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جمعية القلب السعودية
Saudi Heart Association

Acute Coronary Syndromes: Top Trials 2018

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Disclosure

Affiliation/Financial Relationship	Company
Consultant	Abbott Laboratories (paid to the institution), Abiomed (spouse), Boston Scientific, CardioKinetix (paid to the institution), Cardiovascular Systems Inc, Medscape, Siemens Medical Solutions, Spectranetics, The Medicines Company, Roivant Sciences Inc, Volcano Corporation
Research Funding to Institution	AstraZeneca, Bayer, Beth Israel Deaconess, BMS, CSL Behring, Eli Lilly/DSI, Medtronic, Novartis Pharmaceuticals, OrbusNeich
Equity, <1%	Claret Medical, Elixir Medical
Executive Committee	Janssen Pharmaceuticals, Osprey Medical
Advisory Board Funding to Institution	Bristol-Meyers Squibb
DSMB membership paid to the institution	Watermark Research Partners



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Radial Intervention: MTARIX Trial

THE LANCET

Articles

Radial versus femoral access and bivalirudin versus unfractionated heparin in invasively managed patients with acute coronary syndrome (MATRIX): final 1-year results of a multicentre, randomised controlled trial



Published Online
August 25, 2018
[http://dx.doi.org/10.1016/S0140-6736\(18\)31714-8](http://dx.doi.org/10.1016/S0140-6736(18)31714-8)

Marco Valgimigli, Enrico Frigoli, Sergio Leonardi, Pascal Vranckx, Martina Rothenbühler, Matteo Tebaldi, Ferdinando Varbella, Paolo Calabrò, Stefano Garducci, Paolo Rubartelli, Carlo Briguori, Giuseppe Andò, Maurizio Ferrario, Ugo Limbruno, Roberto Garbo, Paolo Sganzerla, Filippo Russo, Marco Nazzaro, Alessandro Lupi, Bernardo Cortese, Arturo Ausiello, Salvatore Ierna, Giovanni Esposito, Giuseppe Ferrante, Andrea Santarelli, Gennaro Sardella, Nicoletta de Cesare, Paolo Tosi, Arnoud van 't Hof, Elmira Omerovic, Salvatore Brugaletta, Stephan Windecker, Dik Heg, Peter Juni, on behalf of the MATRIX Investigators



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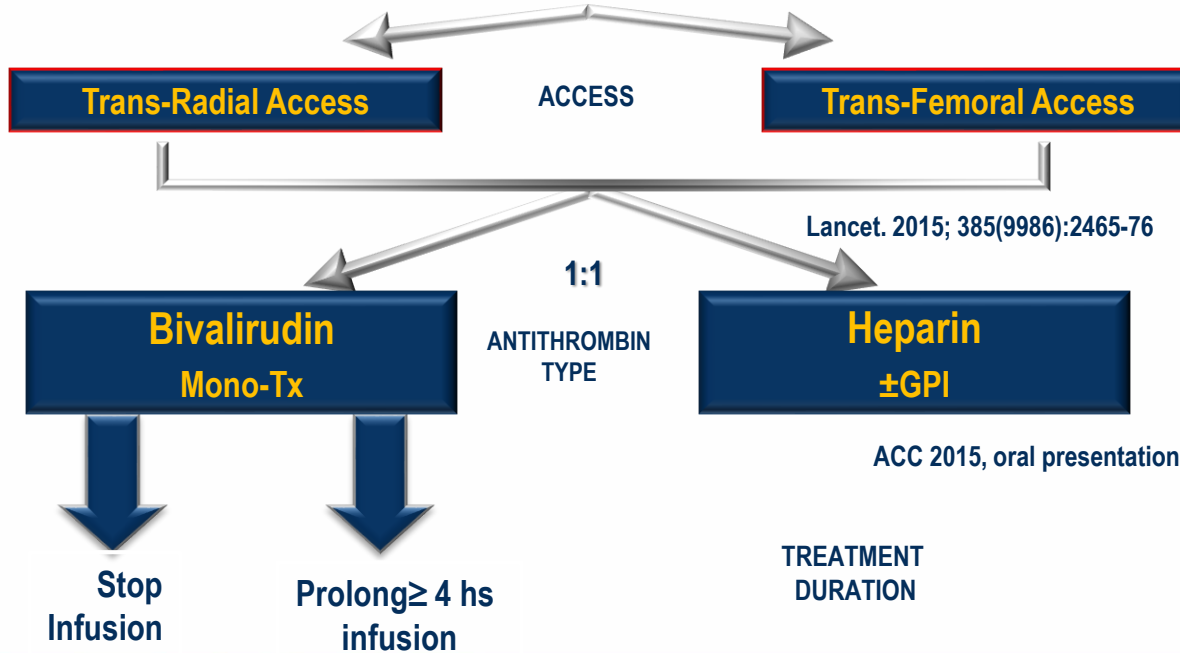


MATRIX Program

NSTEACS or STEMI with invasive management

Aspirin+P2Y12 blocker

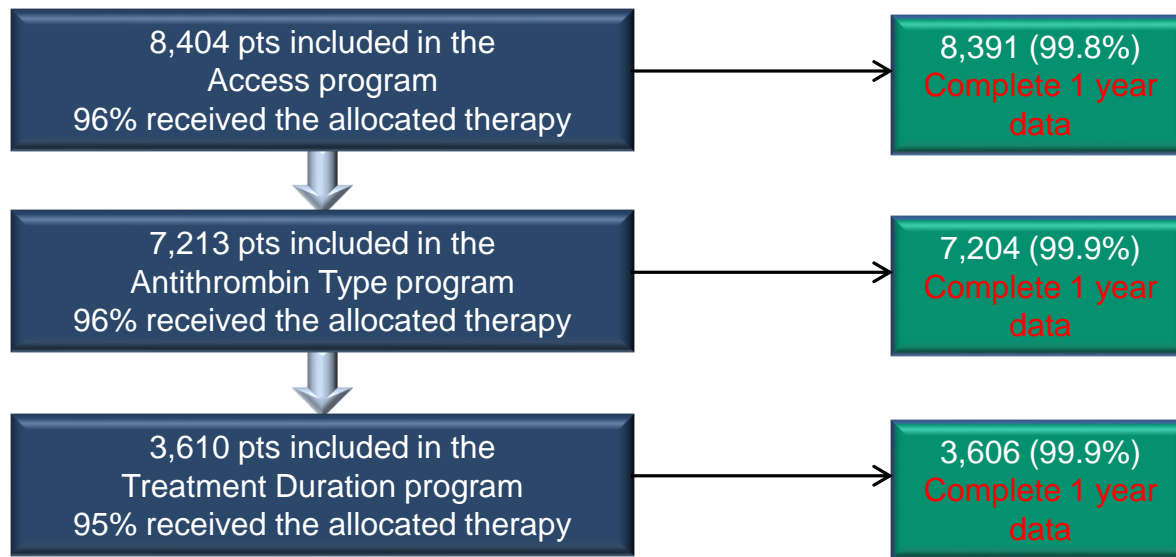
1:1



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MATRIX Trial: Patient Disposition, Baseline Characteristics and Drug Adherence



- Baseline characteristics were well matched
- Adherence to secondary prevention medications was similarly high

