

CULPRIT-SHOCK: Culprit Lesion Only PCI versus Multivessel PCI in Cardiogenic Shock – 1-Year Results

Holger Thiele

on behalf of the CULPRIT-SHOCK Investigators

Disclosure Statement of Financial Interest



Within the past 12 months, I have had a financial interest/arrangement or affiliation with the organization(s) listed below.

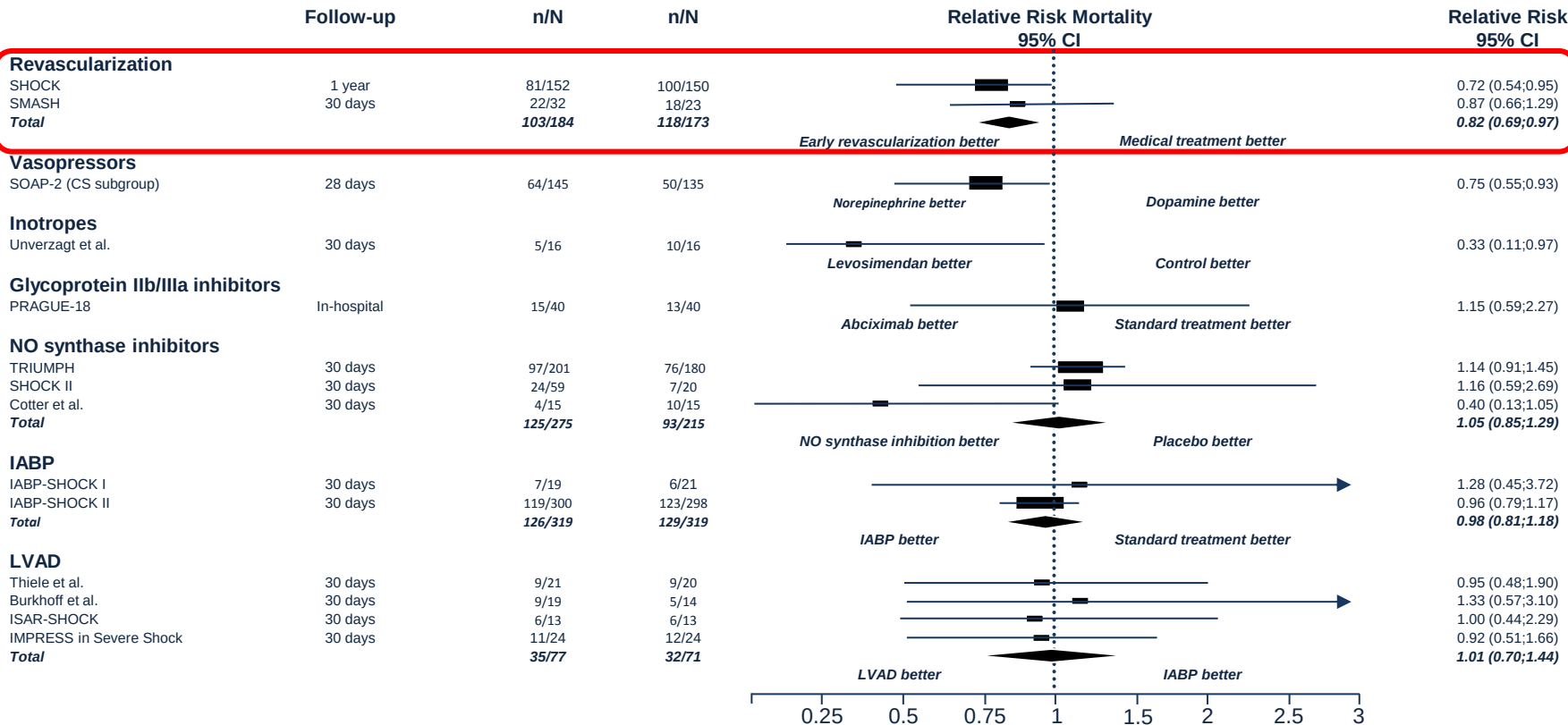
Affiliation/Financial Relationship

- Grant/Research Support
- Consulting Fees/Honoraria
- Major Stock Shareholder/Equity
- Royalty Income
- Ownership/Founder
- Intellectual Property Rights
- Other Financial Benefit

Company

- European Union, German Cardiac Society
German Heart Research Foundation
- None
- None
- None
- None
- None
- None

Randomized Trials Cardiogenic Shock



Multivessel PCI in Cardiogenic Shock

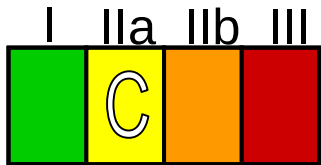
European and American Recommendations 2017



Multivessel coronary artery disease present in up to 80% → higher mortality

Guidelines

ESC



ACC/AHA/SCAI



No recommendation

Appropriate Use Criteria

ACC/AATS/AHA/ASE/ASNC/SCAI/SCCT/STS



A (9)

CULPRIT-SHOCK Trial

Investigator-initiated European multicenter trial; 1:1 randomization



PI + Coordination:

Holger Thiele

Co-PI:

