

OUTCOMES OF PATIENTS WITH MYOCARDIAL INFARCTION AND CARDIOGENIC SHOCK TREATED WITH CULPRIT VESSEL-ONLY VERSUS MULTIVESSEL PRIMARY PCI.

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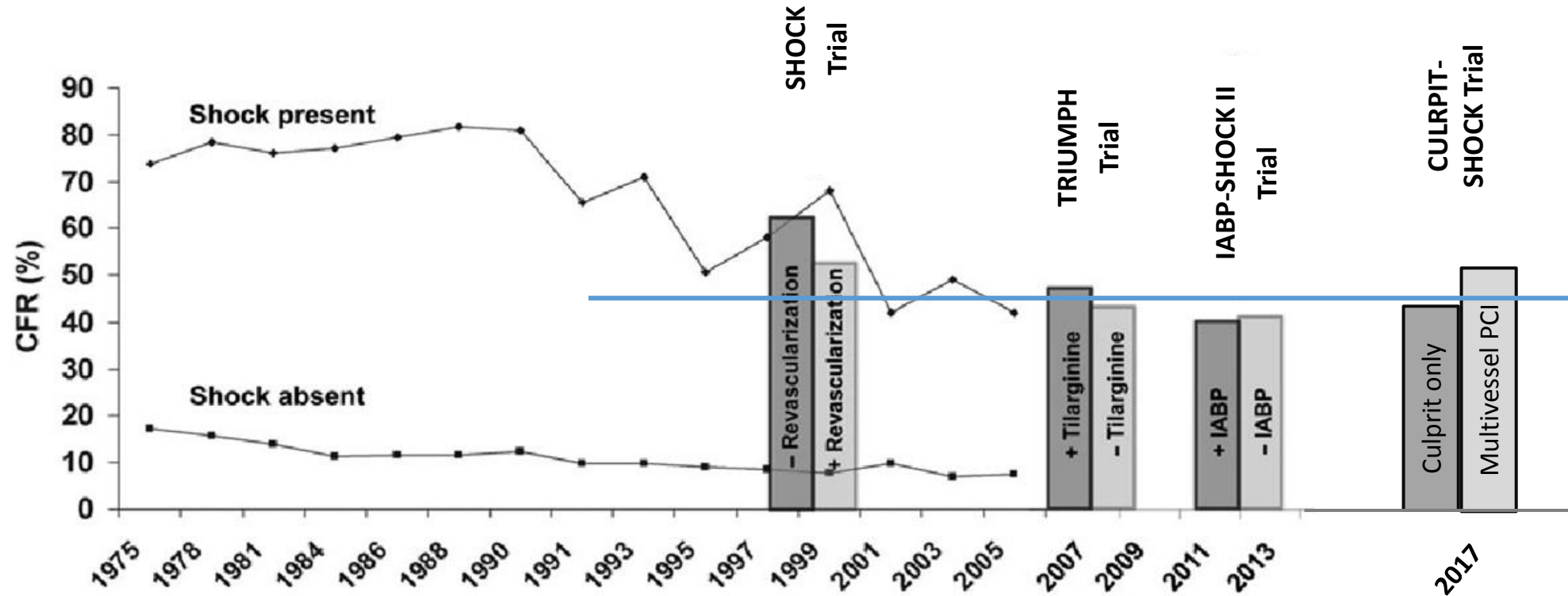
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Introduction

Patients with ST elevation **myocardial infarction (STEMI)** and **cardiogenic shock (CS)** treated with primary percutaneous coronary intervention (pPCI) have high mortality.

Evidence shows contradictory results in the superiority of culprit **vessel-only strategy (CV-pPCI)** compared to immediate **multivessel PCI (MV-pPCI)** for patients with STEMI and multivessel coronary artery disease (MVD) (CS vs non-CS patients).

Cardiogenic Shock - Mortality over Time



**COMPLETE
Trial Design**

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)

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 $\geq 70\%$ 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)