Valgimigli et al., Lancet Aug. 25, 2018 Epub

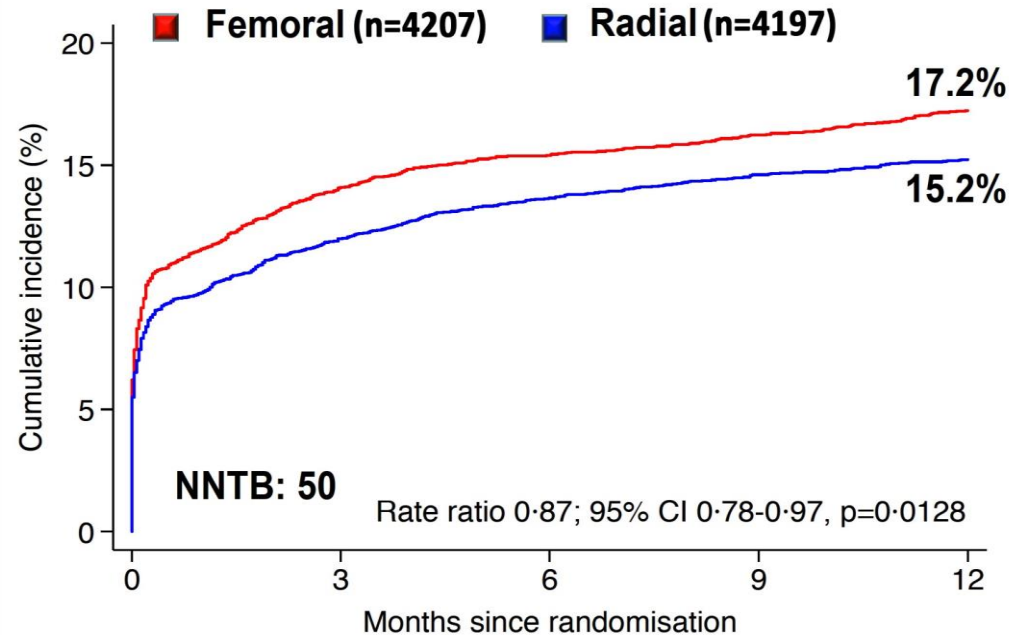


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MATRIX Trial: 1 Year NACE

Access Program



Valgimigli et al., Lancet Aug. 25, 2018 Epub

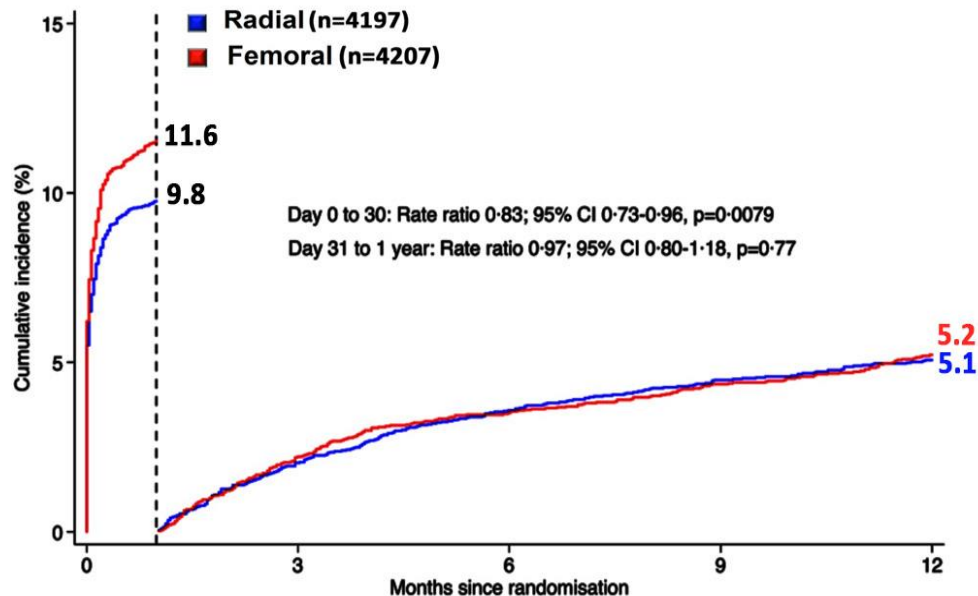


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MATRIX Trial: 1-Year NACE Period Analysis

Access Program



Valgimigli et al., Lancet Aug. 25, 2018 Epub

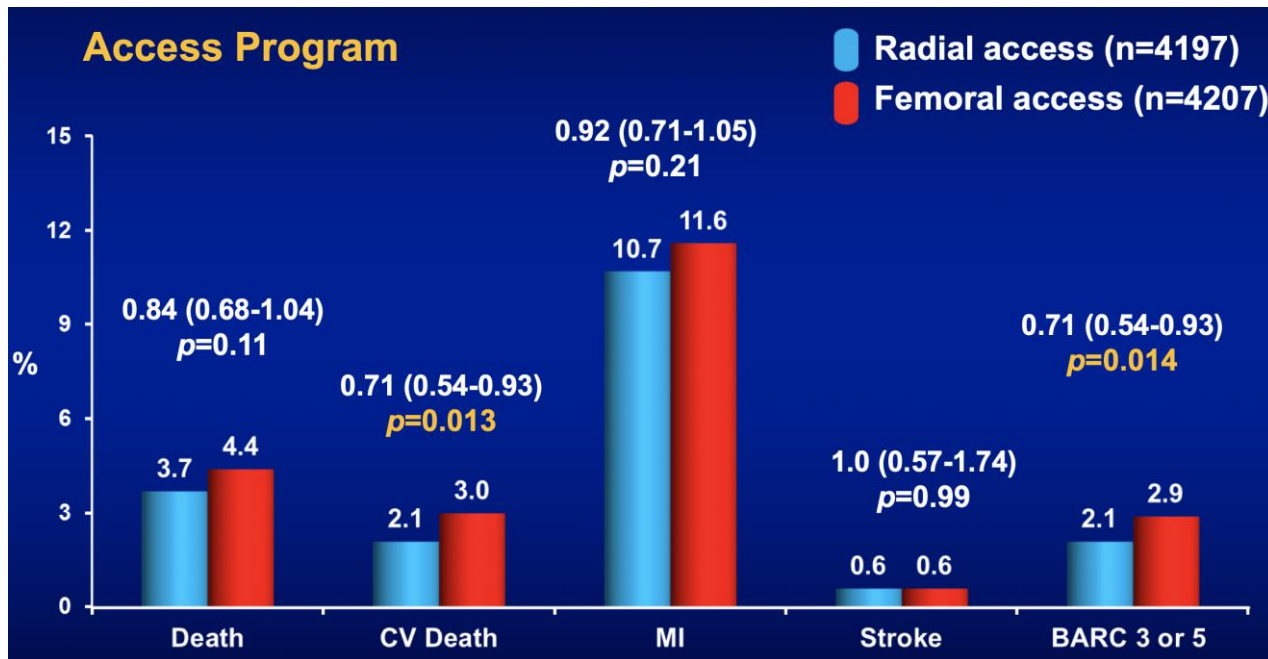


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MATRIX Trial: 1-Year NACE Components (CV) Death, MI, Stroke, and BARC 3 or 5



