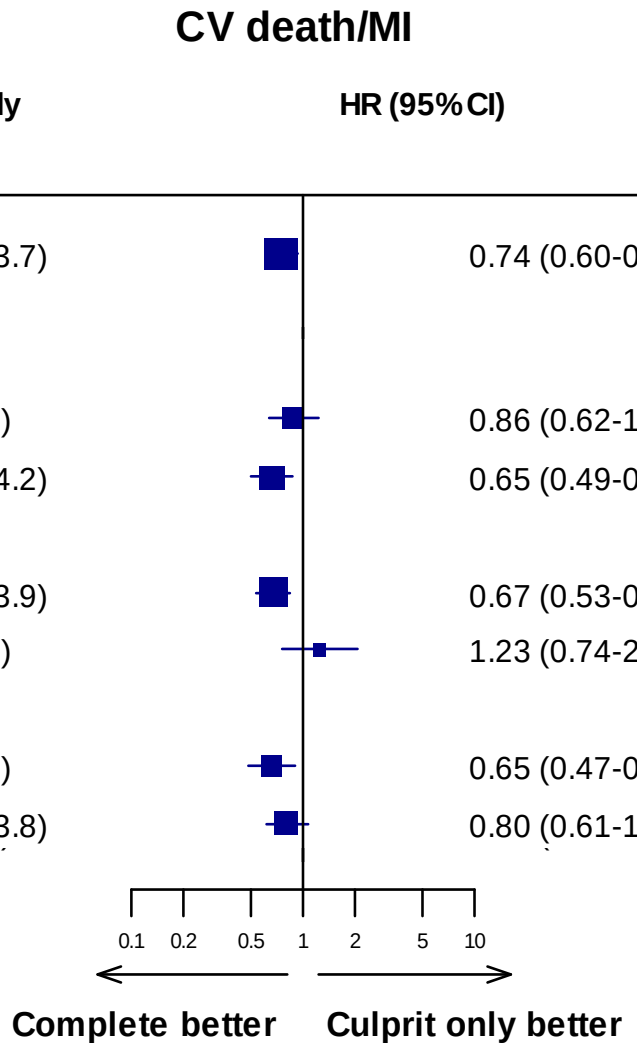
Main Pre-Defined Subgroup Analyses

Subgroup	Complete	Culprit only	HR (95% CI)	P value for Interaction
	no. of events/total no. (%/yr)			
Overall	158/2016 (2.7)	213/2025 (3.7)	0.74 (0.60-0.91)	
Main pre-defined:				
Proximal/mid LAD non-culprit stenosis				0.2
Presence	64/820 (2.7)	78/849 (3.1)	0.86 (0.62-1.20)	
Absence	87/1097 (2.7)	129/1085 (4.2)	0.65 (0.49-0.85)	
Non-culprit stenosis severity ≥ 80% visual or ≥ 60% core lab				0.033
Presence	127/1668 (2.6)	183/1631 (3.9)	0.67 (0.53-0.84)	
Absence	31/346 (3.2)	29/392 (2.6)	1.23 (0.74-2.04)	
Residual SYNTAX score				0.32
<6(median)	60/885 (2.3)	90/870 (3.6)	0.65 (0.47-0.90)	
≥ 6(median)	91/1033 (3.0)	117/1070 (3.8)	0.80 (0.61-1.05)	



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COMPLETE TRIAL

Safety and Other Outcomes

	Complete Revasc. N=2016		Culprit Lesion Only N=2025		HR (95% CI)	P value
	N (%)	%/year	N (%)	%/year		
Stroke	38 (1.9)	0.6	29 (1.4)	0.5	1.31 (0.81-2.13)	0.27
Stent thrombosis	26 (1.3)	0.4	19 (0.9)	0.3	1.38 (0.76-2.49)	0.28
All cause death or new MI	194 (9.6)	3.3	251 (12.4)	4.3	0.77 (0.64-0.93)	0.006
Major bleeding	58 (2.9)	1.0	44 (2.2)	0.7	1.33 (0.90-1.97)	0.15
Contrast-associated acute kidney injury*	30 (1.5)	-	19 (0.9)	-	1.59 (0.89-2.84)	0.11
NYHA class IV heart failure	58 (2.9)	1.0	56 (2.8)	0.9	1.04 (0.72-1.50)	0.83
Clinically non-significant bleeding	32 (1.6)	0.5	27 (1.3)	0.4	1.19 (0.71-1.99)	0.50

* There were 7 vs 0 patients with AKI associated with complete revasc during index hospitalization

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COMPLETE TRIAL

Conclusions

In patients with STEMI and multi-vessel coronary artery disease:

- Compared with culprit-lesion-only PCI, routine non-culprit lesion PCI with the goal of complete revascularization:
  - **Reduced CV death or new MI by 26%** (P=0.004), NNT = 37
  - **Reduced CV death, new MI or IDR by 49%** (P<0.001), NNT = 13
- The benefit of complete revascularization was similar in those undergoing non-culprit lesion PCI during the index hospitalization (median 1 day) and several weeks after hospital discharge (median 3 weeks).
- The benefit of complete revascularization on hard outcomes (CV death or MI) emerges mainly over the long term (>45 days).
- There were no significant differences in bleeding, stent thrombosis, AKI or stroke.

Mehta SR et al. *N Engl J Med* 2019; 381:1411-1421
Wood DA et al. *J Am Coll Cardiol* 2019; 74, 22

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Acknowledgments

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