New Strategies of Primary PCI for STEMI: Results From Recent Trials

인제대학교 의과대학 해운대백병원 순환기내과 송필상

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인제대학교 해운대백병원
INJE UNIVERSITY HAEUNDAE PAIK HOSPITAL

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Randomized Trial of Primary PCI with or without Routine Manual Thrombectomy

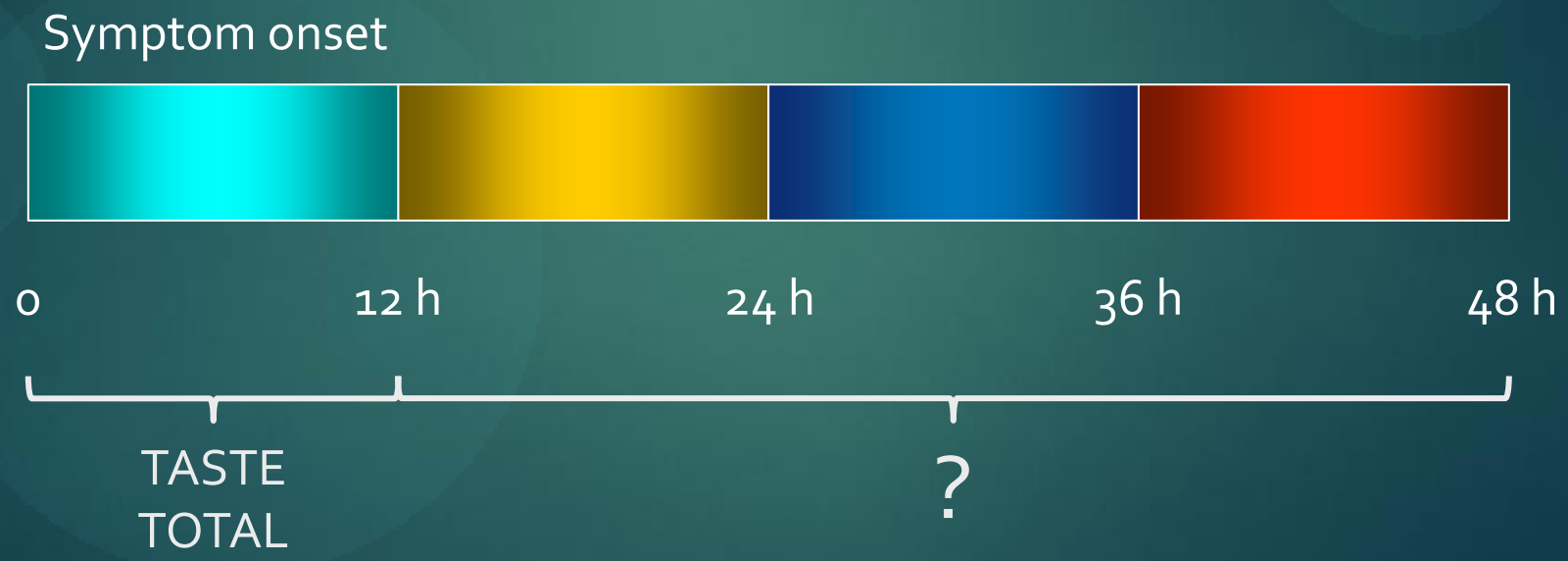
S.S. Jolly, J.A. Cairns, S. Yusuf, B. Meeks, J. Pogue, M.J. Rokoss, S. Kedev, L. Thabane, G. Stankovic, R. Moreno, A. Gershlick, S. Chowdhary, S. Lavi, K. Niemelä, P.G. Steg, I. Bernat, Y. Xu, W.J. Cantor, C.B. Overgaard, C.K. Naber, A.N. Cheema, R.C. Welsh, O.F. Bertrand, A. Avezum, R. Bhindi, S. Pancholy, S.V. Rao, M.K. Natarajan, J.M. ten Berg, O. Shestakovska, P. Gao, P. Widimsky, and V. Džavík, for the TOTAL Investigators*