Valgimigli et al., Lancet Aug. 25, 2018 Epub

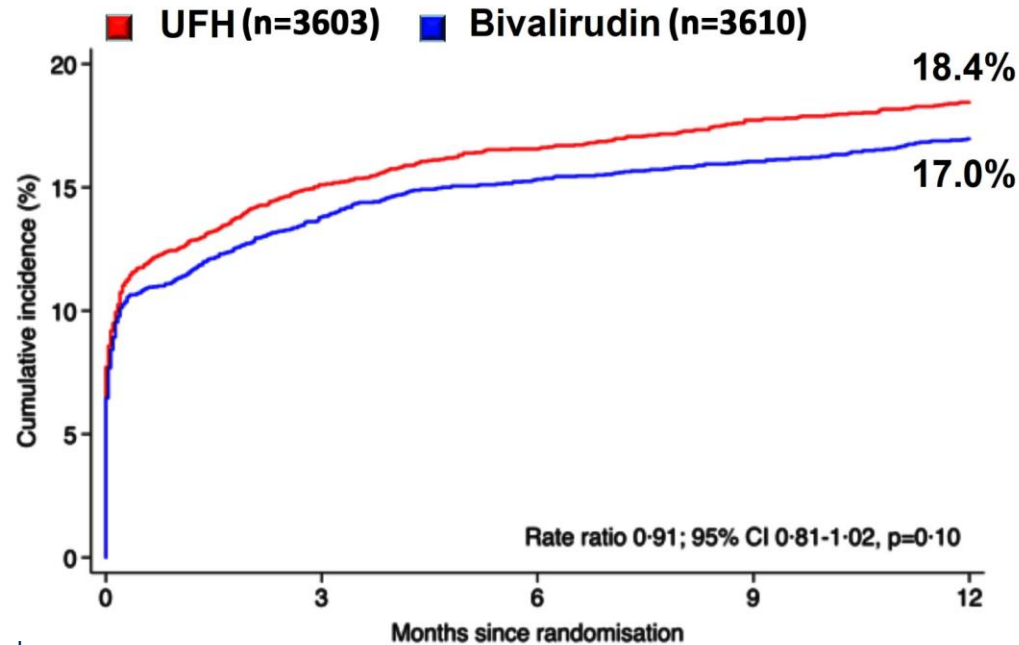


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MATRIX Trial: 1-Year NACE

Antithrombin Program



Valgimigli et al., Lancet Aug. 25, 2018 Epub



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2011 ACCF/AHA/SCAI Guideline for Percutaneous Coronary Intervention

A Report of the American College of Cardiology Foundation/American Heart Association Task Force on Practice Guidelines and the Society for Cardiovascular Angiography and Interventions

ESC Guidelines for the management of acute myocardial infarction in patients presenting with ST-segment elevation

Updated Sept 2015



Primary PCI: Indications and Procedural Aspects

Recommendations	Class ^a	Level ^b	Ref ^c	
Indications for primary PCI				
Primary PCI is the recommended reperfusion therapy over fibrinolysis if performed by an experienced team within 120 min of FMC.	I	A	69, 99	
Primary PCI is indicated for patients with severe acute heart failure or cardiogenic shock, unless the expected PCI related delay is excessive and the patient presents early after symptom onset.	I	B	100	
Procedural aspects of primary PCI				
Stenting is recommended (over balloon angioplasty alone) for primary PCI.	I	A	101, 102	
Primary PCI should be limited to the culprit vessel with the exception of cardiogenic shock and persistent ischaemia after PCI of the supposed culprit lesion.	IIa	B	75, 103–105	
If performed by an experienced radial operator, radial access should be preferred over femoral access.	IIa	B	78, 79	
If the patient has no contraindications to prolonged DAPT (indication for oral anticoagulation, or estimated high long-term bleeding risk) and is likely to be compliant, DES should be preferred over BMS.	IIa	A	80, 82, 106, 107	
Routine thrombus aspiration should be considered.	IIa	B	83–85	
Routine use of distal protection devices is not recommended.	IIa	III	C	86, 108
Routine use of IABP (in patients without shock) is not recommended.	III	A	97, 98	

The use of radial artery access can be useful to decrease access site complications.



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ORIGINAL ARTICLE

PCI Strategies in Patients with Acute Myocardial Infarction and Cardiogenic Shock

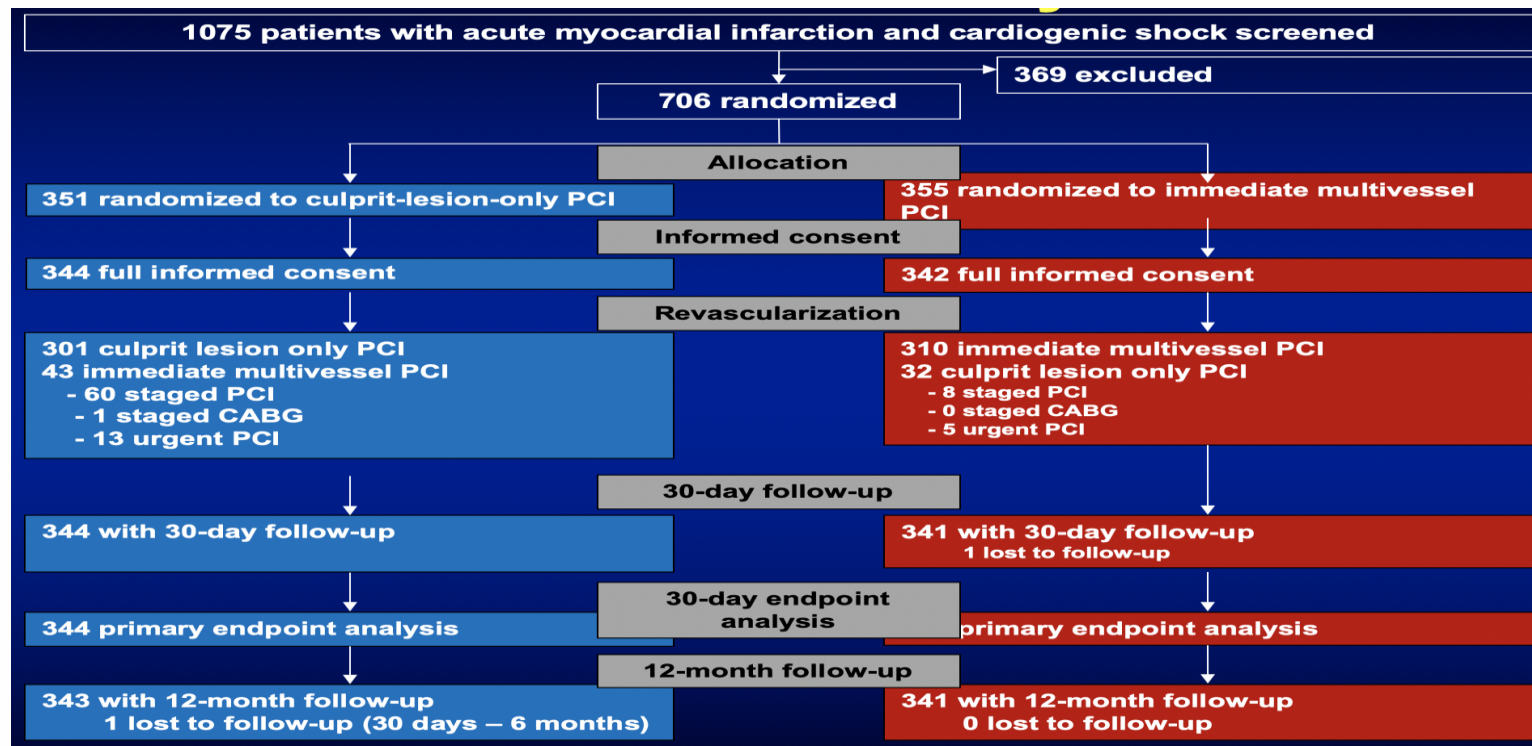
H. Thiele, I. Akin, M. Sandri, G. Fuernau, S. de Waha, R. Meyer-Saraei, P. Nordbeck, T. Geisler, U. Landmesser, C. Skurk, A. Fach, H. Lapp, J.J. Piek, M. Noc, T. Goslar, S.B. Felix, L.S. Maier, J. Stepinska, K. Oldroyd, P. Serpytis, G. Montalescot, O. Barthelemy, K. Huber, S. Windecker, S. Savonitto,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



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CULPRIT-SHOCK Trial: Study Flow Chart