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

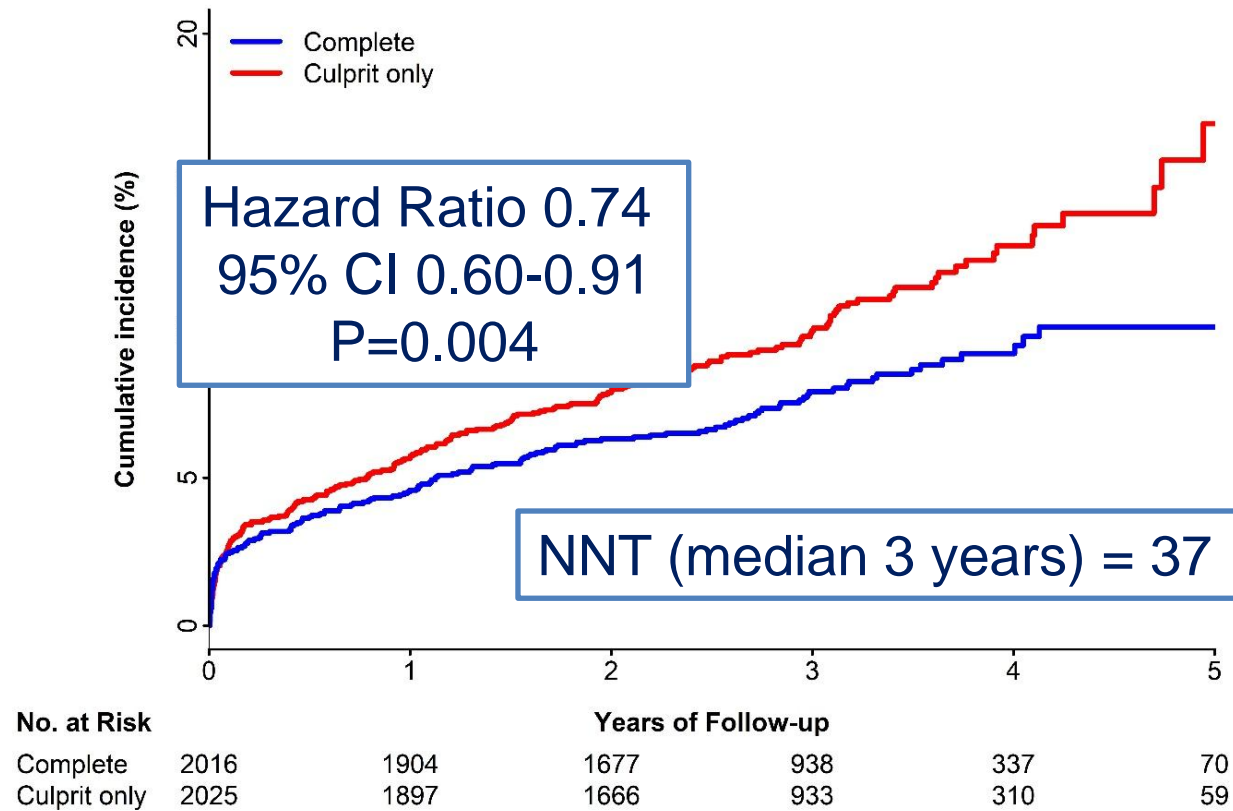
Guideline-Directed Medical Therapy
 ASA, P2Y12 inhibitor (Ticagrelor strongly recommended), Statin, BB, ACE/ARB + Risk Factor Modification

