

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

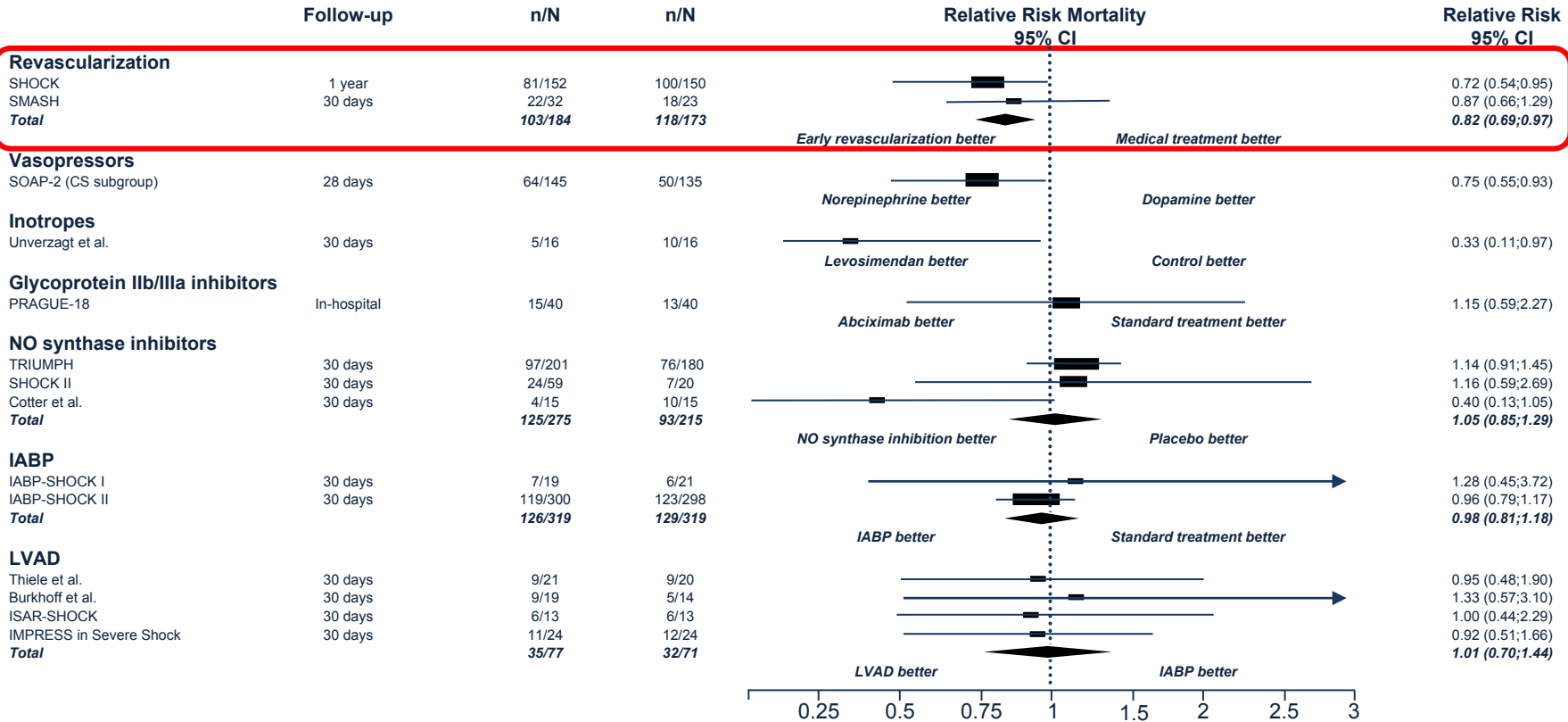
- Grant/Research Support
- Consulting Fees/Honoraria
- Major Stock Shareholder/Equity
- Royalty Income
- Ownership/Founder
- Intellectual Property Rights
- Other Financial Benefit

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



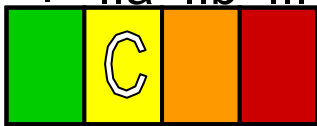
Multivessel coronary artery disease present in up to 80% → higher mortality