Thiele et al., N Engl J Med 2018 Epub Aug. 25, 2018

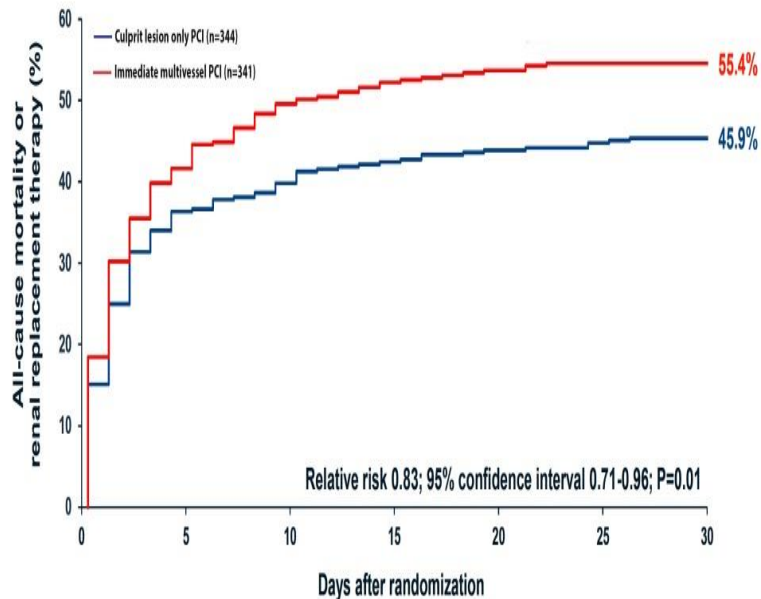


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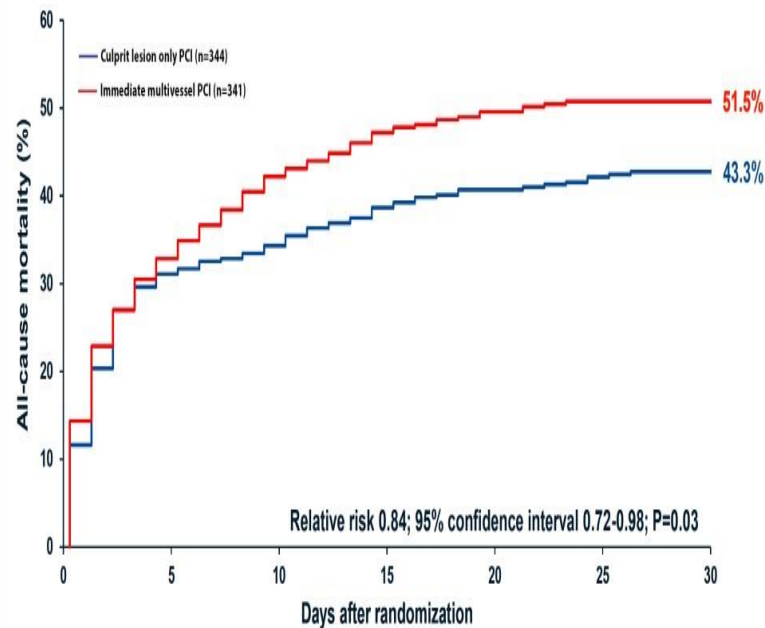


CULPRIT-SHOCK Trial: Primary Endpoint at 30 Days

All-Cause Mortality or Renal Replacement Therapy



All-Cause Mortality



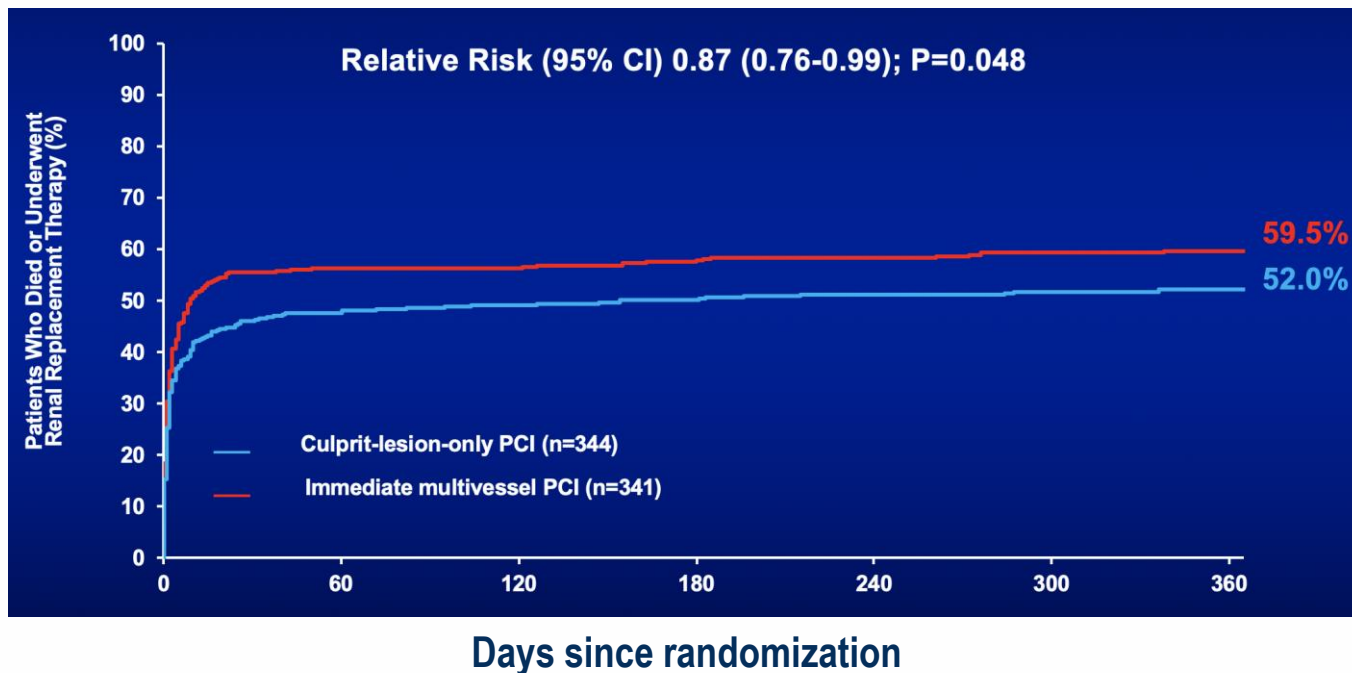
Thiele et al., N Engl J Med 2017;377:2419



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CULPRIT-SHOCK Trial: 1-Year All-Cause Mortality or Renal Replacement Therapy