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

First Co-Primary Outcome: CV Death or New MI



Mehta et al.: NEJM 2019;381:1411-1421

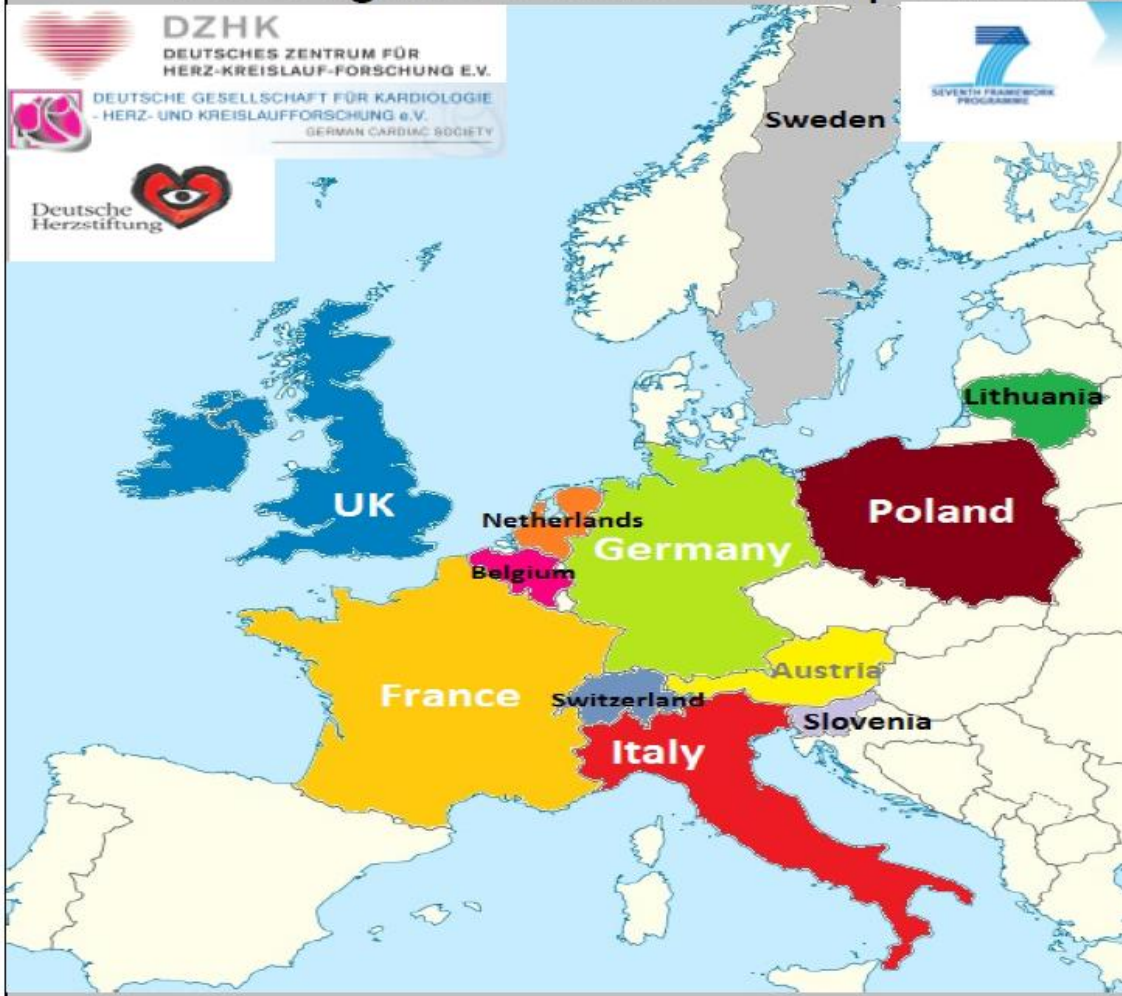
Efficacy Outcomes

	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

Mehta et al.: NEJM 2019;381:1411-1421

CULPRIT-SHOCK Trial

Investigator-initiated European multicenter trial; 1:1 randomization



PI + Coordination:

Holger Thiele

Co-PI:

Steffen Desch

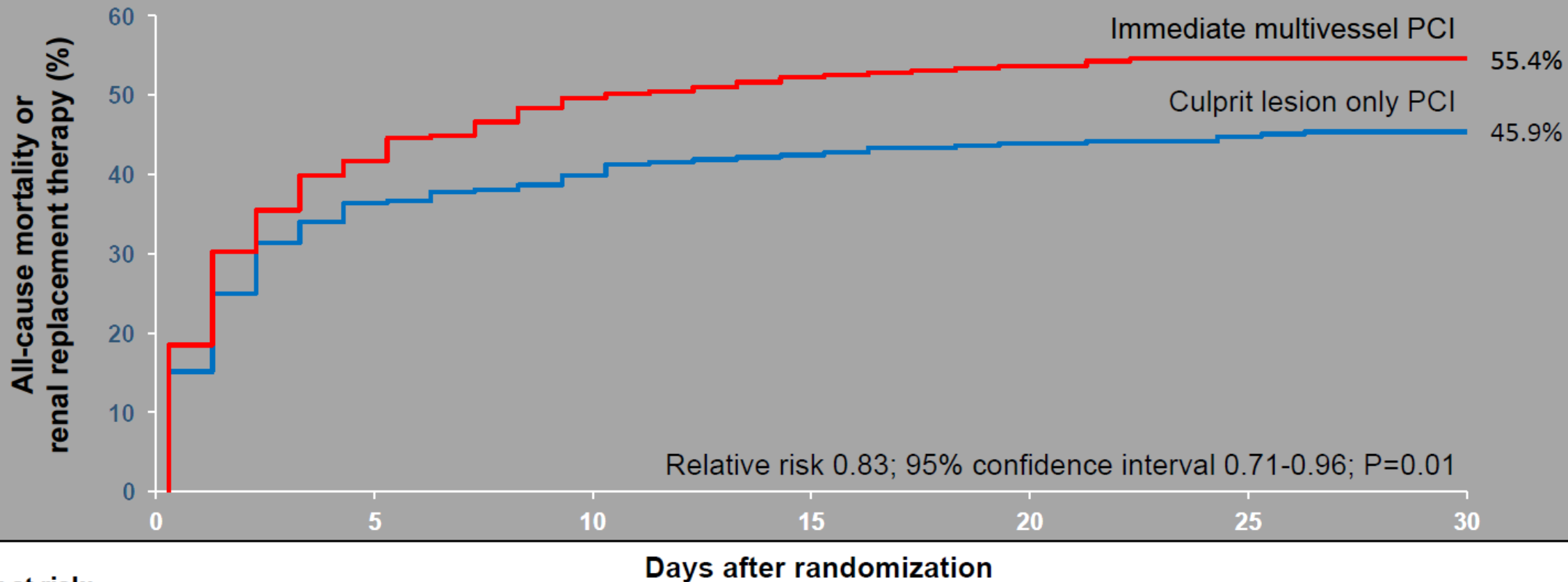
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National Coordinators (83 centers):

- Kurt Huber
- Gilles Montalescot
- Jan Piek
- Holger Thiele
- Pranas Serpytis
- Janina Stepinska
- Christiaan Vrints
- Marko Noc
- Keith Oldroyd
- Stefan Windecker
- Stefano Savonitto