Effect of Thrombus Aspiration in Patients With Myocardial Infarction Presenting Late After Symptom Onset

Steffen desch, et al. TCT 2015

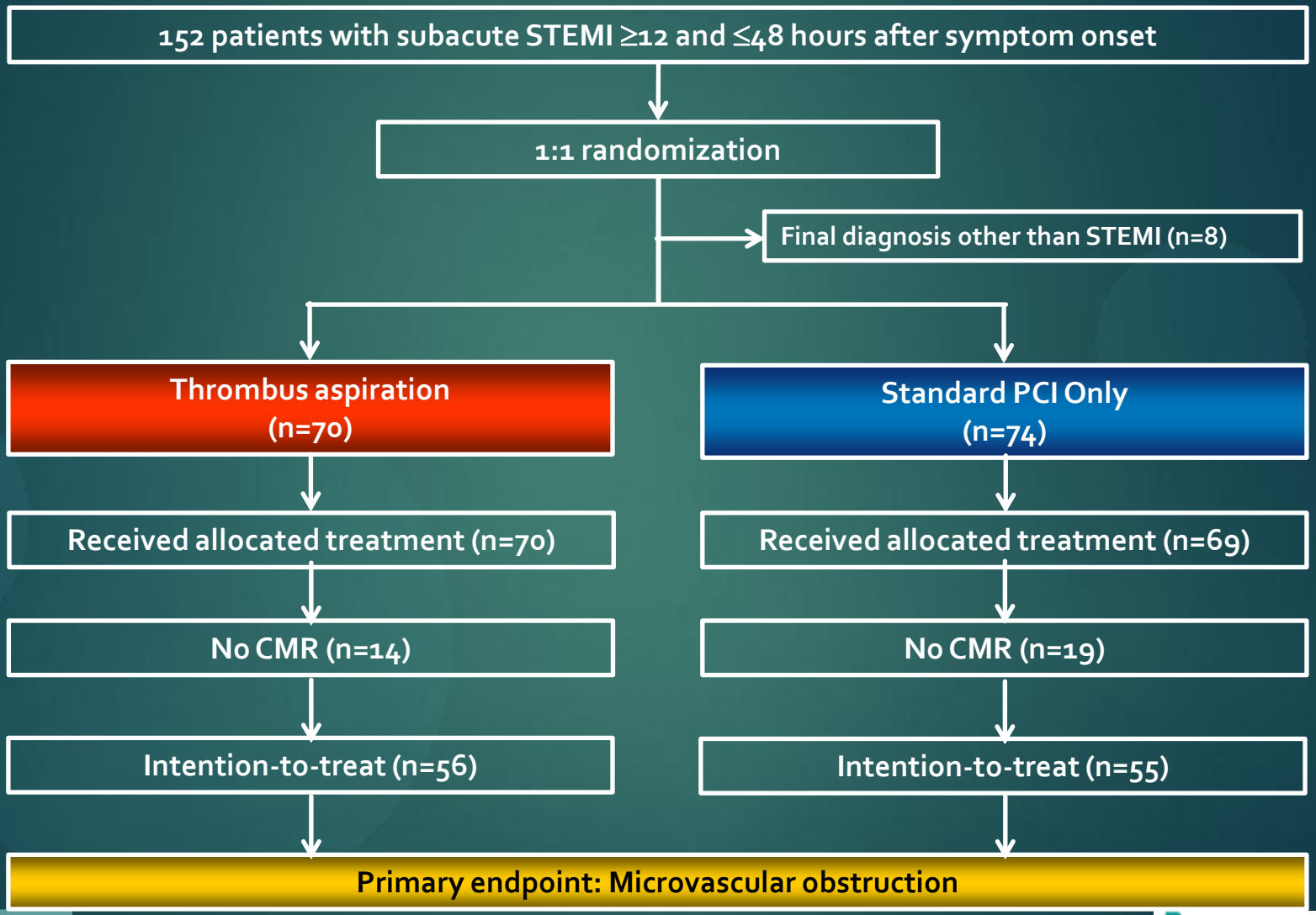
Background

- Recent trials on thrombus aspiration in STEMI reported disappointing results with no reduction in mortality and possibly an increase in stroke.