Guidelines



ESC



I IIa IIb III





ACC/AHA/SCAI



No recommendation

Appropriate Use Criteria

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

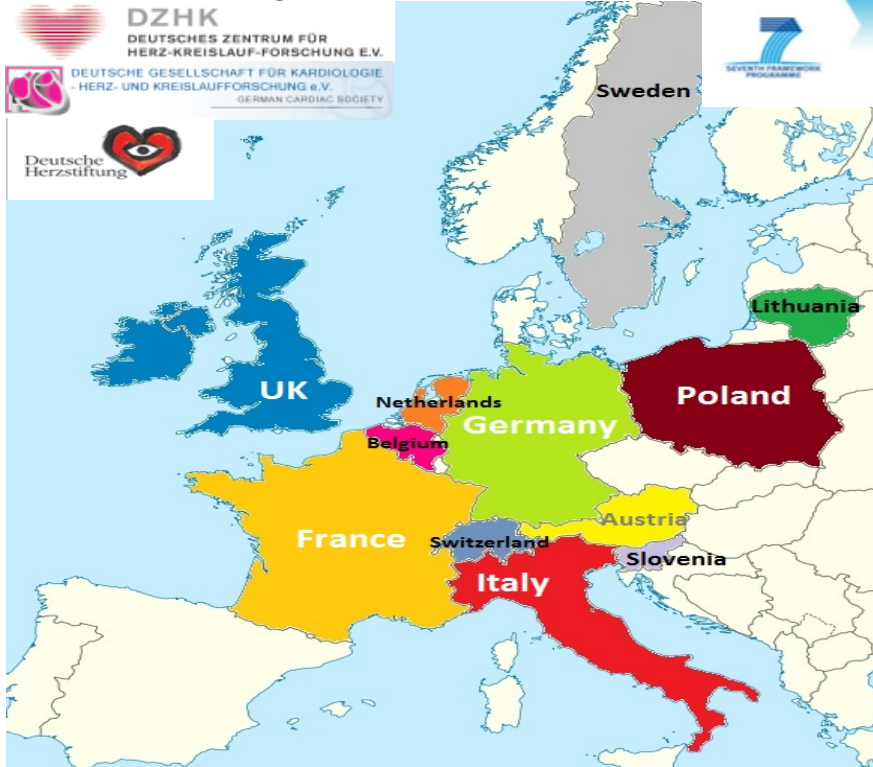


A (9)

CULPRIT-SHOCK Trial



Investigator-initiated European multicenter trial; 1:1 randomization



PI + Coordination:

Holger Thiele

Co-PI:

Uwe Zeymer

Steffen Desch

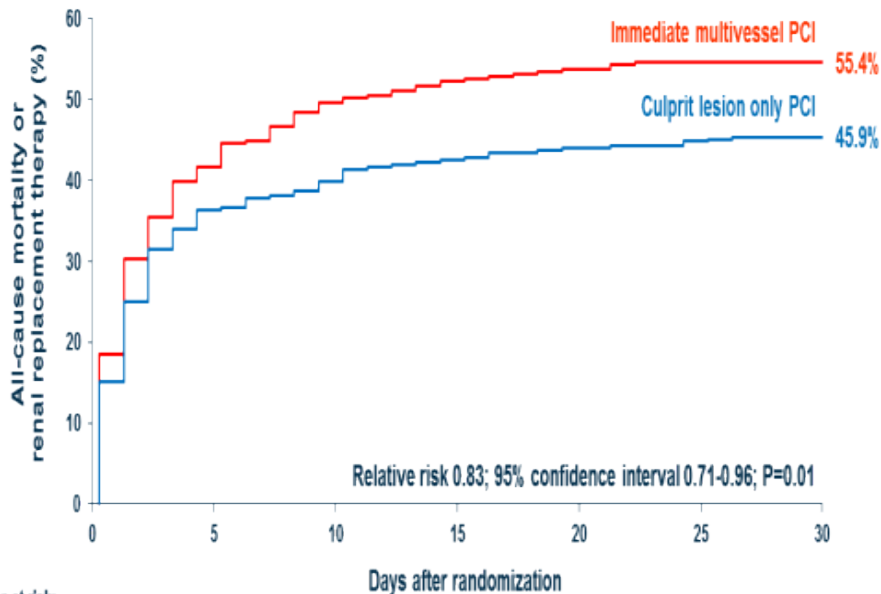
National Coordinators (83 centers):

- 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



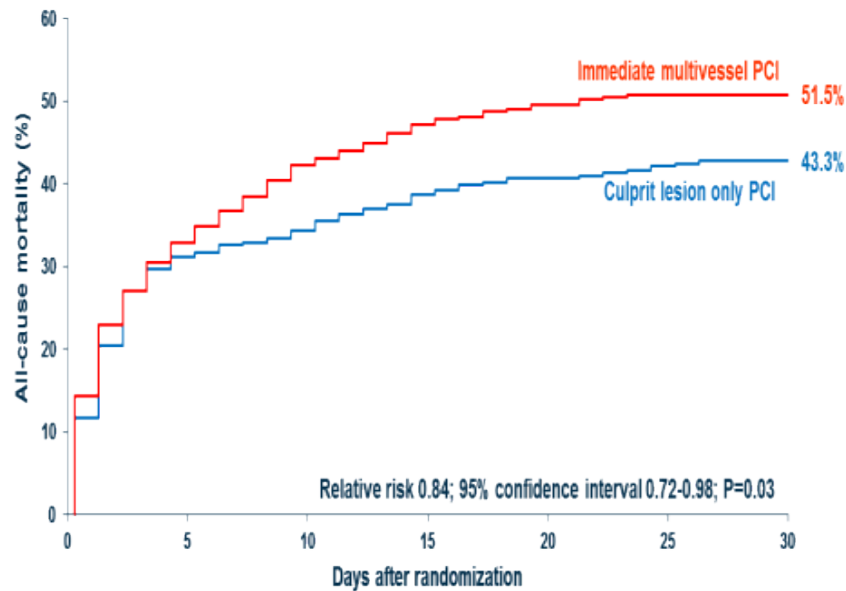
Primary study endpoint – 30 days
All-cause mortality or renal replacement therapy