Primary Study Endpoint

All-Cause Mortality or Renal Replacement Therapy

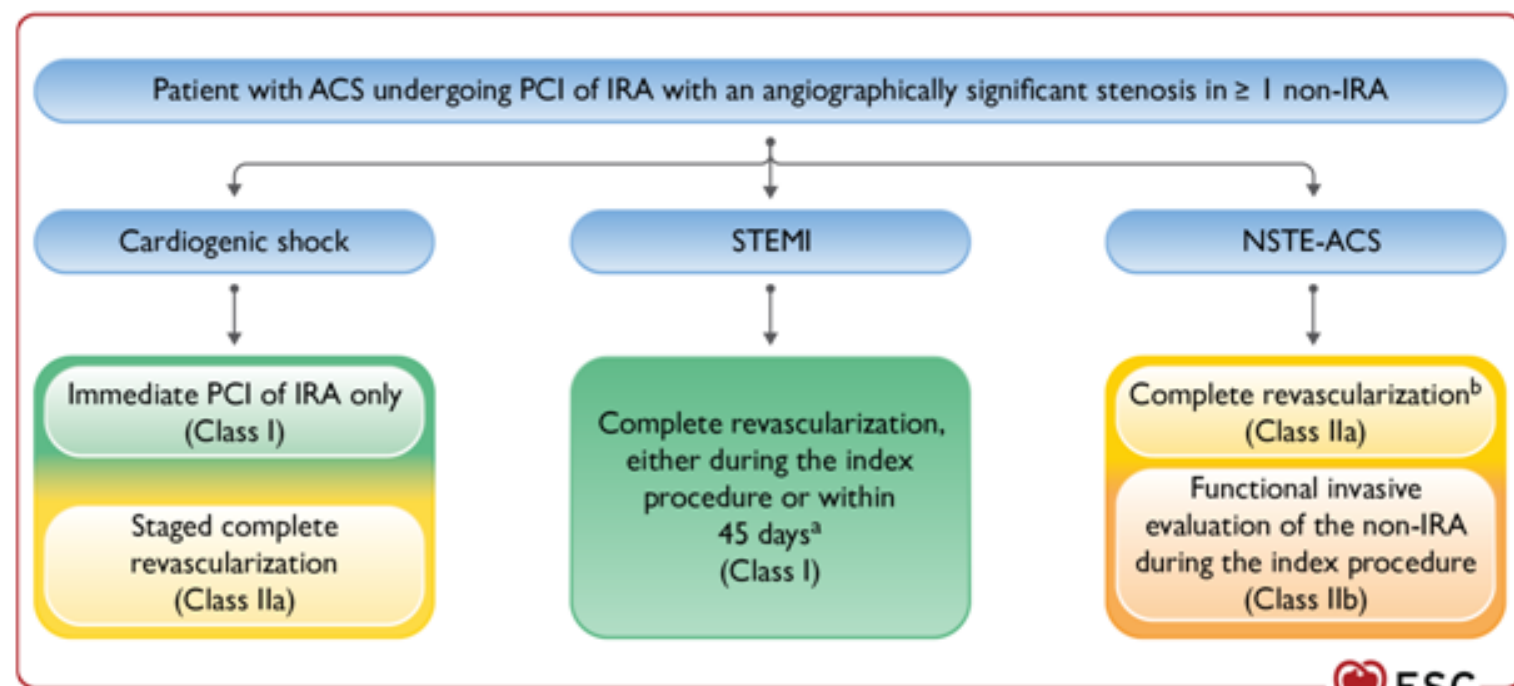


Number at risk:

	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

Figure 14

Algorithm for the management of acute coronary syndrome patients with multivessel coronary artery disease



Aims

- To compare the characteristics and prognosis of patients with CS-STEMI and MVD treated with culprit **vessel-only pPCI vs. multivessel PCI** during the initial procedure, using data from:
 - the National Registry of Cardiovascular Interventions (NRCI),
 - National Registry of Paid Health Services,
 - and Registry of Death Records.

Methods

The National Registry of Cardiovascular Interventions (NRCI)

Prospective multicentre registry on all PCIs performed from all 24 PCI centres in the Czech Republic since 2005



Data Linked with the Registry of Deceased Persons

From January 1st, 2016, to December 31st, 2020, **23,703 primary PCI patients with STEMI**

1,213 had Cardiogenic shock and multivessel coronary disease (MVD)

921 (75.9%) treated with CV-pPCI

292 (24.1%) treated with MV-pPCI

Baseline Characteristics

	All patients N (total %)	CV-pPCI N (%)	MV-pPCI N (%)	p
Total	1213 (100)	921 (75.9)	292 (24.1)	-
Male	896 (73.9)	668 (74.6)	228 (25.4)	< 0.001
Age years (mean ± SD)	68±11.4	68.1±11.2	66.2±11.4	0.780
< 40	10 (0.8)	7 (70.0)	3 (30.0)	
40–49	62 (5.1)	39 (62.9)	23 (37.1)	
50–59	196 (16.2)	144 (73.5)	52 (26.5)	
60–69	405 (33.4)	313 (77.3)	92 (22.7)	0.125
70–79	342 (28.2)	260 (76.0)	82 (24.0)	
≥ 80	198 (16.3)	158 (79.8)	40 (20.2)	
Previous PCI	183 (15.1)	148 (80.9)	35 (19.1)	0.890
Previous CABG	71 (5.9)	57 (80.3)	14 (19.7)	0.376
Chronic kidney disease/failure	87 (7.2)	63 (72.4)	24 (27.6)	0.426
After CPR	728 (60.0)	556 (76.4)	172 (23.6)	0.657
Artificial lung ventilation	821 (67.7)	615 (74.9)	206 (25.1)	0.227

PCI - percutaneous coronary intervention; CV -pPCI – culprit vessel only primary PCI, MV-pPCI – multivessel primary PCI; N- number; SD - standard deviation; CABG – coronary artery bypass grafting; CPR – cardiopulmonary resuscitation