Uwe Zeymer

Steffen Desch

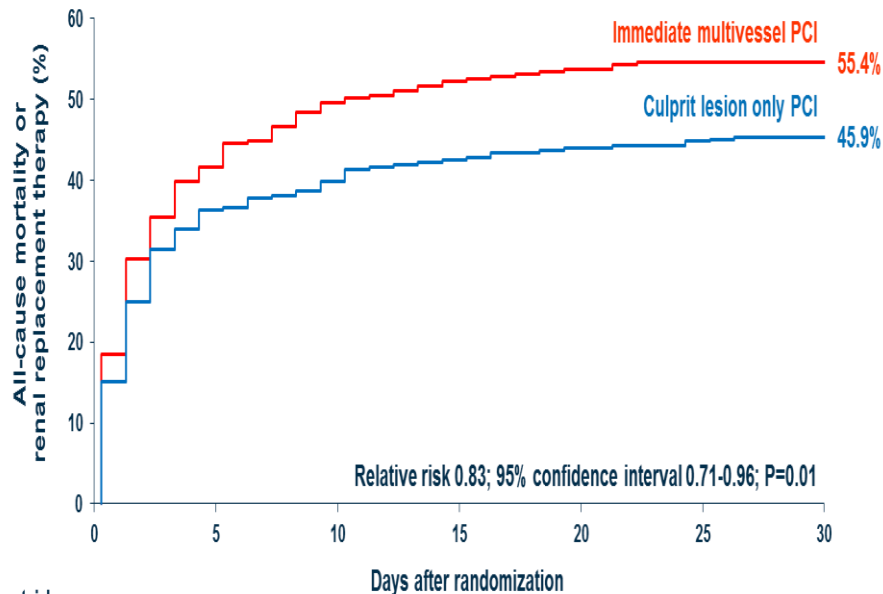
National Coordinators (83 centers):

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

CULPRIT-SHOCK Trial – 30-Day Results



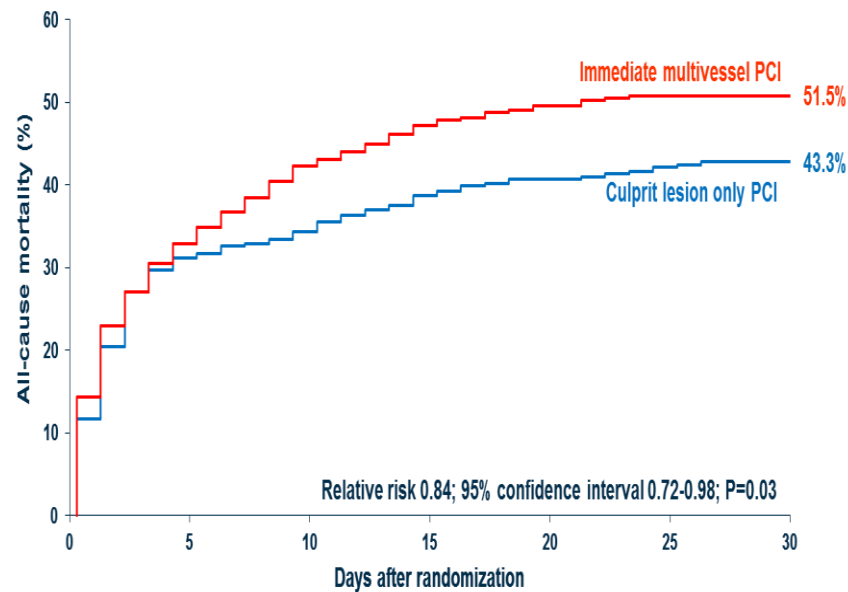
Primary study endpoint – 30 days
All-cause mortality or renal replacement therapy



Number at risk:

Culprit lesion only PCI	344	219	207	198	192	189	184
Immediate multivessel PCI	341	199	172	162	156	153	152

All-cause mortality – 30 days



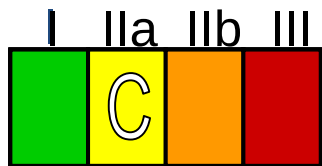
Number at risk:

Culprit lesion only PCI	344	237	226	211	203	198	193
Immediate multivessel PCI	341	229	197	179	170	166	165

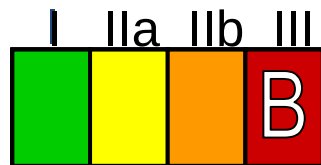
ESC STEMI Guidelines 2017 → Revascularization Guidelines 2018

STEMI (NSTEMI), Cardiogenic Shock

2017



2018



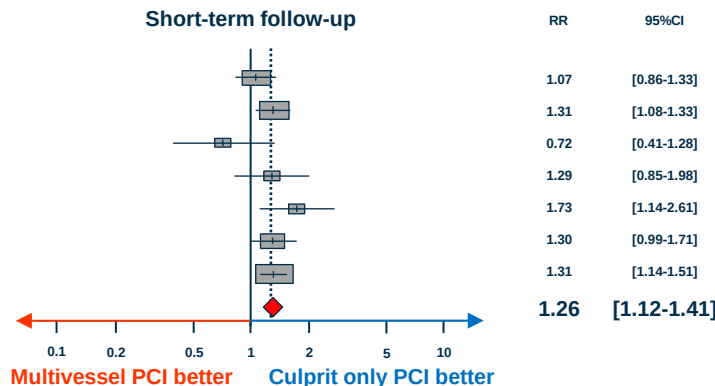
Multivessel PCI in Cardiogenic Shock?

Metaanalysis Mortality – Registry-Data

	MV-PCI		C-PCI	
	Events	Total	Events	Total
IABP-SHOCK II	75	167	119	284
ALKK	81	173	201	562
KAMIR	13	124	56	386
Yang et al.	19	60	68	278
Cavender et al.	20	43	42	156
EHS-PCI	40	82	95	254
NCDR	158	433	737	2654
Overall	406	1082	1318	4574