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 |

Multivessel PCI in Shock - Guideline Evolution



ESC STEMI Guidelines 2017 → Revascularization Guidelines 2018

STEMI (NSTEMI), Cardiogenic Shock

2017

2018



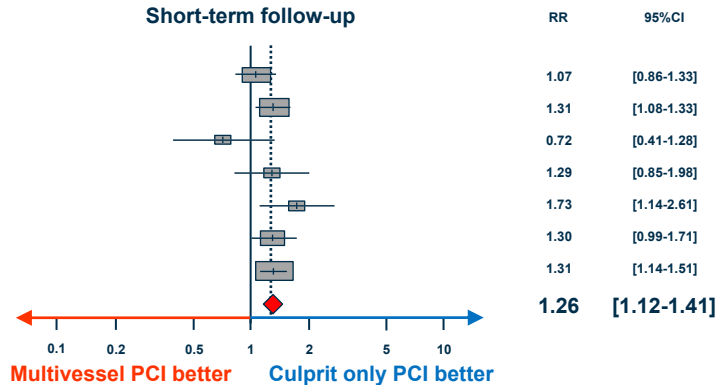
Multivessel PCI in Cardiogenic Shock?



Metaanalysis Mortality – Registry-Data

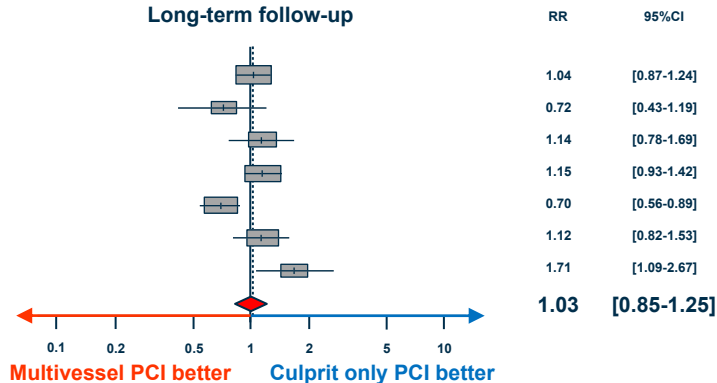
| | MV-PCI | | C-PCI | |
|-----------------|------------|-------------|-------------|-------------|
| | Events | Total | Events | Total |
| IABP-SHOCK II | 75 | 167 | 119 | 284 |
| ALKK | 81 | 173 | 201 | 562 |
| KAMIR | 13 | 124 | 56 | 386 |
| Yang et al. | 19 | 60 | 68 | 278 |
| Cavender et al. | 20 | 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: $p=0.77$



Statistical Methodology



Primary Study Endpoint:

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

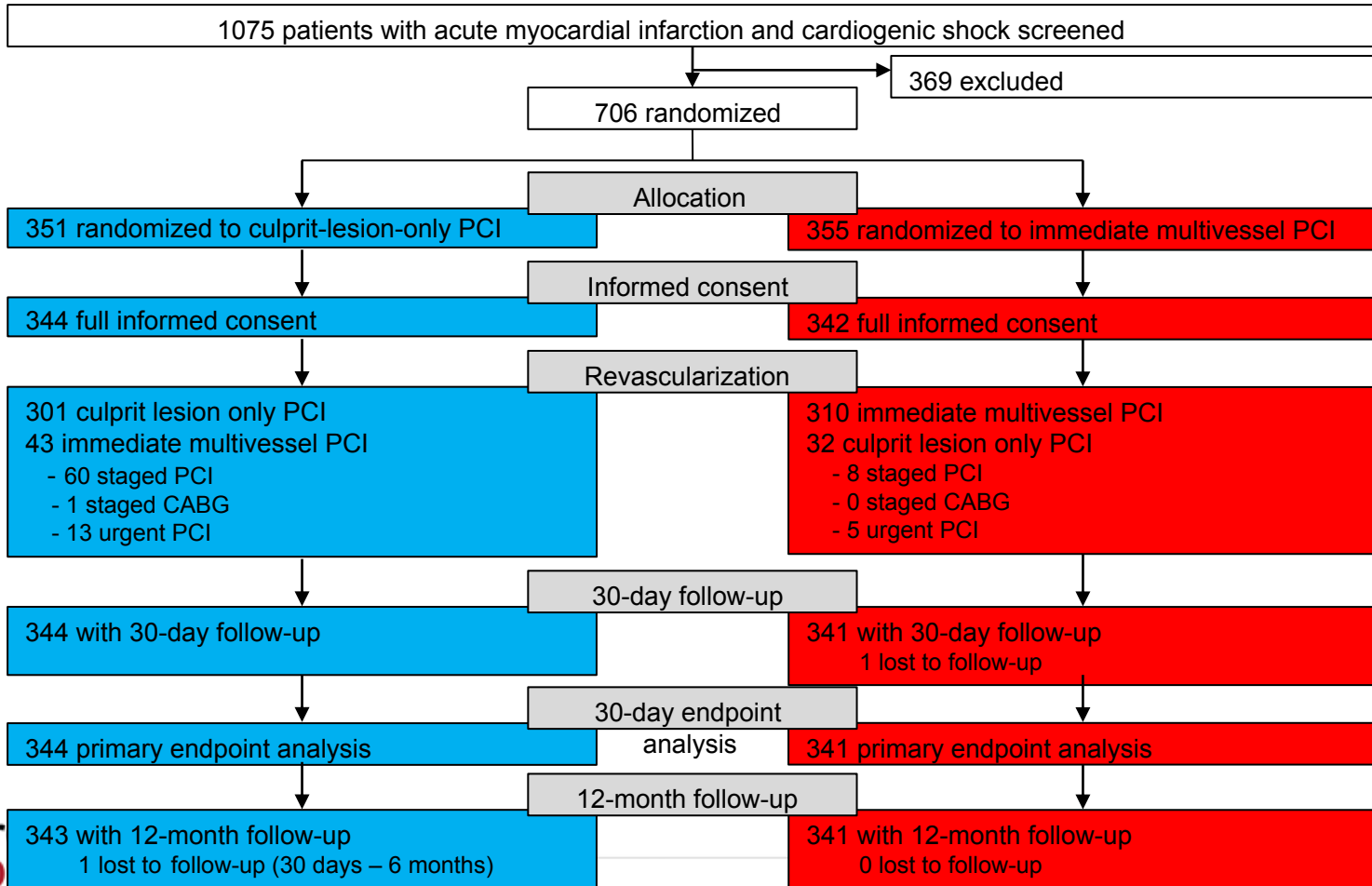
Secondary Study Endpoints:

- § 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

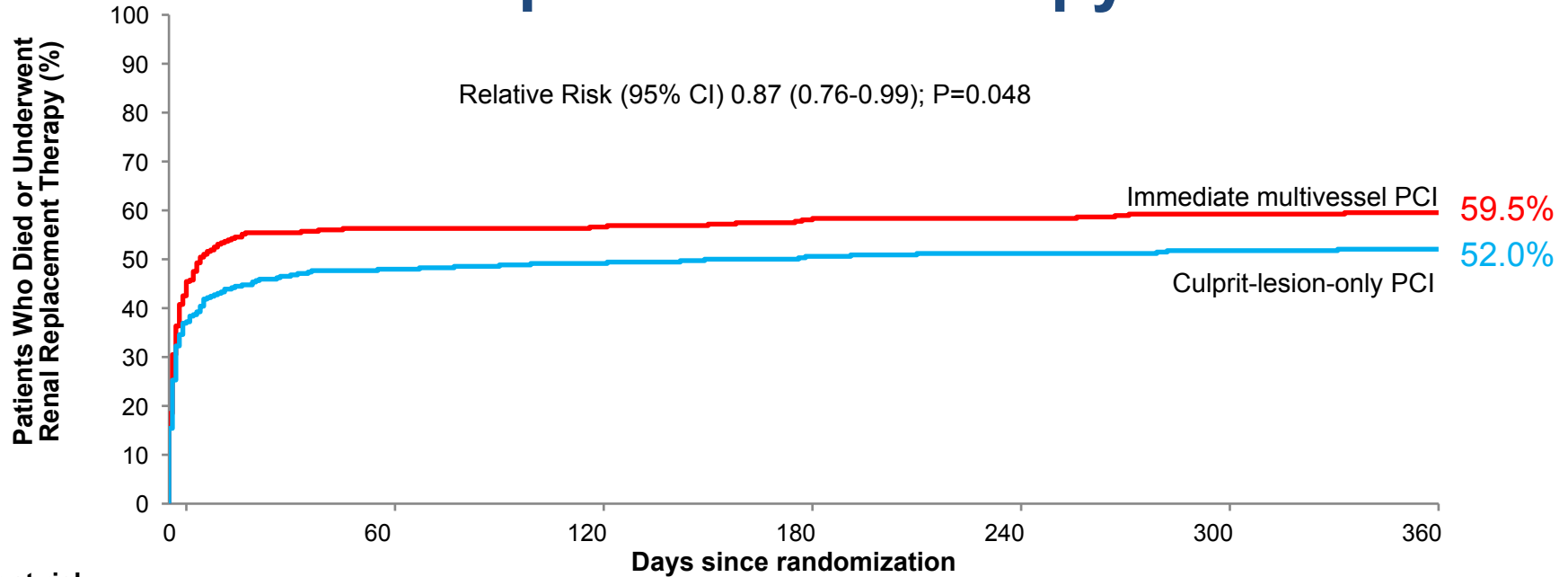
Sample Size:

- § **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 Chi²-test; power: 80%, alpha=0.048 for final analysis → **684 patients**
- § **To compensate losses in follow-up → 706 patients**