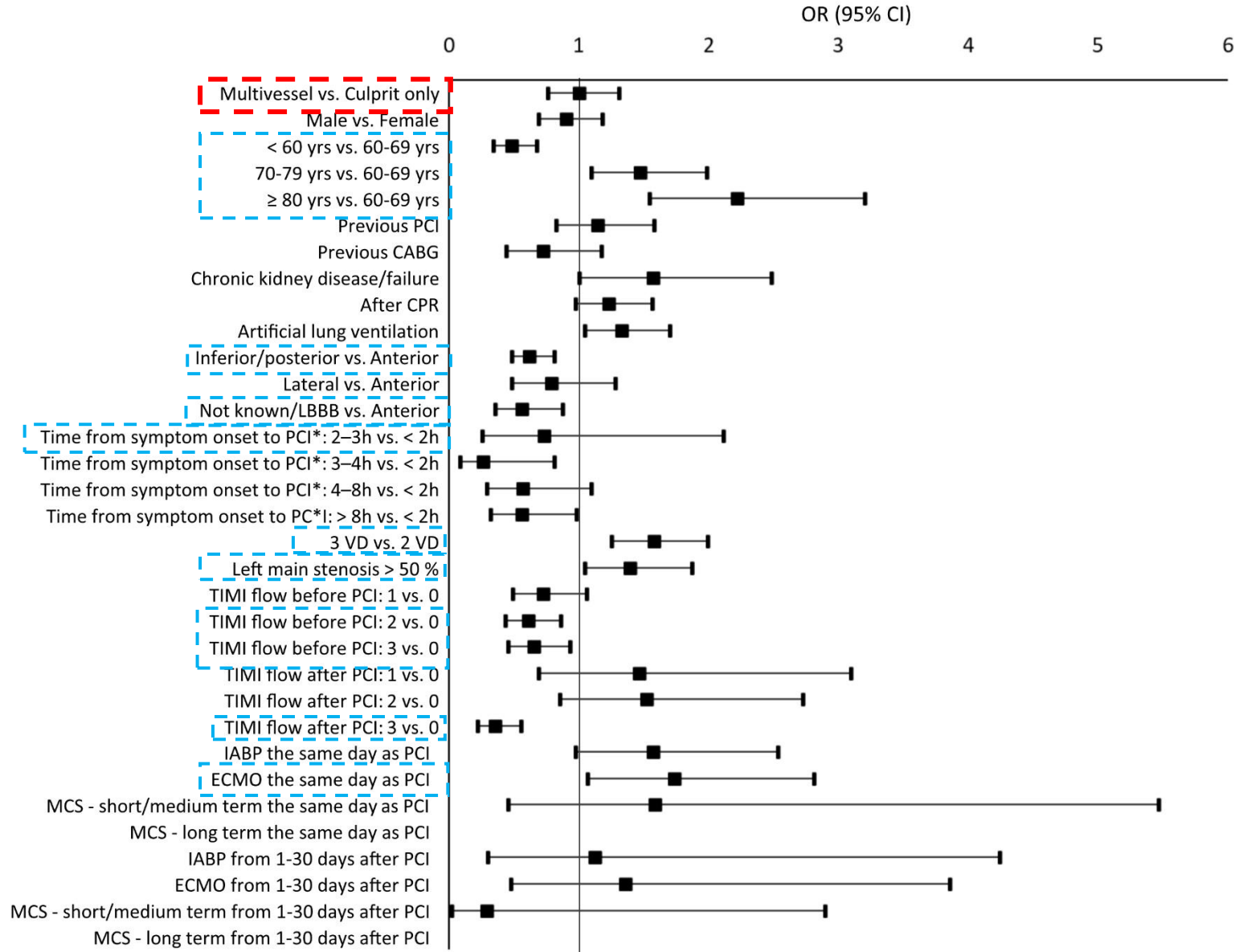
		All patients N (total %)	CV-pPCI N (%)	MV-pPCI N (%)	p
MI location					
	Anterior	640 (52.8)	468 (73.1)	172 (26.9)	0.671
	Inferior/posterior	401 (33.1)	335 (83.5)	66 (16.5)	
	Lateral	95 (7.8)	65 (68.4)	30 (31.6)	
	Not known/LBBB	77 (6.3)	53 (68.8)	24 (31.2)	
No. of diseased vessels *					
	1	0 (0.0)	0 (0.0)	0 (0.0)	-
	2	547 (45.1)	445 (81.4)	102 (18.6)	< 0.001
	3	666 (54.9)	476 (71.5)	190 (28.5)	
Left main stenosis > 50 %					
		239 (19.7)	149 (62.3)	90 (37.7)	< 0.001
TIMI flow after PCI					
	0	110 (9.1)	63 (57.3)	47 (42.7)	< 0.001
	1	56 (4.6)	41 (73.2)	15 (26.8)	
	2	145 (12.0)	110 (75.9)	35 (24.1)	
	3	902 (74.4)	707 (78.4)	195 (21.6)	
Procedures					
	IABP the same day as PCI	78 (6.4%)	47 (5.1%)	31 (10.6%)	0.001
	ECMO on the same day as PCI	80 (6.6%)	49 (5.3%)	31 (10.6%)	0.003
	MCS - short/medium term the same day as PCI	11 (0.9%)	5 (0.5%)	6 (2.1%)	0.028
	MCS - long-term the same day as PCI	0 (0.0%)	0 (0.0%)	0 (0.0%)	-
	IABP from 1-30 days after PCI	9 (0.7%)	6 (0.7%)	3 (1.0%)	0.456
	ECMO from 1-30 days after PCI	15 (1.2%)	8 (0.9%)	7 (2.4%)	0.062
	MCS - short/medium term from 1-30 days after PCI	4 (0.3%)	1 (0.1%)	3 (1.0%)	0.045
	MCS - long-term from 1-30 days after PCI	3 (0.2%)	1 (0.1%)	2 (0.7%)	0.146
Complications					
	Vessel complications requiring surgery	5 (0.4)	2 (0.2)	3 (1.0)	0.094
	Severe bleeding	3 (0.2)	2 (0.2)	1 (0.3)	0.563