Heterogeneity: $\tau^2=0.007$, $I^2=31.0\%$, $p=0.19$

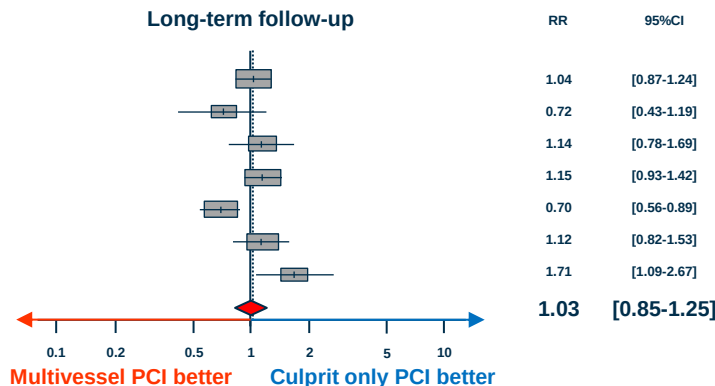
Test for overall effect: $p=0.001$



	MV-PCI		C-PCI	
	Events	Total	Events	Total
IABP-SHOCK II	91	167	149	284
KAMIR	16	124	69	386
Yang et al.	21	60	85	278
Cavender et al.	32	43	101	156
Mylotte et al.	37	66	82	103
van der Schaaf et al.	22	37	66	124
SHOCK	7	9	26	57
Overall	226	506	578	1387

Heterogeneity: $\tau^2=0.043$, $I^2=67.8\%$, $p=0.005$

Test for overall effect: $p=0.77$



Primary Study Endpoint:

- **30-day all-cause mortality or renal replacement therapy**

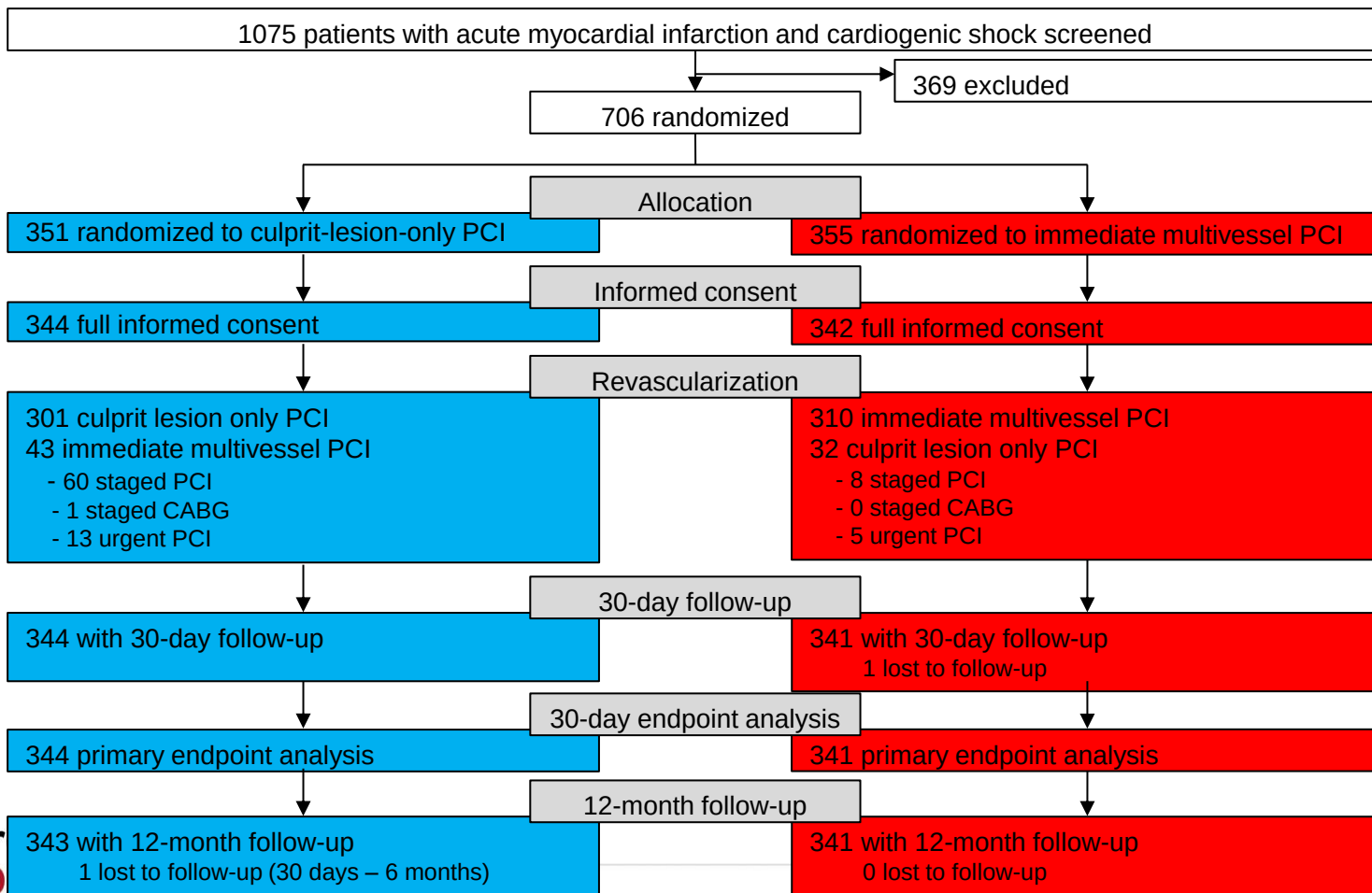
Secondary Study Endpoints:

- 30-day all-cause mortality
- Renal failure with requirement of renal replacement therapy
- Time to hemodynamic stabilization
- Duration of catecholamine therapy
- Serial creatinine-clearance
- Length of ICU-stay
- SAPS-II score
- Requirement and length of mechanical ventilation
- All-cause death within 6 and 12 months follow-up
- Recurrent infarction within 30-days, 6 and 12 months follow-up
- Death or recurrent infarction at 6 and 12 months follow-up
- Rehospitalization for congestive heart failure within 30 days, 6-, and 12-months follow-up
- Death/recurrent infarction/rehospitalization for congestive heart failure within 30 days, 6-, and 12-months follow-up
- Need for recurrent revascularization (PCI and/or CABG) within 30 days, 6-, and 12-months follow-up
- Peak creatine kinase, creatine kinase-MB