Trial Flow



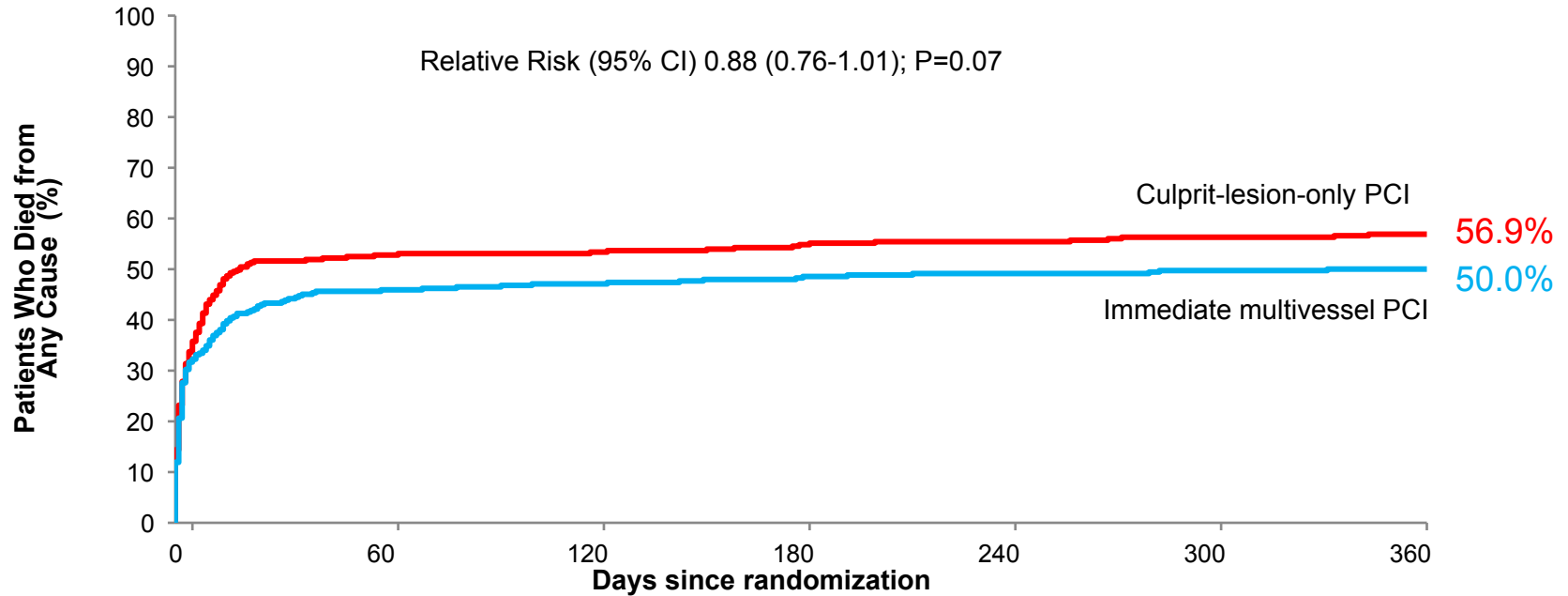
1-Year All-Cause Mortality or Renal Replacement Therapy



Number at risk:

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

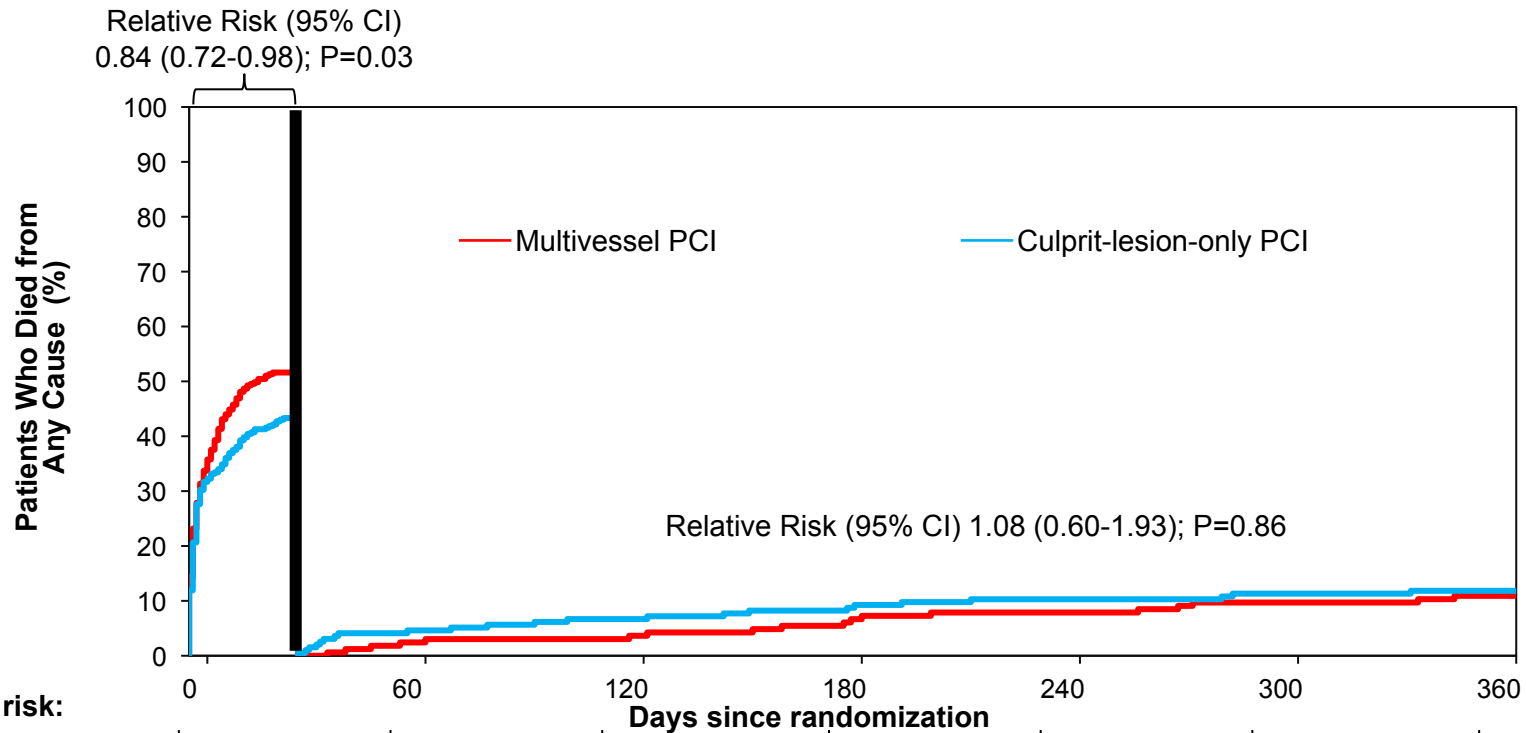
1-Year All-Cause Mortality



Number at risk:

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

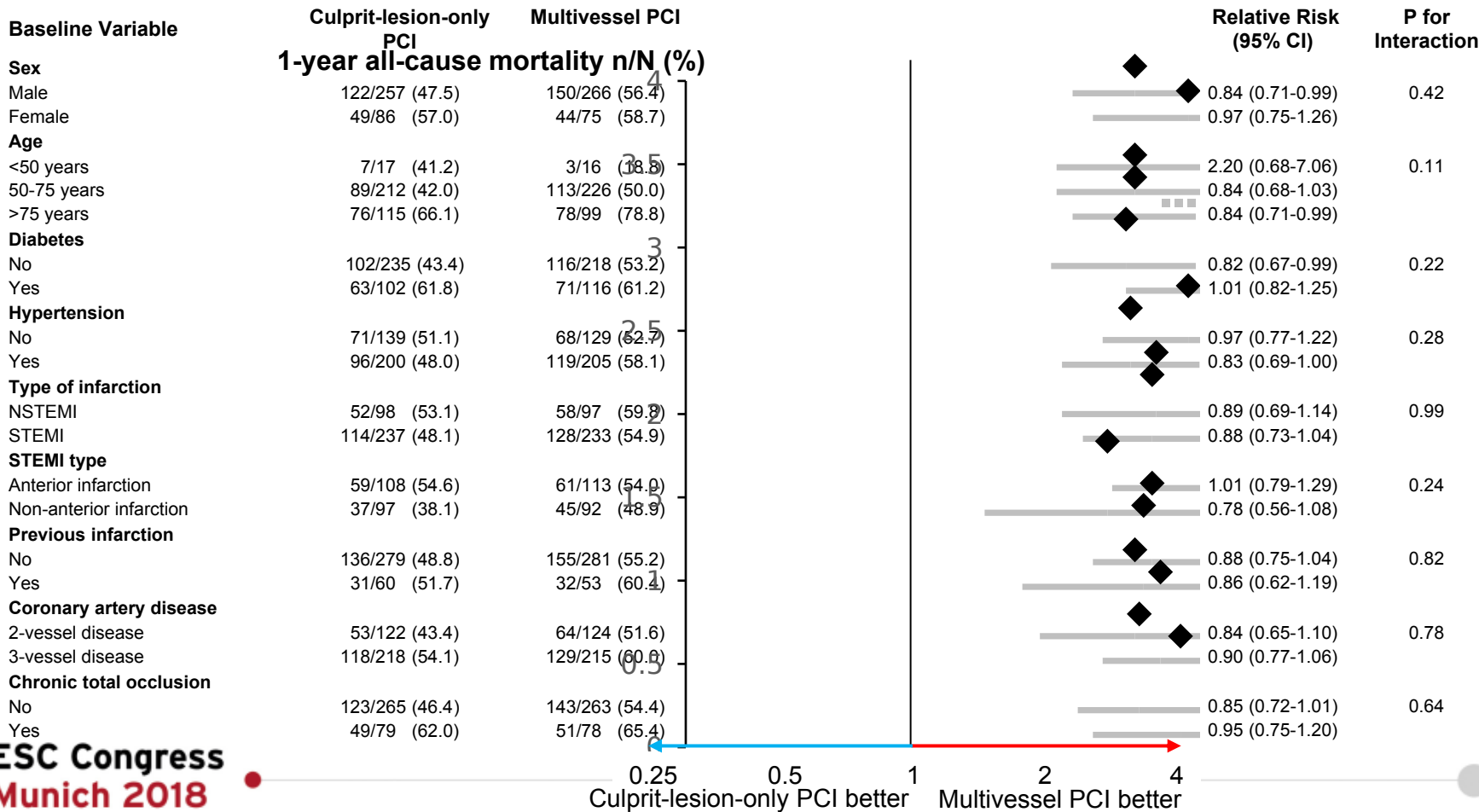
1-Year All-Cause Mortality – Landmark Analysis