All-cause mortality

	CV-pPCI	MV-pPCI
30- days mortality	50.5%	51.4%
1-year mortality	59.0%	61.3%

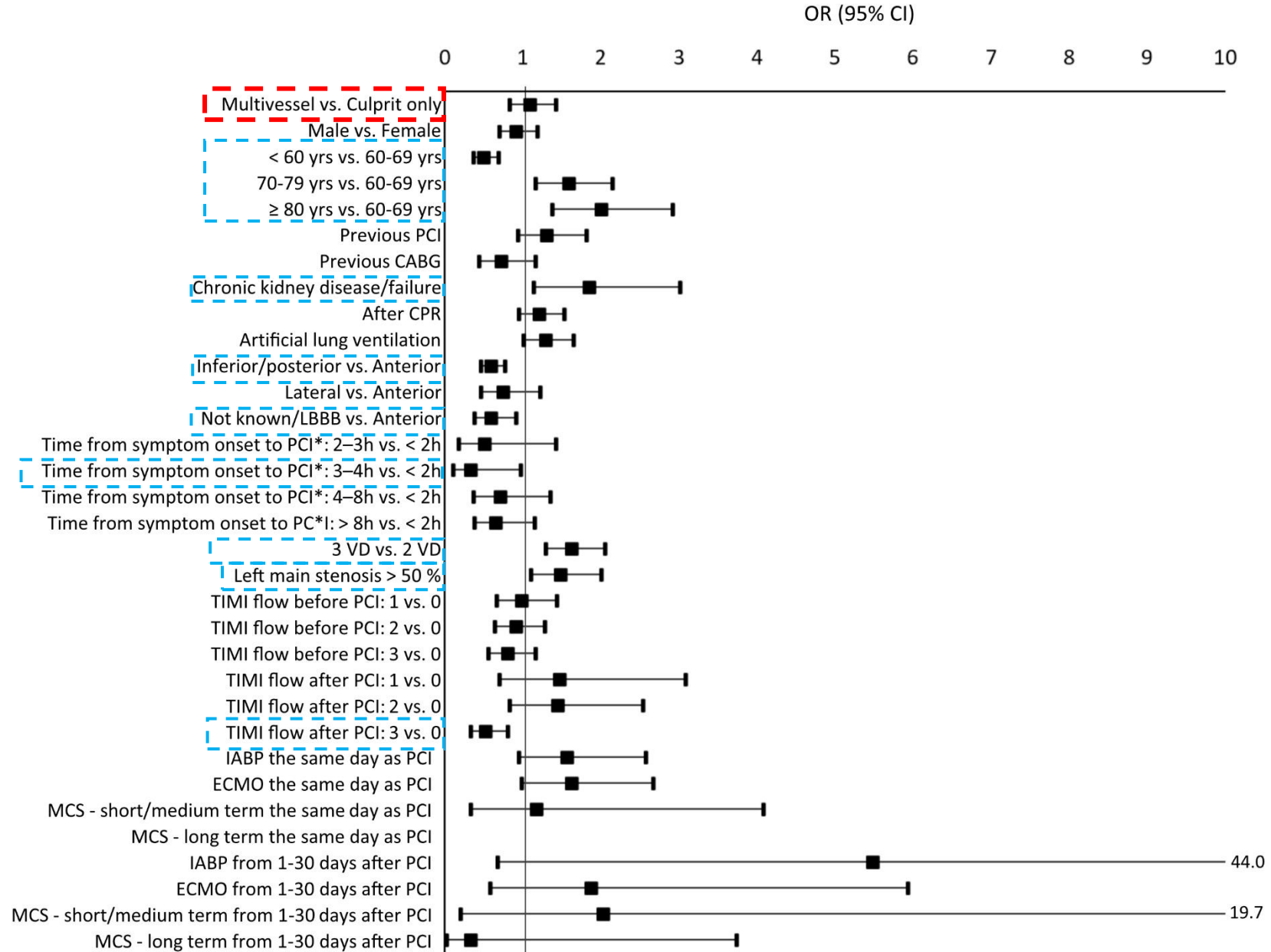
Predictors of 30-day all-cause mortality

Univariate logistic regression analysis



Predictors of 1-year all-cause mortality

Univariate logistic regression analysis



Predictors of 30-day and 1-year all-cause mortality

Multivariate logistic regression analysis

Predictor	30-days mortality		1-year mortality	
	OR (95% IS)	p	OR (95% IS)	p
Primary PCI	0.90 (0.68; 1.18)	0.439	0.99 (0.75; 1.30)	0.923
Gender	1.16 (0.89; 1.51)	0.273	1.15 (0.88; 1.51)	0.292
3VD vs. 2VD	1.60 (1.27; 2.03)	<0.001	1.64 (1.30; 2.07)	<0.001
Left main stenosis > 50 %	1.01 (1.00; 1.03)	0.139	1.02 (1.00; 1.04)	0.101
IABP the same day as PCI	1.48 (0.91; 2.40)	0.110	1.45 (0.88; 2.40)	0.147
ECMO on the same day as PCI	1.83 (1.12; 2.98)	0.016	1.70 (1.03; 2.81)	0.037

PCI- percutaneous coronary intervention; 3VD – 3-vessel disease; 2VD – 2-vessel disease; IABP – intra-aortic balloon pump; ECMO – extracorporeal membrane oxygenation.