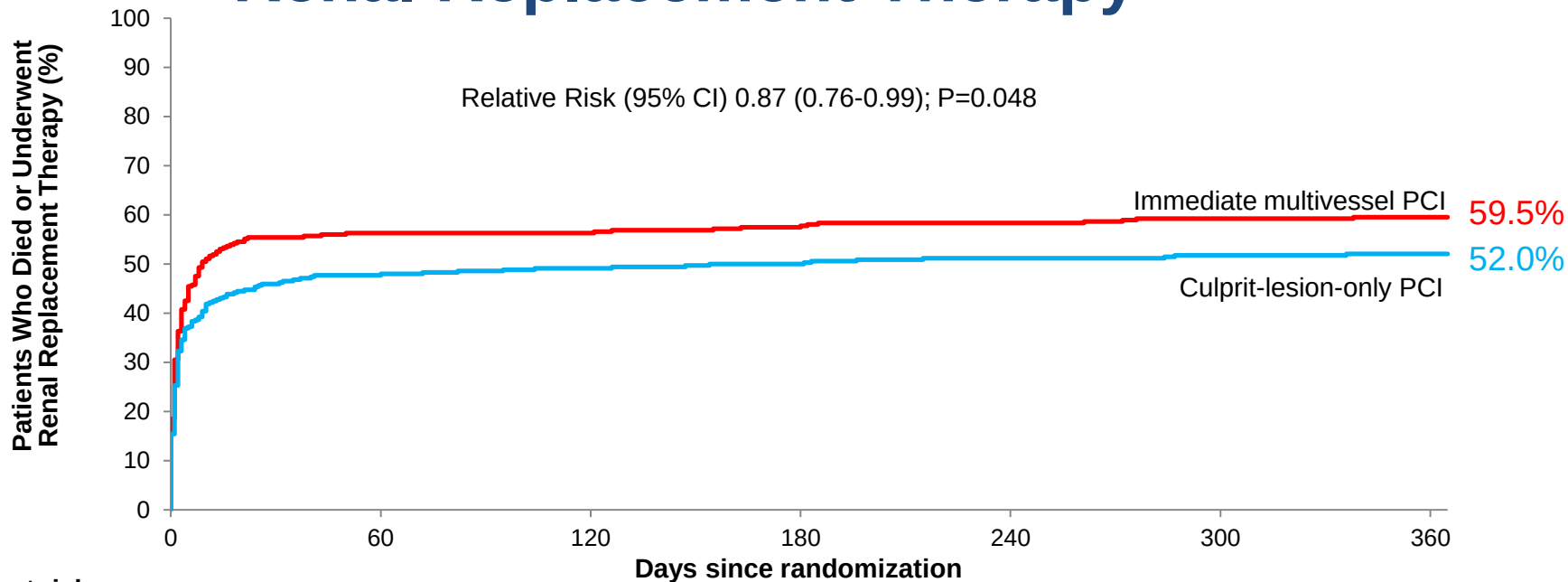
Sample Size:

- **Estimated 50% event rate in multivessel PCI versus 38% in culprit lesion only group for primary endpoint**
- **1 interim analysis (50% of patients)**
- 2-sided χ^2 -test; power: 80%, $\alpha=0.048$ for final analysis → **684 patients**
- **To compensate losses in follow-up → 706 patients**

Trial Flow



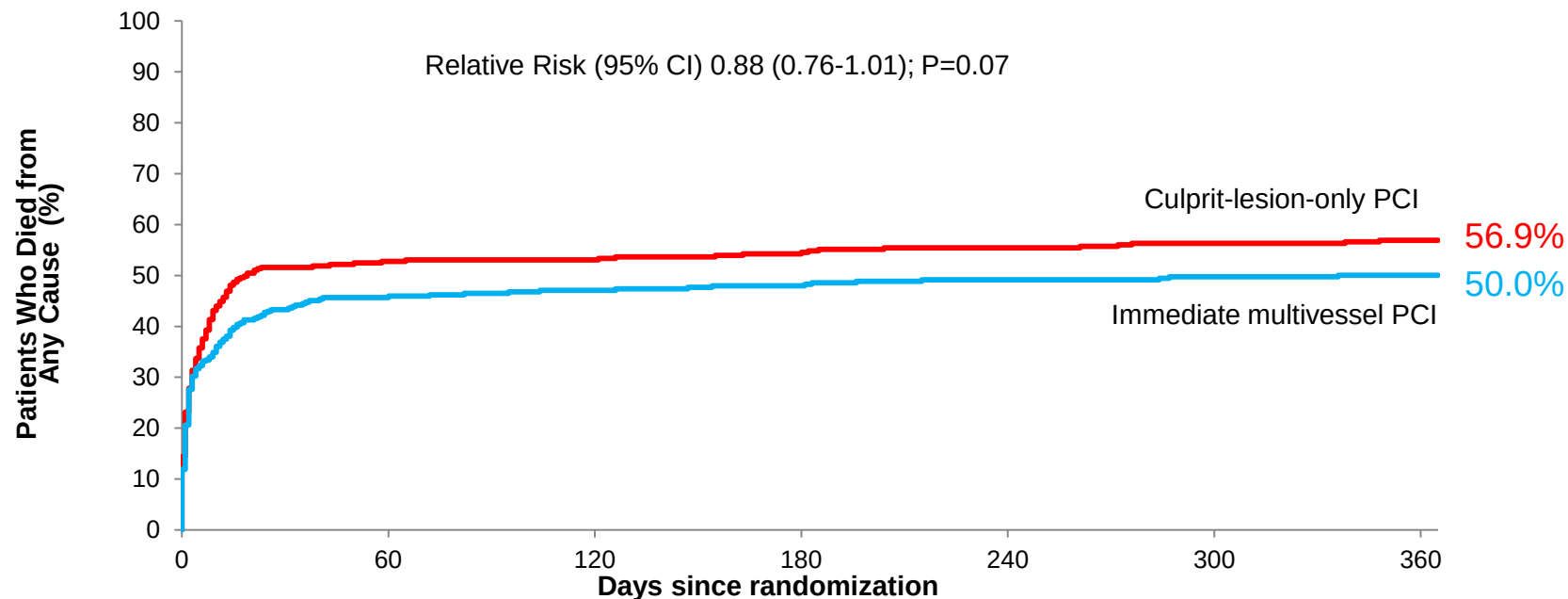
1-Year All-Cause Mortality or Renal Replacement Therapy