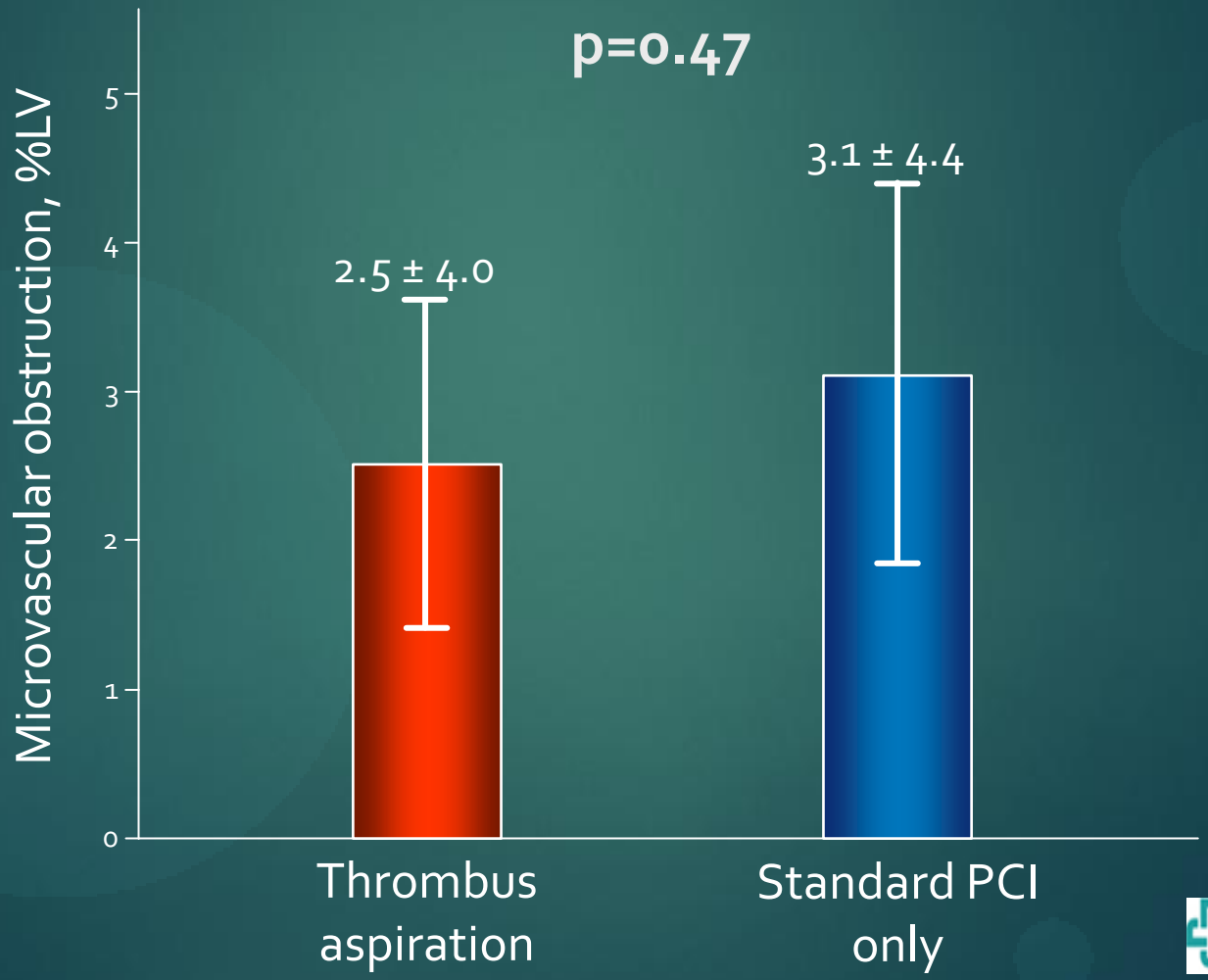
Frobert et al. N Engl J Med 2013;369:1587-97
Jolly et al. N Engl J Med 2015;372:1389-98