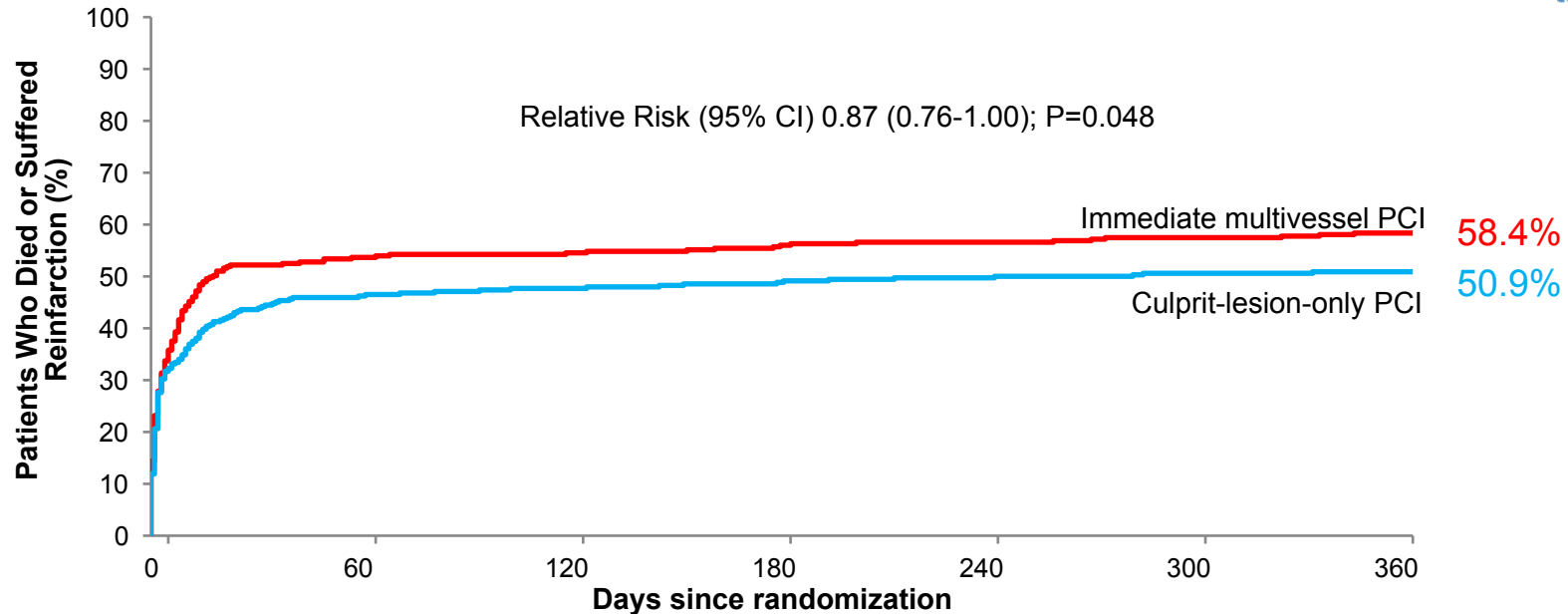
Number at risk:

| | 0 | 60 | 120 | 180 | 240 | 300 | 360 |
|-------------------------|-----|-----|-----|-----|-----|-----|-----|
| Multivessel PCI | 165 | 161 | 160 | 156 | 152 | 149 | 131 |
| Culprit-lesion-only PCI | 195 | 186 | 181 | 178 | 174 | 172 | 147 |