Number at risk:

Culprit-lesion-only PCI	344	179	174	171	167	165	142
Immediate multivessel PCI	341	149	149	145	142	139	122

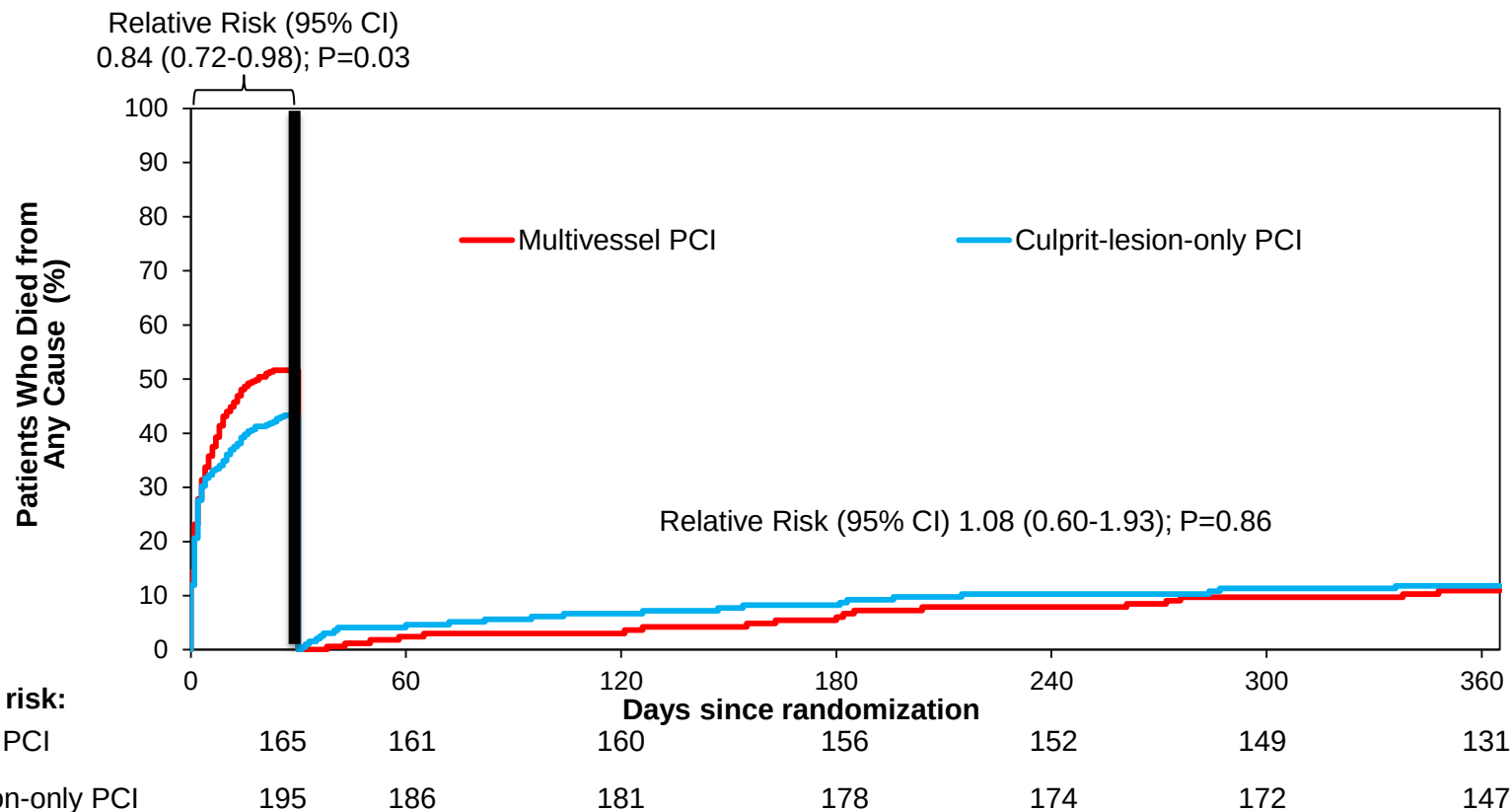
1-Year All-Cause Mortality



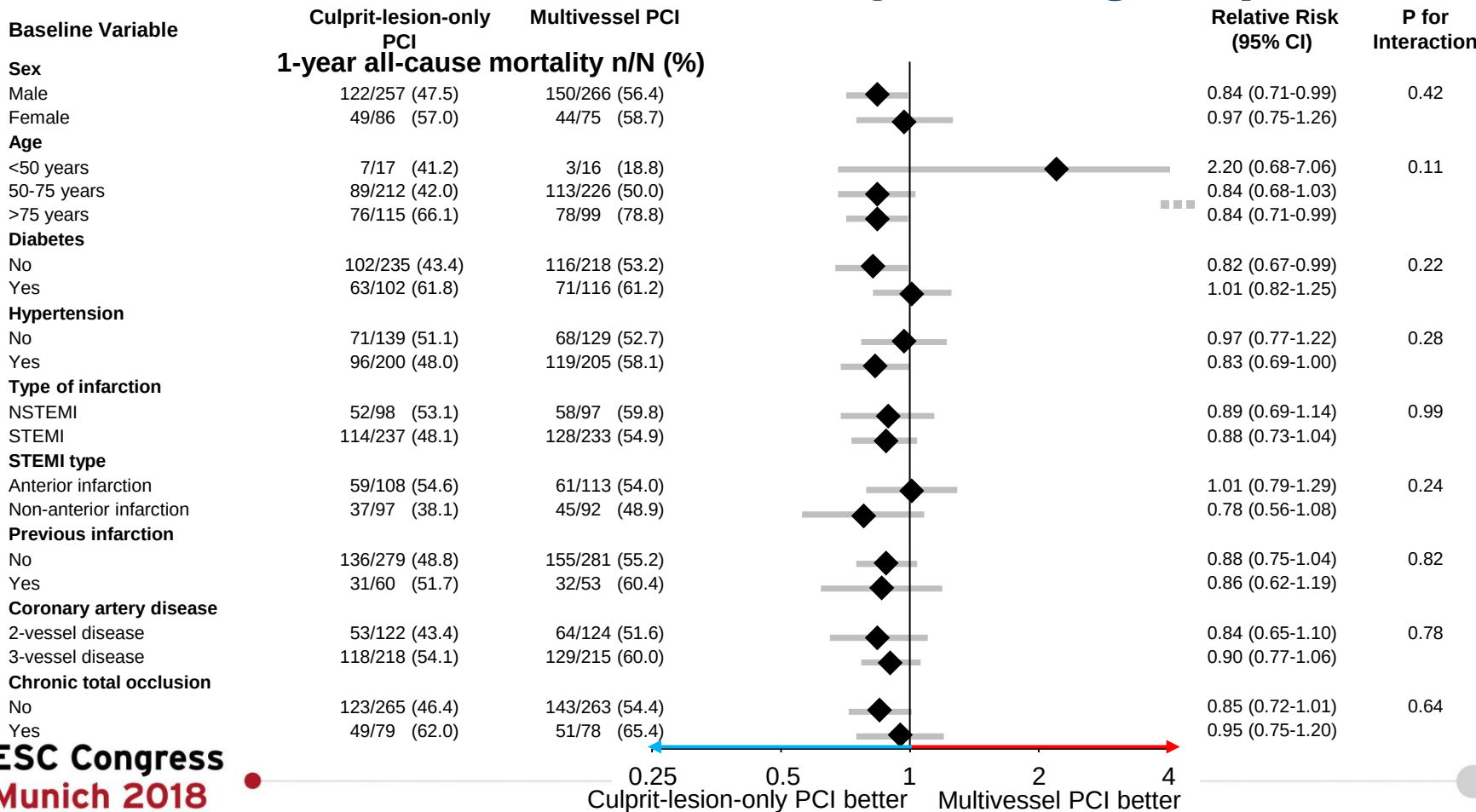