Study Flow



Results

Primary Endpoint: Microvascular Obstruction



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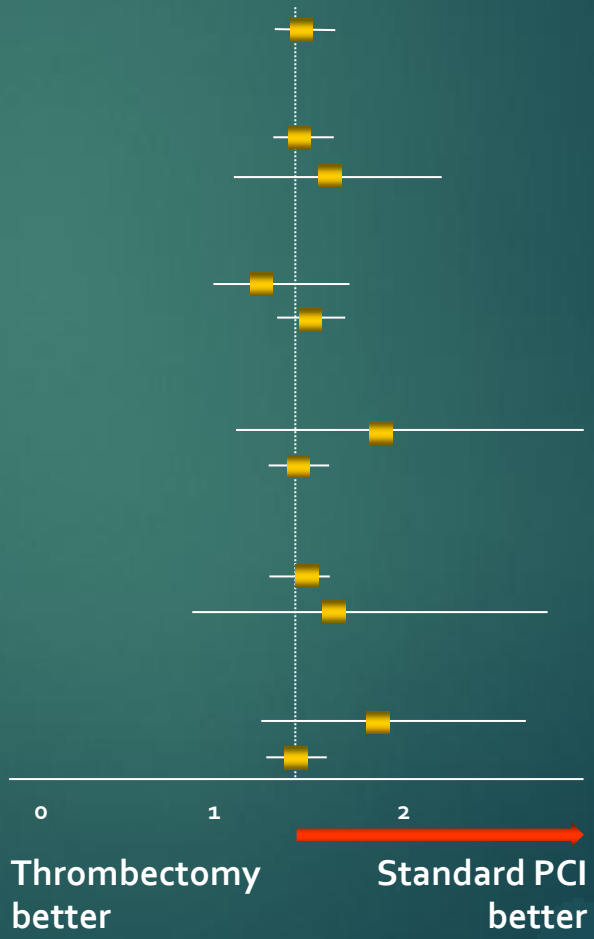
MVO in Predefined Subgroups

Baseline variable	No. of patients	Mean Difference in MVO %LV (95% CI)	*p* value for interaction
All Patients	111		
Male sex	86/111		0.95
Female sex	25/111		
Diabetes	32/111		0.29
No diabetes	79/111		
TIMI thrombus grade 0-4	38/111		0.82
TIMI thrombus grade 5	73/111		
TIMI-flow pre PCI 0-1	77/111		0.53
TIMI-flow pre PCI 2-3	34/111		
GP IIb/IIIa-inhibitor	32/111		0.35
No GP IIb/IIIa-inhibitor	79/111		



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Secondary Endpoints: Clinical Outcome

	Thrombus aspiration (n = 70)	Standard PCI (n = 74)	*P* Value
All-cause death, n (%)	2 (3)	4 (5)	0.68
Cardiovascular death, n (%)	2 (3)	3 (4)	1.0
Reinfarction, n (%)	0	0	-
TVR, n (%)	2 (3)	0	0.24
TLR, n (%)	2 (3)	0	0.24
Stent thrombosis, n (%)	0	0	-
Stroke, n (%)	0	1 (1)	0.24

Conclusion

- In patients with subacute STEMI routine manual thrombus aspiration before PCI failed to show a significant reduction in the primary endpoint of MVO assessed by CMR.