Conclusions

Our data from a large all-comers registry suggests that selective use of MV-pPCI does not increase the mortality rate in patients with CS-STEMI and MVD compared to CV-pPCI.



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Original Article

Outcomes of patients with myocardial infarction and cardiogenic shock treated with culprit vessel-only versus multivessel primary PCI

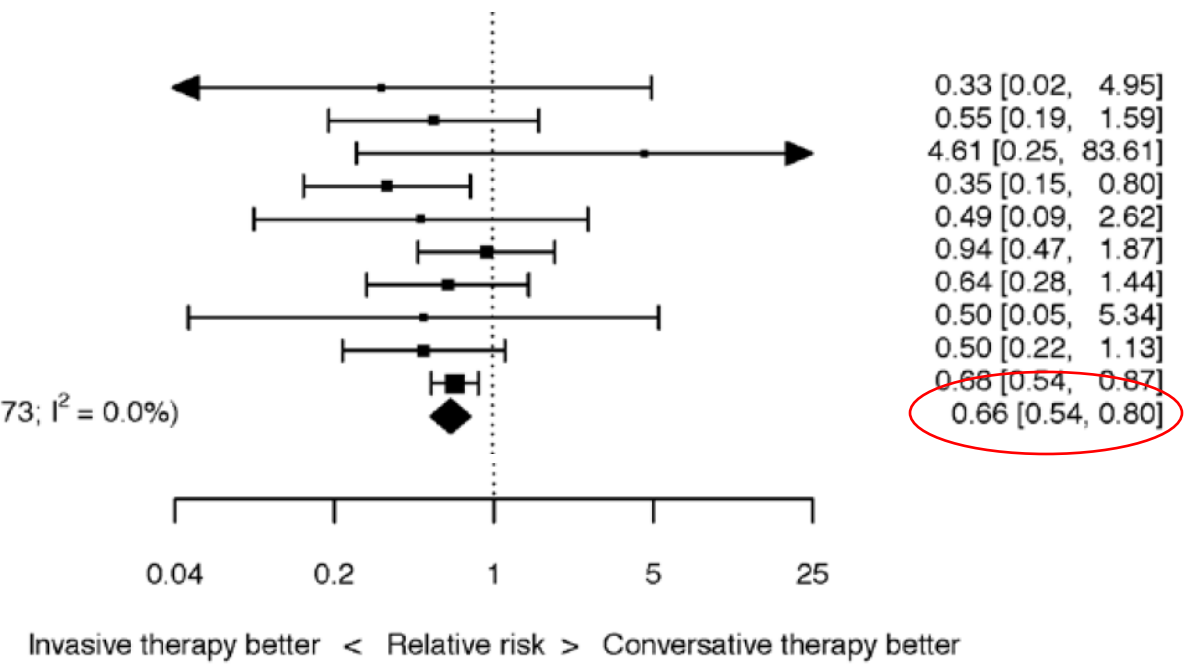
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Hlinomaz O, Motovska Z, Kala P, Hromadka M, Precek J, Mrozek J, Červinka P, Kettner J, Matejka J, Zohoor A, Bis J, Jarkovsky J. Outcomes of patients with myocardial infarction and cardiogenic shock treated with culprit vessel-only versus multivessel primary PCI. Hellenic J Cardiol. 2023 Aug 24; S1109-9666(23)00146-X. doi: 10.1016/j.hjc.2023.08.009. Epub ahead of print. PMID: 37633488.

STEMI and MVD – non-shock patients

Infarkt myokardu

Study and Year	Active Events	N	Control Events	N	Relative risk [95% CI]
Unstable CAD – Multivessel disease following STEMI					
Help-AMI, 2009	1	52	1	17	0.33 [0.02, 4.95]
Politi, 2010	6	130	7	84	0.55 [0.19, 1.59]
Dambrink, 2012	4	79	0	40	4.61 [0.25, 83.61]
PRAMI, 2013	7	234	20	231	0.35 [0.15, 0.80]
CvLPRIT, 2015	2	150	4	146	0.49 [0.09, 2.62]
DANAMI 3, 2015	15	313	16	314	0.94 [0.47, 1.87]
Zhang, 2015	9	215	14	213	0.64 [0.28, 1.44]
Hamza, 2016	1	50	2	50	0.50 [0.05, 5.34]
Compare ACUTE, 2017	7	295	28	590	0.50 [0.22, 1.13]
Complete, 2019	109	2016	160	2025	0.68 [0.54, 0.87]
Multivessel disease following STEMI studies ($p < 0.0001$, $Q = 6.10$, $df = 9$, p for heterogeneity = 0.73; $I^2 = 0.0\%$)					0.66 [0.54, 0.80]



Celková mortalita 0,84 (0,69-1,04); $p=0,11$
KV mortalita 0,68 (0,47-0,98); $p=0,04$