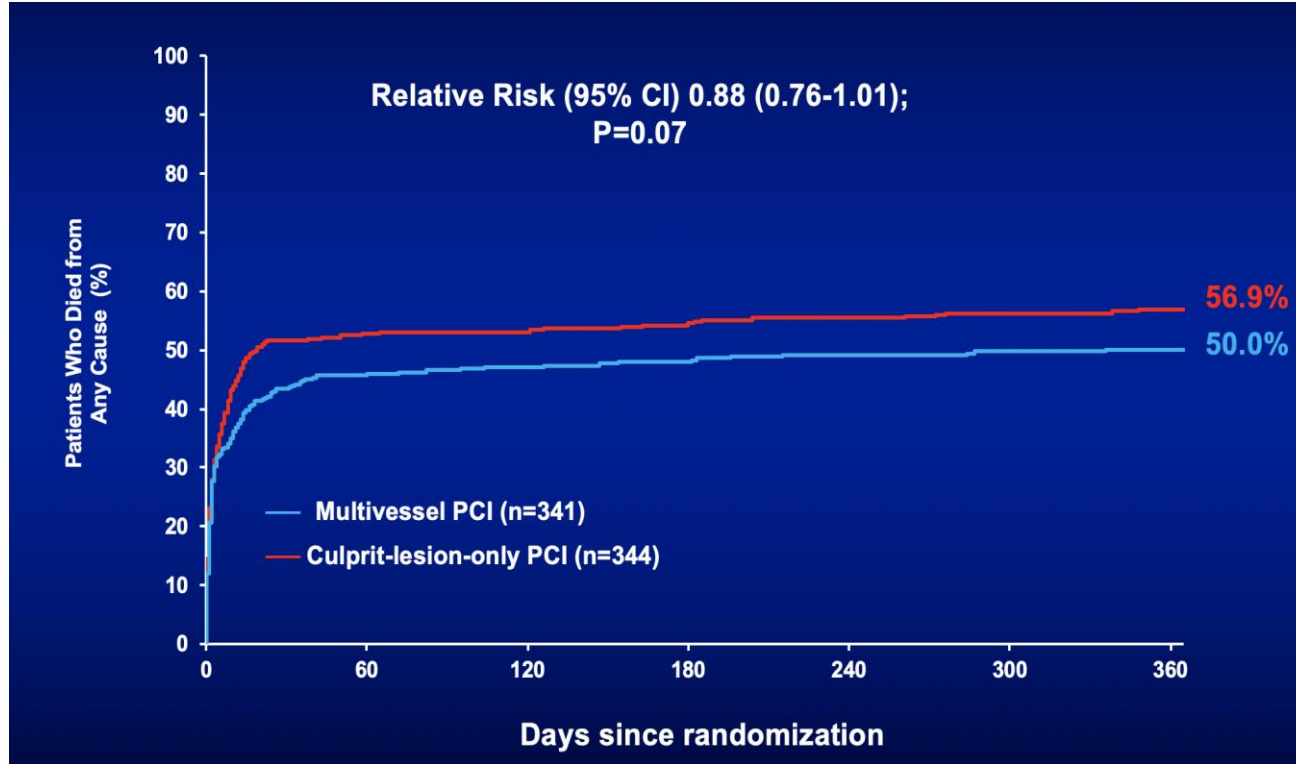
Thiele et al., *N Engl J Med* 2018 Epub Aug. 25, 2018



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CULPRIT-SHOCK Trial: 1-Year All-Cause Mortality



Thiele et al., N Engl J Med 2018 Epub Aug. 25, 2018

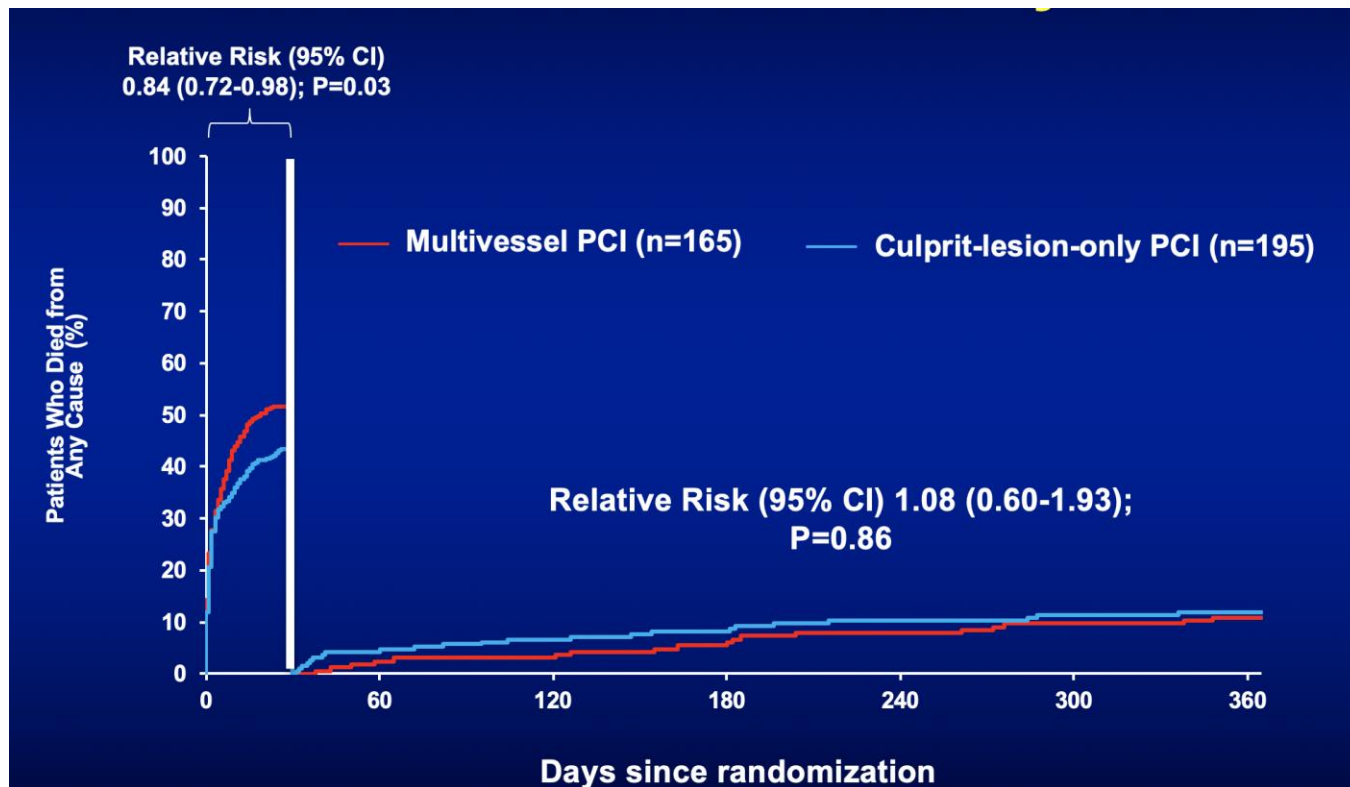
Days since randomization



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CULPRIT-SHOCK Trial: Landmark Analysis at 1-Year All-Cause Mortality



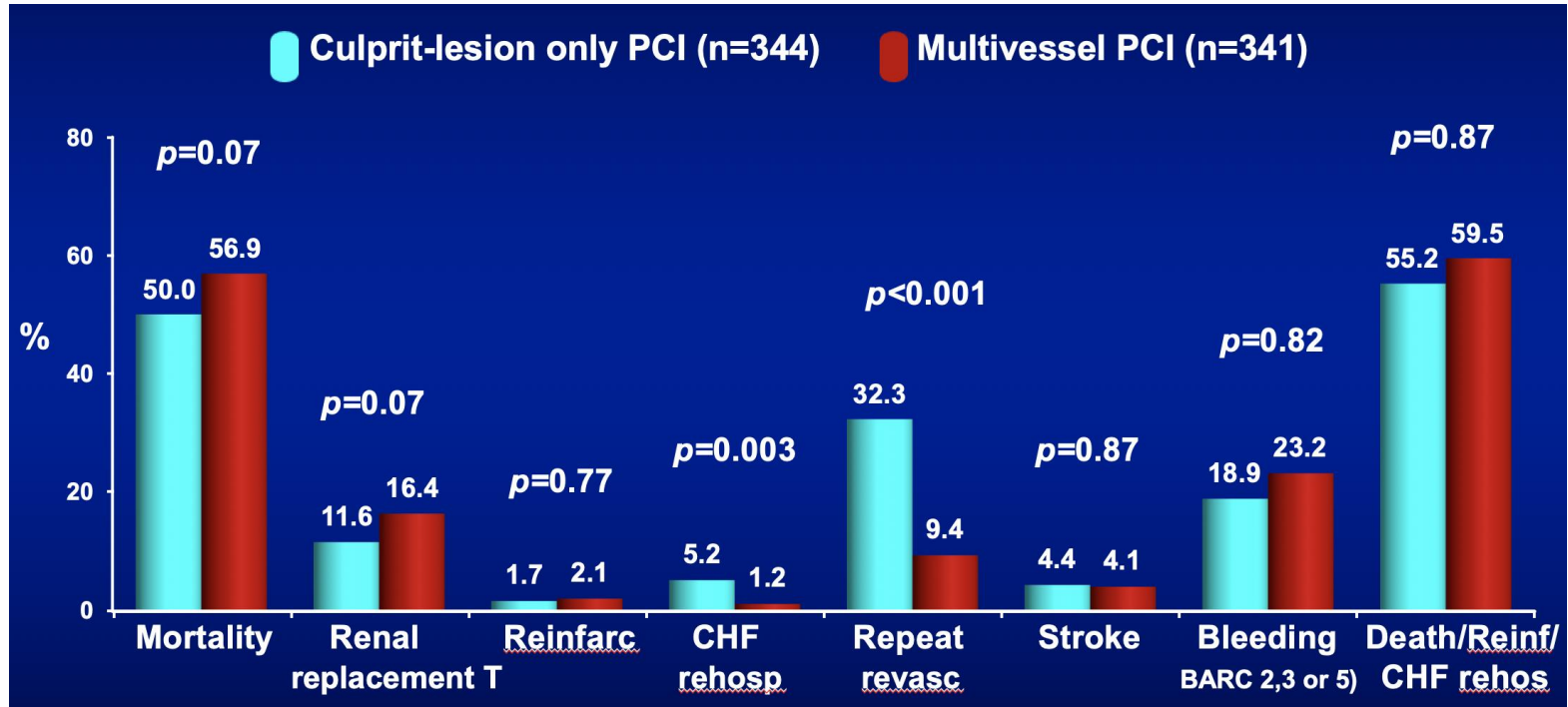
Thiele et al., N Engl J Med 2018 Epub Aug. 25, 2018