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ORIGINAL ARTICLE

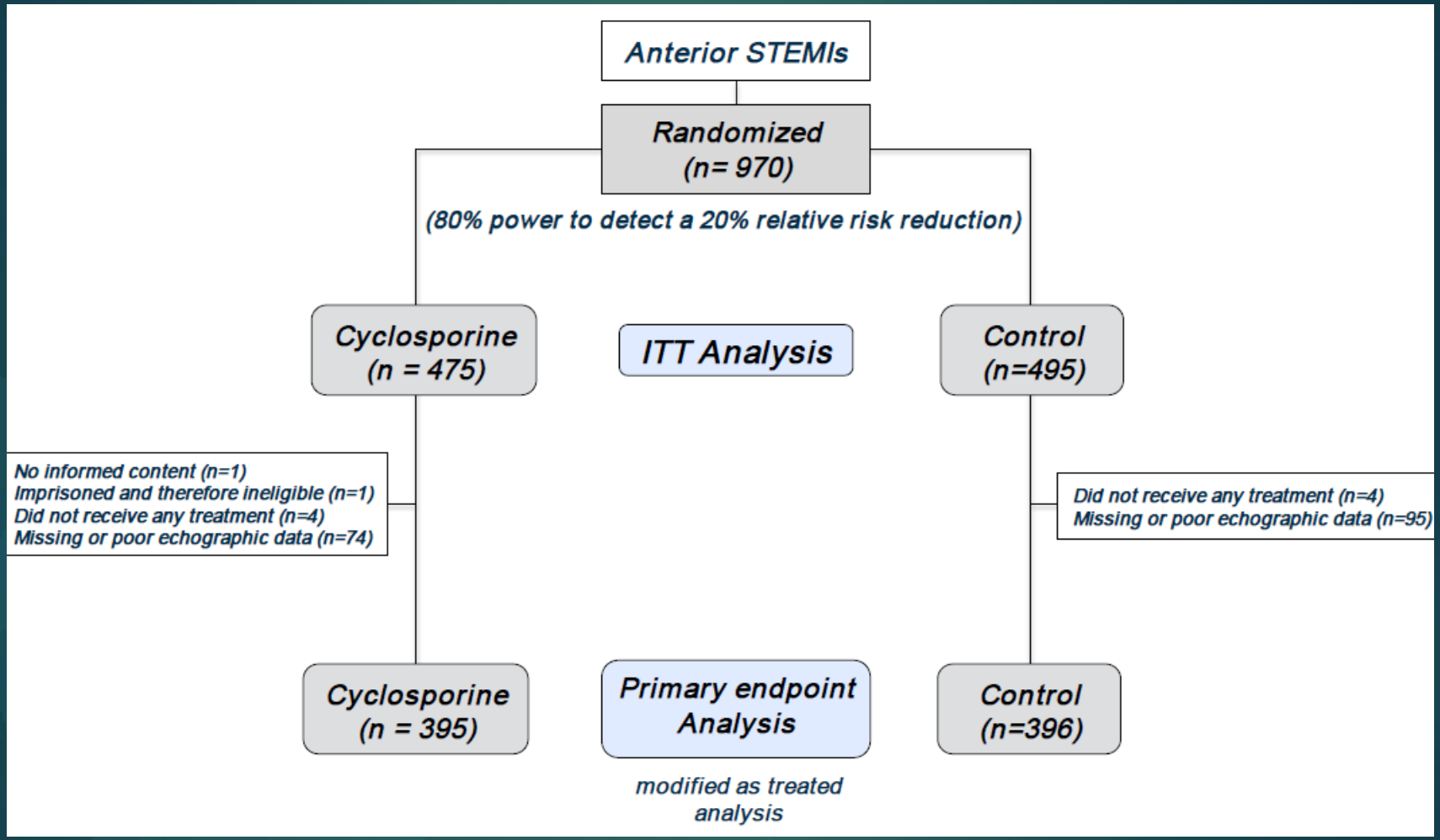
Cyclosporine before PCI in Patients with Acute Myocardial Infarction

T.-T. Cung et al. N Engl J Med 2015;373:1021-31

Background

- The opening of the mitochondrial permeability transition pore (PTP) plays a major role in reperfusion injury (*Biochem J 1995; 307: 93-8*).
- Inhibition of cyclophilin D, a major component of the PTP, reduces the severity of myocardial reperfusion injury (*Nature 2005; 434: 658-62*).
- In a proof-of-concept phase 2 trial, the administration of cyclosporine immediately before primary PCI reduced the myocardial infarct size in patients with STEMI (*N Engl J Med 2008; 359: 473-81*).