COMPLETE TRIAL

Procedural Characteristics

	Complete N=2016	Culprit-only N=2025		Complete N=2016	Culprit-only N=2025
Index PCI for STEMI			NCL diameter	2.8 mm	2.9 mm
Primary	91.9%	93.1%	Mean NCL stenosis (visual)	79.3%	78.7%
Pharmaco-invasive	3.2%	3.0%	NCL stenosis (visual)		
Rescue	4.9%	3.9%	50-69% and FFR<0.80	0.6%	0.6%
Radial access	80.8%	80.7%	70-79%	41.3%	45.1%
Residual diseased vessels			80-89%	33.5%	32.6%
1	76.1%	77.1%	90-99%	22.3%	19.7%
≥2	23.9%	22.9%	100%	2.1%	2.0%
NCL location			SYNTAX score (Core Lab)		
Left main	0.4%	0.1%	Baseline	16.3	16.0
LAD	38.0%	41.2%	Culprit lesion specific	8.8	8.6
Proximal LAD	9.8%	10.4%	Non-culprit lesion specific	4.5	4.5
Mid LAD	21.7%	23.7%	Residual (after index PCI)	7.2	7.0
Circumflex	36.4%	35.6%			
RCA	25.3%	23.2%			

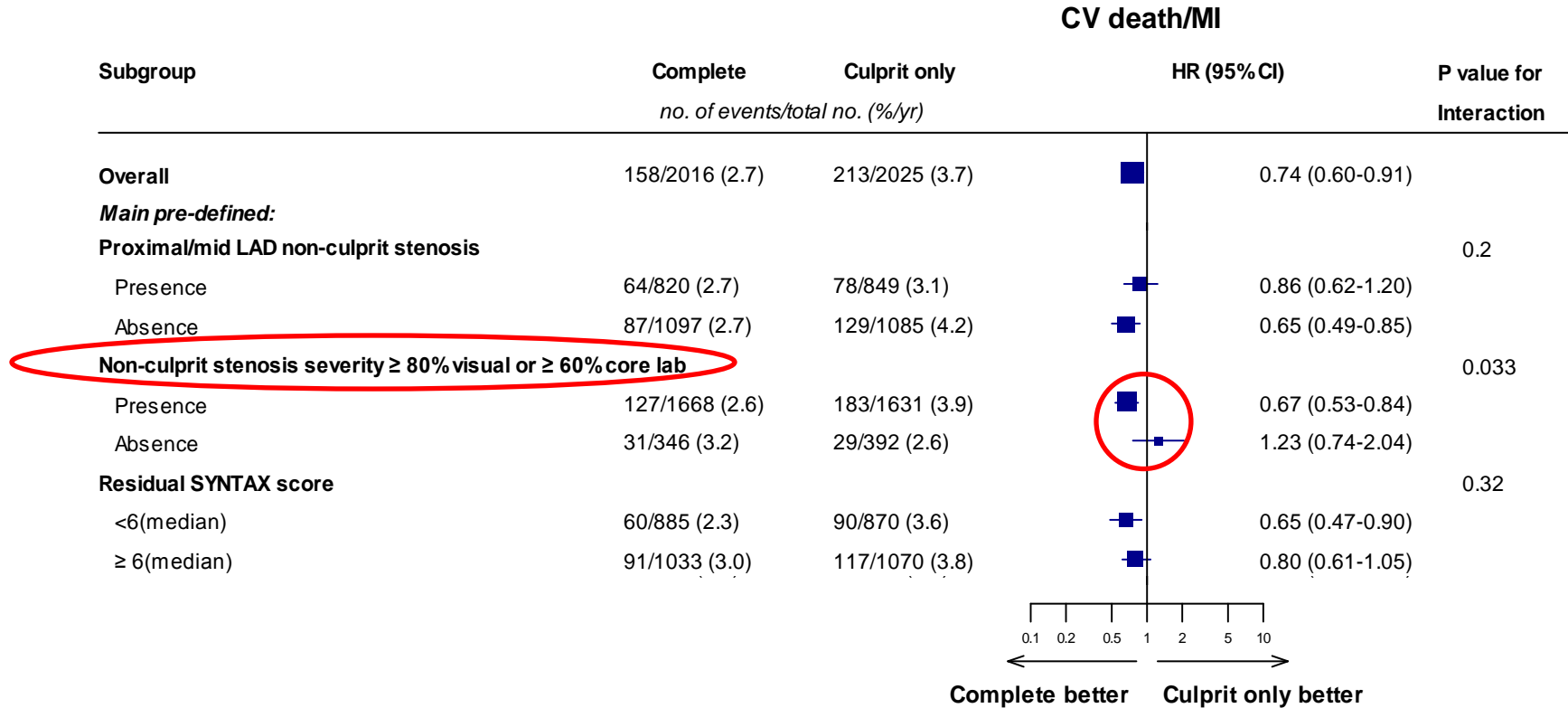
Complete revascularization was achieved in 90.1% after NCL PCI

Sub-types of MI

Subtype of MI	Complete Revasc. N=2016		Culprit Lesion Only N=2025		HR (95% CI)
	N (%)	%/year	N (%)	%/year	
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)

Mehta et al.: NEJM 2019;381:1411-1421

Main Pre-Defined Subgroup Analyses



Mehta et al.: NEJM 2019;381:1411-1421