Number at risk:

Multivessel PCI	341	161	160	156	152	149	131
Culprit-lesion-only PCI	344	186	181	178	174	172	147

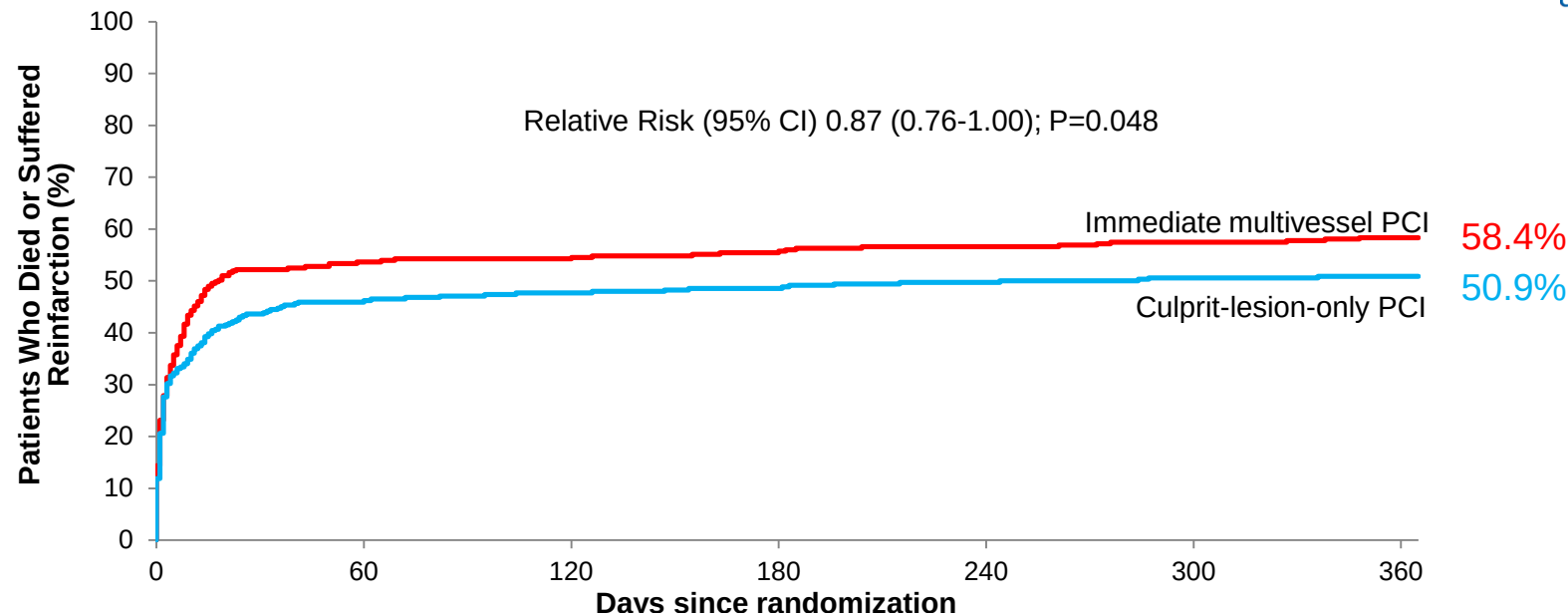
1-Year All-Cause Mortality – Landmark Analysis