1-Year All-Cause Mortality – Subgroups



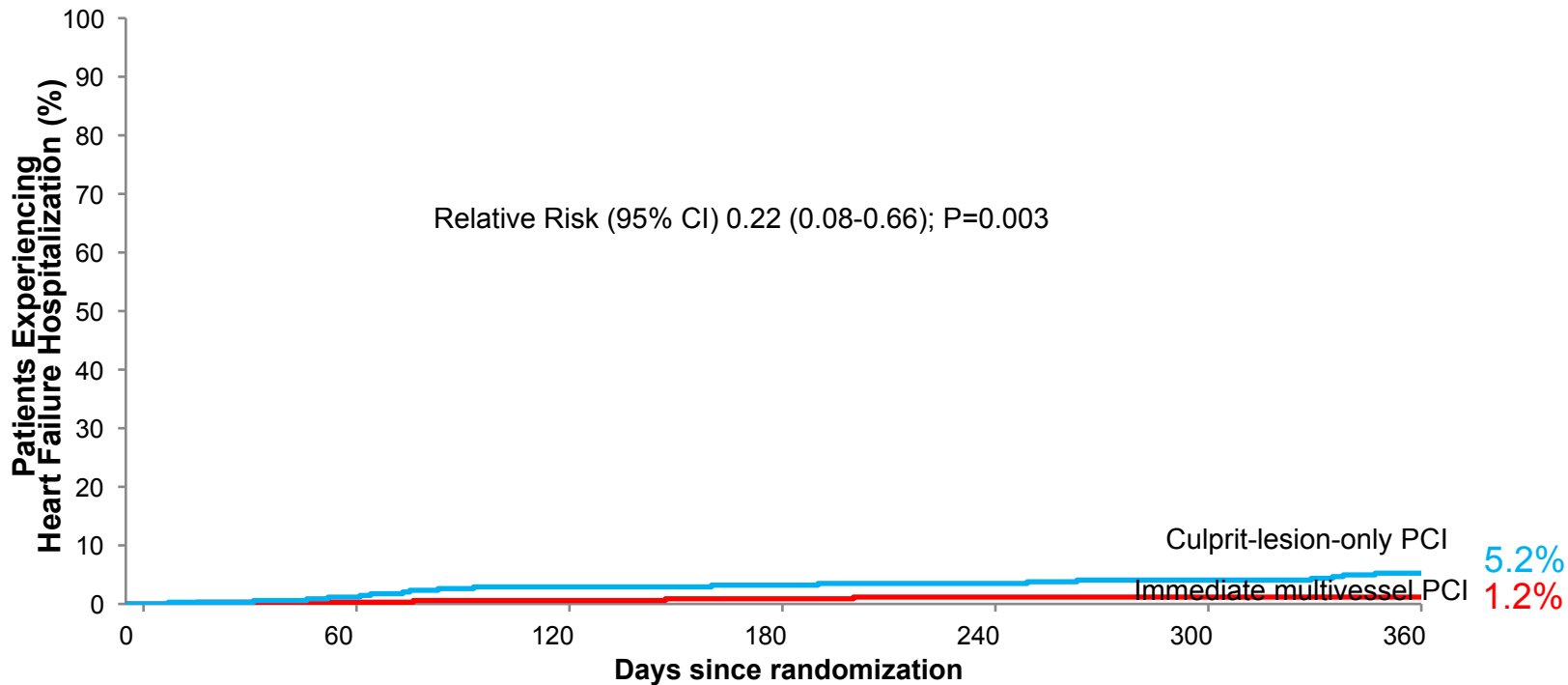
1-Year All-Cause Mortality or Reinfarction



Number at risk:

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

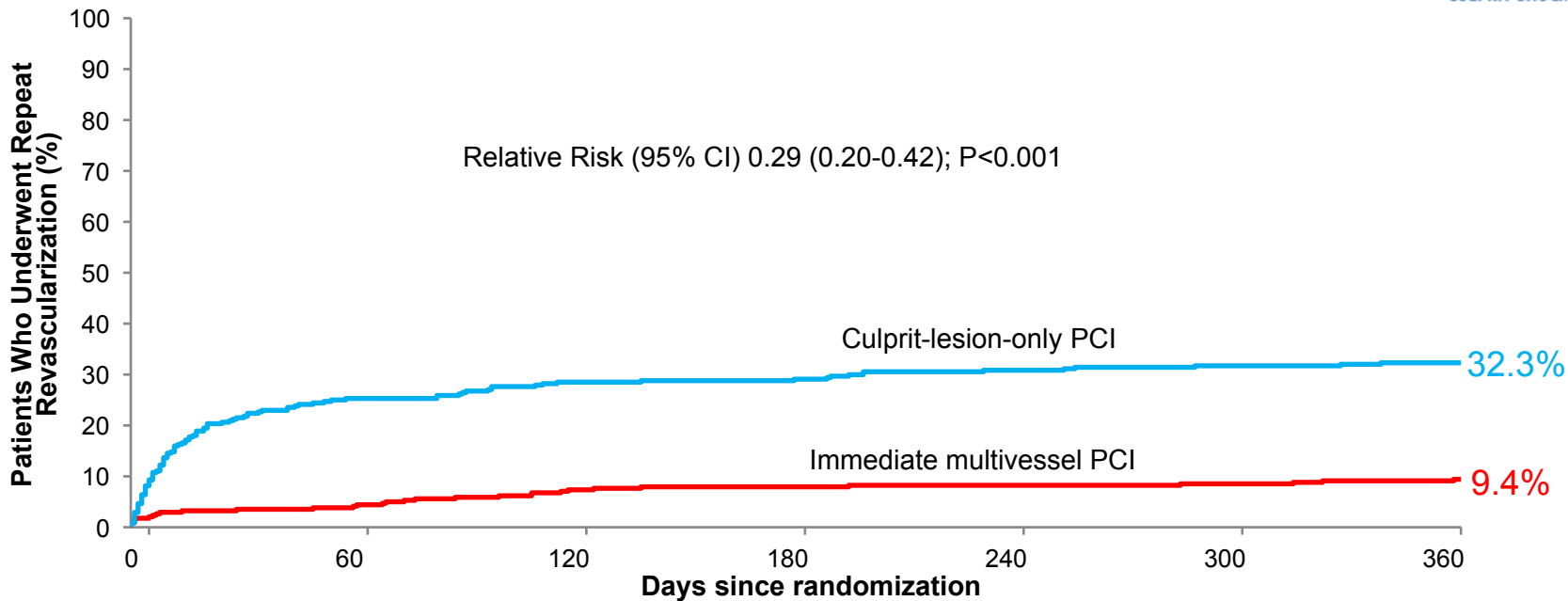
1-Year Rehospitalization Congestive Heart Failure



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*