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CULPRIT-SHOCK: 1-Year Clinical Endpoints and Safety



Thiele et al., N Engl J Med 2018 Epub Aug. 25,2018



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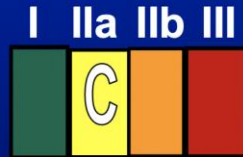


CULPRIT-SHOCK Trial: MV PCI in Shock Guideline Evolution

ESC STEMI Guidelines 2017 → Revascularization Guidelines 2018

STEMI (NSTEMI), Cardiogenic Shock

2017



2018



Ibanez et al., Eur Heart J 2018;39:119;

Neumann et al. Eur Heart J 2018;Epub 08.25.2018



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COMPARE-ACUTE Trial: FFR-Guided Revascularization

ORIGINAL ARTICLE

Fractional Flow Reserve–Guided Multivessel Angioplasty in Myocardial Infarction

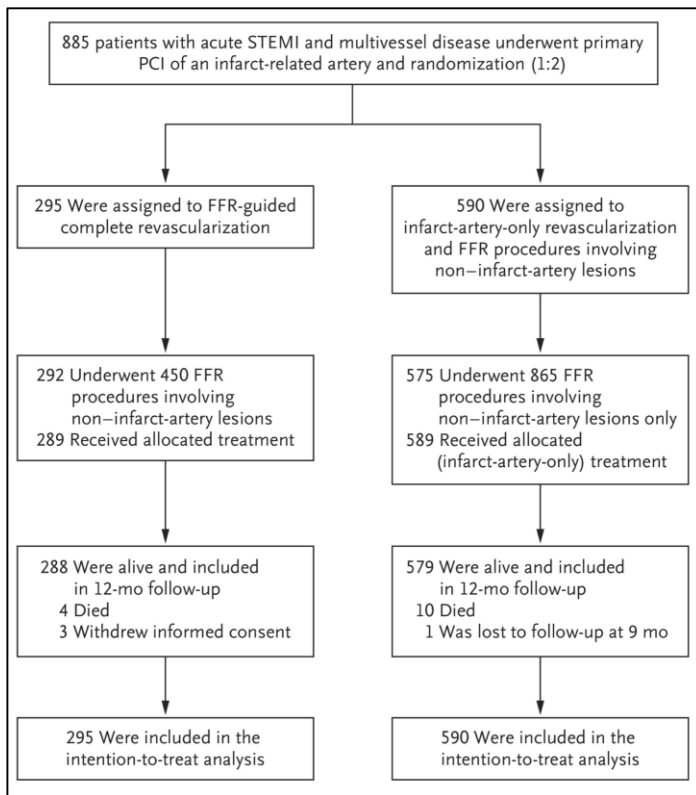
Pieter C. Smits, M.D., Ph.D., Mohamed Abdel-Wahab, M.D., Franz-Josef Neumann, M.D., Bianca M. Boxma-de Klerk, Ph.D., Ketil Lunde, M.D., Carl E. Schotborgh, M.D., Zsolt Piroth, M.D., David Horak, M.D., Adrian Wlodarczak, M.D., Paul J. Ong, M.D., Rainer Hambrecht, M.D., Oskar Angerås, M.D., et al., for the Compare-Acute Investigators*



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COMPARE-ACUTE Trial: FFR-Guided Revascularization



Type of Data	Complete Revascularization (N = 295)	Infarct-Artery-Only Treatment (N = 590)	P Value
Mean time for index procedure — min	65±31	59±28	0.001
Mean volume of contrast material used during index PCI — ml	224±104	202±75	0.007
FFR procedure successful — no. (%)	292 (99.0)	575 (97.5)	0.13
Reason for FFR procedure failure — no. (%)			
Failure to cross lesion	2 (0.7)	7 (1.2)	
Logistic and technical problems	1 (0.3)	3 (0.5)	
Patient with asthma	0	2 (0.3)	
Unknown	0	3 (0.5)	
Patients with lesions — no./total no. (%)			
FFR ≤0.80	158/292 (54.1)	275/575 (47.8)	0.08
FFR >0.80	134/292 (45.9)	300/575 (52.2)	
Mean FFR value	0.78±0.12	0.79±0.12	0.42
Patients with treated (FFR-guided) non-infarct-related coronary artery lesions — no./total no. (%)	163/295 (55.3)†	NA	
During index PCI procedure	136/163 (83.4)		
Delayed during index hospitalization‡	27/163 (16.6)		
Treatment method — no./total no. (%)		NA	
Drug-eluting stent only	161/163 (98.8)		
Bare-metal stent only	1/163 (0.6)		
Balloon dilation only	1/163 (0.6)		
Mean no. of stents used per patient	1.6±0.9	NA	
Dimensions of stents — mm			
Mean length	34.3±21.0	NA	
Mean diameter	2.9±0.4	NA	
Length of hospital stay — days			0.36
Median	4	4	
Range	1–35	1–71	
Patients receiving predischARGE noninvasive stress tests — no./total no. (%)	21/294 (7.1)	71/590 (12.0)	0.03

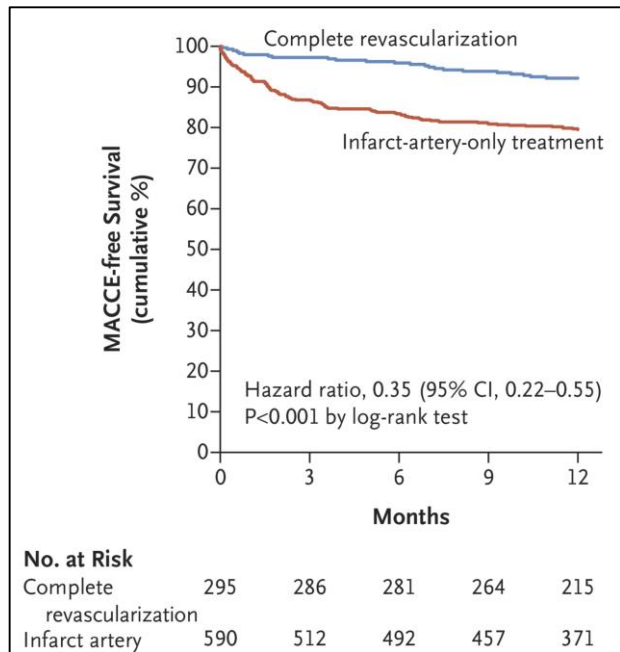


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COMPARE-ACUTE Trial: FFR-Guided Revascularization