1-Year All-Cause Mortality – Subgroups



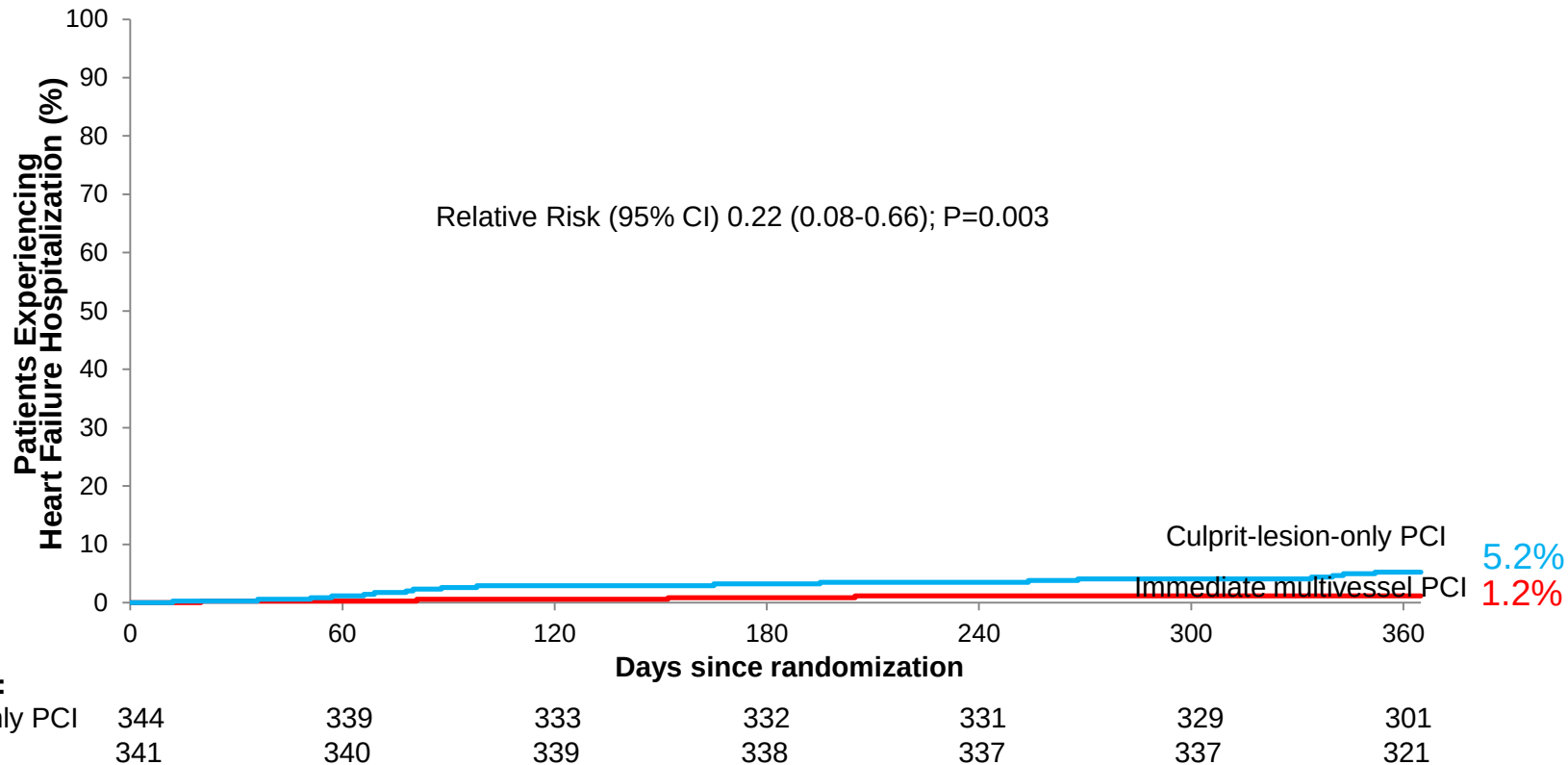
1-Year All-Cause Mortality or Reinfarction



Number at risk:

Multivessel PCI	341	158	156	152	148	145	126
Culprit-lesion-only PCI	344	185	179	176	172	169	145

1-Year Rehospitalization Congestive Heart Failure



Number at risk:

Culprit-lesion-only PCI

344

339

333

332

331

329

301

Multivessel PCI

341

340

339

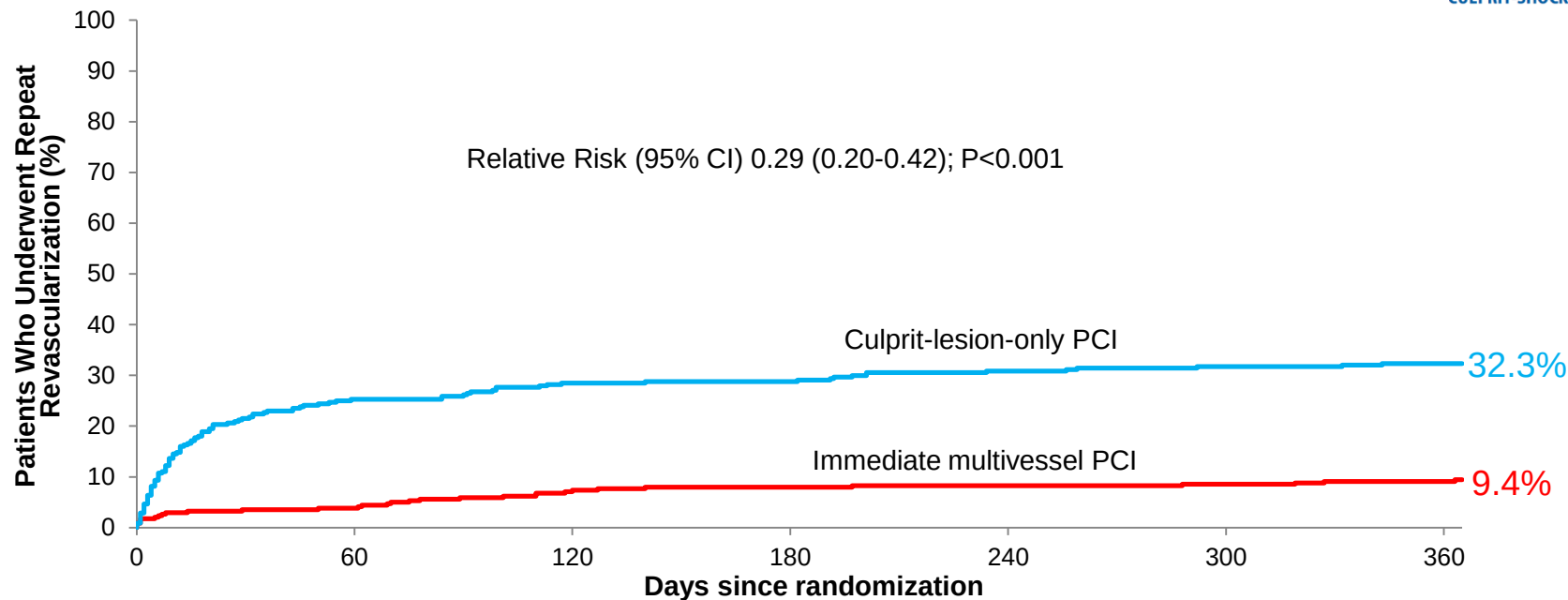
338

337

337

321

1-Year Repeat Revascularization



Number at risk:

Culprit-lesion only PCI	344	256	245	244	237	234	223
Multivessel PCI	341	327	316	313	312	311	293

1-Year Clinical Endpoints and Safety



	Culprit-lesion- only PCI (n=344)	Multivessel PCI (n=341)	Relative Risk	95% CI	P-Value
All-cause mortality; n/total (%)	172/344 (50.0)	194/341 (56.9)	0.88	0.76–1.01	0.07
Renal replacement therapy; n/total (%)	40/344 (11.6)	56/341 (16.4)	0.71	0.49–1.03	0.07
Reinfarction; n/total (%)	6/344 (1.7)	7/341 (2.1)	0.85	0.29–2.50	0.77
Death/reinfarction; n/total (%)	175/344 (50.9)	199/341 (58.4)	0.87	0.76–1.00	0.048
Rehospitalization for congestive heart failure; n/total (%)	18/344 (5.2)	4/341 (1.2)	4.46	1.53–13.04	0.003
Death/reinfarction/rehospitalization for congestive heart failure; n/total (%)	190/344 (55.2)	203/341 (59.5)	0.87	0.93–1.06	0.87
Repeat revascularization; n/total (%)	111/344 (32.3)	32/341 (9.4)	3.44	2.39–4.95	<0.001
Repeat PCI; n/total (%)	107/344 (31.1)	29/341 (8.5)	3.66	2.50–5.36	
Repeat CABG; n/total (%)	4/344 (1.2)	3/341 (0.9)	1.32	0.30–5.86	
All-cause mortality or renal replacement therapy; n/total (%)	179/344 (52.0)	203/341 (59.5)	0.87	0.76–0.99	0.048
Stroke; n/total (%)	15/344 (4.4)	14/341 (4.1)	1.06	0.52–2.17	0.87
Bleeding (BARC 2, 3 or 5); n/total (%)	65/344 (18.9)	79/341 (23.2)	0.82	0.61–1.09	0.82
Any bleeding event; n/total (%)	75/344 (21.8)	86/341 (25.2)	0.86	0.66–1.13	0.86

Summary and Conclusions



- In patients with acute myocardial infarction and cardiogenic shock culprit-lesion-only PCI - with possible staged revascularization - compared with immediate multivessel PCI is associated with a reduction in all-cause death or renal replacement therapy at 30 days.
- This effect in the composite endpoint is persistently observed at 12 months follow-up.
- The 30-day difference in all-cause mortality is attenuated over time. However, there is no increase in mortality after 30-days until 1-year follow-up.
- Culprit-lesion-only PCI is possibly associated with a higher incidence of heart failure hospitalizations and more frequent repeat revascularization at 1-year.
- The 1-year results of CULPRIT-SHOCK support the recent change in ESC guideline recommendations.



ORIGINAL ARTICLE

One-Year Outcomes after PCI Strategies in Cardiogenic Shock

H. Thiele, I. Akin, M. Sandri, S. de Waha-Thiele, R. Meyer-Saraei, G. Fuernau,
I. Eitel, P. Nordbeck, T. Geisler, U. Landmesser, C. Skurk, A. Fach, A. Jobs,
H. Lapp, J.J. Piek, M. Noc, T. Goslar, S.B. Felix, L.S. Maier, J. Stepinska,
K. Oldroyd, P. Serpytis, G. Montalescot, O. Barthelemy, K. Huber, S. Windecker,
L. Hunziker, S. Savonitto, P. Torremante, C. Vrints, S. Schneider, U. Zeymer, and
S. Desch, for the CULPRIT-SHOCK Investigators*