Randomization of Patients



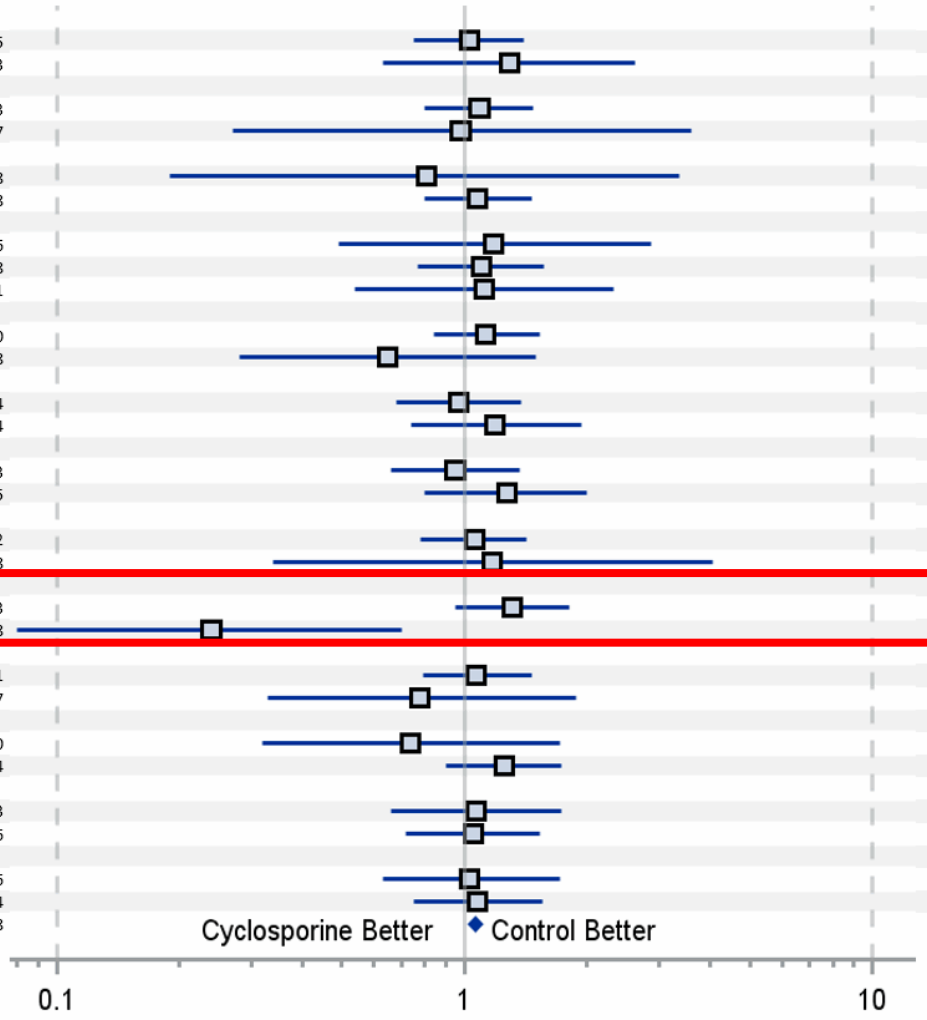
Clinical Outcomes at 1 Year

Outcome	Cyclosporine (N=395)	Control (N=396)	Odds Ratio (95% CI)	P Value
	number (percent)			
Primary composite outcome*	233 (59.0)	230 (58.1)	1.04 (0.78–1.39)	0.77
Death from any cause	28 (7.1)	26 (6.6)	1.09 (0.63–1.90)	0.76
Cardiovascular death	24 (6.1)	24 (6.1)	1.01 (0.56–1.81)	0.98
Heart-failure worsening or rehospitalization for heart failure	90 (22.8)	90 (22.7)	1.01 (0.72–1.41)	0.97
Heart-failure worsening	62 (15.7)	67 (16.9)	0.92 (0.63–1.34)	0.65
Rehospitalization for heart failure	42 (10.6)	41 (10.4)	1.03 (0.65–1.63)	0.89
Left ventricular remodeling	169 (42.8)	161 (40.7)	1.09 (0.82–1.46)	0.53
Cardiogenic shock	26 (6.6)	24 (6.1)	1.09 (0.61–1.94)	0.77
Recurrent myocardial infarction	9 (2.3)	15 (3.8)	0.59 (0.26–1.37)	0.22
Stroke	7 (1.8)	12 (3.0)	0.58 (0.22–1.48)	0.25
Major bleeding	7 (1.8)	9 (2.3)	0.73 (0.27–2.00)	0.54

The primary outcome was a composite of death from any cause, worsening of heart failure during the initial hospitalization, rehospitalization for heart failure, or adverse left ventricular remodeling at 1 year

Subgroups analysis

Subgroup	No. of Patients	Cyclo No. of events / total	Control No. of events / total	Odds ratio (95% CI)	p-value for interaction
Sex					0.64
Male	660	196/335	188/325	1.03 (0.75;1.40)	
Female	135	39/62	42/73	1.29 (0.63;2.62)	
Initial TIMI Flow					0.78
<2	709	208/346	211/363	1.09 (0.80;1.47)	
≥2	55	15/28	15/27	0.98 (0.27;3.59)	
Final TIMI Flow					0.75
<2	54	20/26	22/28	0.81 (0.19;3.36)	