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
Secondary				
NACE (any first event)	25 (8.5)	174 (29.5)	0.25 (0.16–0.38)	<0.001
Death from any cause) or myocardial infarction	11 (3.7)	38 (6.4)	0.57 (0.29–1.12)	0.10
Major bleeding	3 (1.0)	8 (1.4)	0.75 (0.20–2.84)	0.67
Any bleeding				
At 12 mo	9 (3.1)	28 (4.7)	0.64 (0.30–1.36)	0.25
At 48 hr	5 (1.7)	8 (1.4)	1.25 (0.41–3.83)	0.69
Hospitalization for heart failure, unstable angina, or chest pain	13 (4.4)	47 (8.0)	0.54 (0.29–0.99)	0.04
Any revascularization†	19 (6.4)	161 (27.3)	0.47 (0.29–0.76)	0.002
Stent thrombosis	2 (0.7)	1 (0.2)	0.58 (0.12–2.80)	0.50

Smits, P. C (2017). *NEJM*, 376(13), 1234-1244.



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COMPARE-ACUTE Trial: FFR-Guided Revascularization

In patients with STEMI and multivessel disease who underwent primary PCI of an infarct-related artery, the addition of FFR-guided complete revascularization of non–infarct-related arteries in the acute setting resulted in a risk of a composite cardiovascular outcome that was lower than the risk among those who were treated for the infarct-related artery only.

Smits, P. C (2017). *NEJM*, 376(13), 1234-1244.



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GLOBAL LEADERS Trial

THE LANCET

Articles

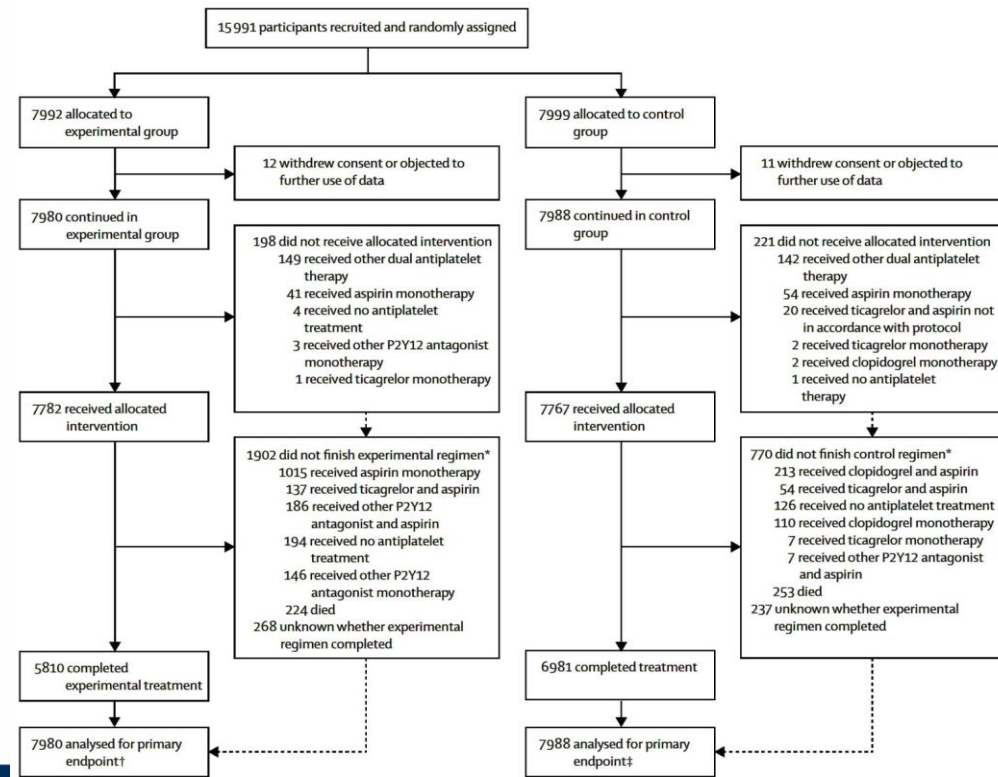
Ticagrelor plus aspirin for 1 month, followed by ticagrelor monotherapy for 23 months vs aspirin plus clopidogrel or ticagrelor for 12 months, followed by aspirin monotherapy for 12 months after implantation of a drug-eluting stent: a multicentre, open-label, randomised superiority trial

Pascal Vranckx*, Marco Valgimigli*, Peter Juni*, Christian Hamm, Philippe Gabriel Steg, Dik Heg, Gerrit Anne van Es, Eugene P McFadden, Yoshinobu Onuma, Cokky van Meijeren, Ply Chichareon, Edouard Benit, Helge Möllmann, Luc Janssens, Maurizio Ferraro, Aris Moschovitis, Aleksander Zurawski, Marcello Dominici, Robert Jan Van Geuns, Kurt Huber, Ton Slagboom, Patrick W Serruys, Stephan Windecker, on behalf of the GLOBAL LEADERS Investigators



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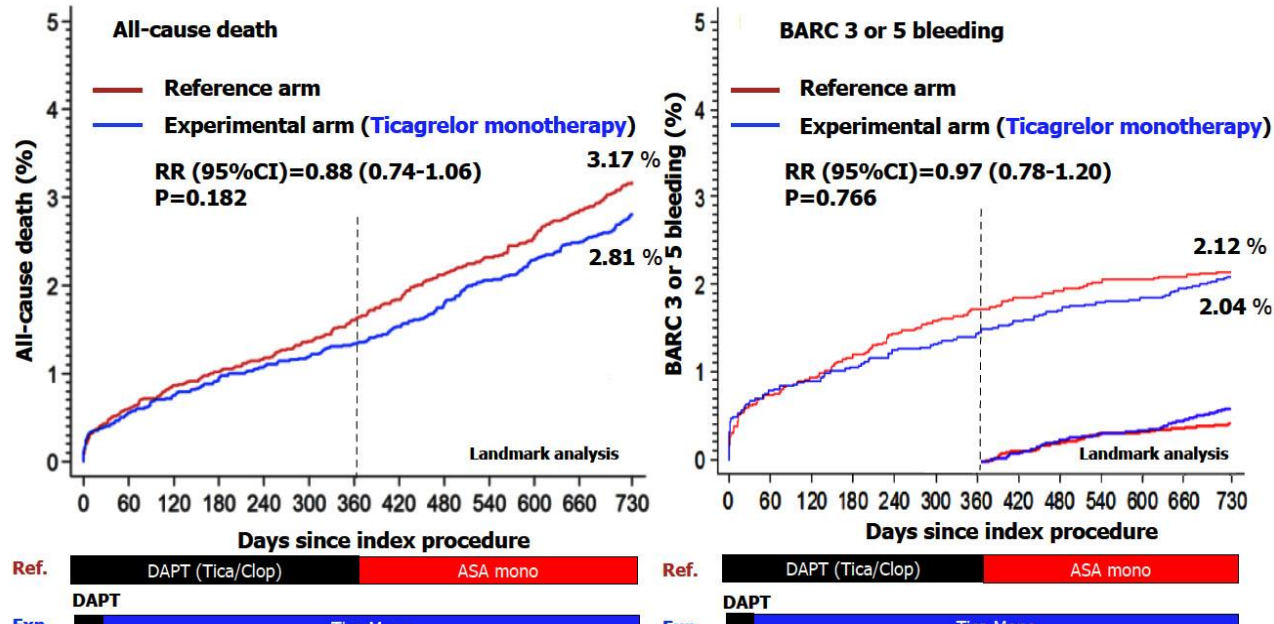
See Online/Comment
[http://dx.doi.org/10.1016/S0140-6736\(18\)31884-1](http://dx.doi.org/10.1016/S0140-6736(18)31884-1)



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GLOBAL LEADERS Trial



Interpretation Ticagrelor in combination with aspirin for 1 month followed by ticagrelor alone for 23 months was not superior to 12 months of standard dual antiplatelet therapy followed by 12 months of aspirin alone in the prevention of all-cause mortality or new Q-wave myocardial infarction 2 years after percutaneous coronary intervention.

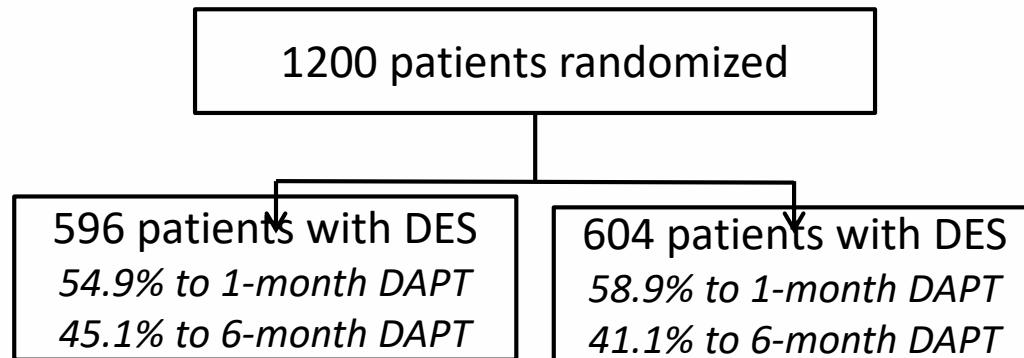
SENIOR trial

Drug-eluting stents in elderly patients with coronary artery disease (SENIOR): a randomised single-blind trial

Olivier Varenne, Stéphane Cook, Georgios Sideris, Sasko Kedev, Thomas Cuisset, Didier Carrié, Thomas Hovasse, Philippe Garot, Rami El Mahmoud, Christian Spaulding, Gérard Helft, José F Diaz Fernandez, Salvatore Brugaletta, Eduardo Pinar-Bermudez, Josepa Mauri Ferre, Philippe Commeau, Emmanuel Teiger, Kris Bogaerts, Manel Sabate, Marie-Claude Morice, Peter R Sinnaeve, for the SENIOR investigators

Inclusion criteria

- Age \geq 75 year, undergoing PCI
 - Randomized to DES or BMS
- Pre-specified DAPT duration
 - On-month if stable CAD
 - 6-month if ACS



Primary endpoint

- MACCE: Death, MI, stroke or ischemia-driven target lesion revascularization
- Within on-year of index PCI

Varenne et al, Lancet 2018 Jan 6;391(10115):41-50



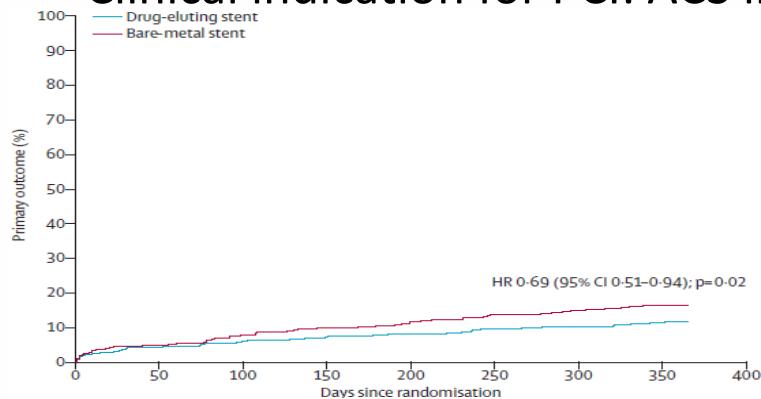
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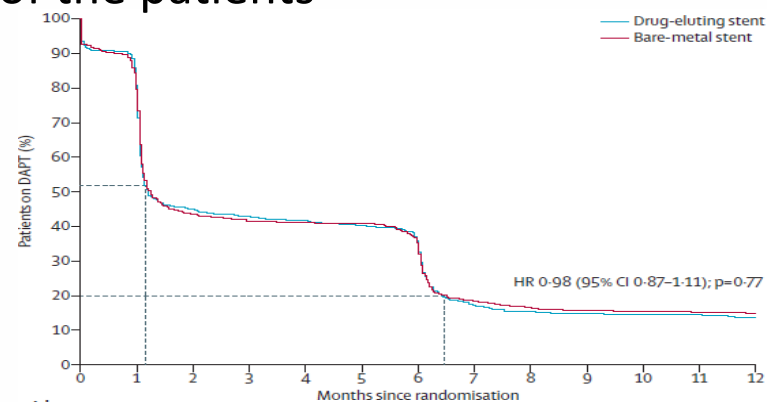
SENIOR trial

Varenne et al, Lancet 2018 Jan 6;391(10115):41-50

- Mean age 8.4 ± 4.3 years
- Clinical indication for PCI: ACS in 45.3% of the patients



Secondary endpoints				
All-cause mortality				
30 days	9 (2%)	15 (2%)	0.61 (0.20-1.42)	0.23
180 days	24 (4%)	30 (5%)	0.81 (0.46-1.39)	0.44
1 year	36 (6%)	48 (8%)	0.76 (0.49-1.16)	0.20
Cardiovascular death				
30 days	7 (1%)	14 (2%)	0.51 (0.13-0.26)	0.13
180 days	15 (3%)	25 (4%)	0.61 (0.29-1.14)	0.12
1 year	22 (4%)	36 (6%)	0.62 (0.34-1.04)	0.07
Myocardial infarction				
30 days	12 (2%)	11 (2%)	1.11 (0.44-2.93)	0.81
180 days	13 (2%)	17 (3%)	0.77 (0.33-1.65)	0.48
1 year	21 (4%)	22 (4%)	0.97 (0.51-1.82)	0.92
Stroke				
30 days	2 (<1%)	1 (<1%)	2.03 (0.18-22.37)	0.56
180 days	8 (1%)	1 (<1%)	8.15 (1.02-64.85)	0.02
1 year	12 (2%)	5 (1%)	2.43 (0.88-7.04)	0.08
Ischaemia-driven target lesion revascularisation				
30 days	2 (<1%)	3 (<1%)	0.67 (0.00-1.88)	0.66
180 days	7 (1%)	23 (4%)	0.31 (0.08-0.66)	0.003
1 year	10 (2%)	35 (6%)	0.29 (0.11-0.54)	0.0002



Secondary endpoints				
Bleeding complications*				
BARC 2-5				
30 days	11 (2%)	13 (2%)	0.85 (0.32-2.07)	0.69
180 days	20 (3%)	20 (3%)	1.01 (0.52-1.96)	0.97
1 year	26 (5%)	29 (5%)	0.90 (0.51-1.54)	0.68
BARC 3-5				
30 days	10 (2%)	8 (1%)	1.26 (0.43-4.37)	0.62
180 days	15 (3%)	14 (2%)	1.08 (0.48-2.47)	0.83
1 year	20 (3%)	14 (2%)	1.39 (0.49-1.82)	0.58

**In the elderly, with short DAPT duration,
DES > BMS**



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