≥2	701	199/343	201/358	1.08 (0.80;1.46)	
Symptom Onset					0.99
<2h	84	26/48	18/36	1.18 (0.49;2.86)	
2-6h	510	157/262	143/248	1.10 (0.77;1.56)	
>6h	134	31/53	46/81	1.12 (0.54;2.32)	
Diabetes					0.22
No	693	202/343	196/350	1.13 (0.84;1.53)	
Yes	102	33/54	34/48	0.65 (0.28;1.50)	
Hypertension					0.46
No	488	133/244	135/244	0.97 (0.68;1.38)	
Yes	307	102/153	95/154	1.19 (0.74;1.93)	
Dyslipidemia					0.31
No	481	136/238	142/243	0.95 (0.66;1.37)	
Yes	314	99/159	88/155	1.27 (0.80;2.00)	
Rentrop score					0.78
<2	713	210/351	212/362	1.06 (0.78;1.42)	
≥2	51	13/23	14/28	1.17 (0.34;4.06)	
Killip at baseline					<0.01
=1	610	179/307	157/303	1.31 (0.95;1.81)	
>1	97	31/49	42/48	0.24 (0.08;0.70)	
Age					0.51
<75 Yr	670	184/329	185/341	1.07 (0.79;1.46)	
≥75 Yr	125	51/68	45/57	0.78 (0.33;1.87)	
Ejection Fraction					0.27
<40%	143	49/63	66/80	0.74 (0.32;1.71)	
≥40%	607	165/313	140/294	1.25 (0.90;1.72)	
LAD					0.95
Proximal-MainLeft	327	116/164	113/163	1.07 (0.66;1.72)	
Medial-Distal-Diag	433	105/207	112/226	1.05 (0.72;1.53)	
Thrombus aspiration					0.86
No	253	60/117	69/136	1.03 (0.63;1.71)	
Yes	512	164/258	157/254	1.08 (0.75;1.55)	
Overall	795	235/397	230/398	1.06 (0.80;1.41)	



Discussion

- This difference may be related to
  - a limited use of direct stenting
  - possibly to a higher rate of thrombus aspiration
  - the inclusion of only patients with anterior infarcts
  - a higher rate of use of loading doses of P2Y12 inhibitors
  - the formulation of cyclosporine (Sandimmune versus CicloMulsion).

Conclusions

- Cyclosporine did not reduce the risk of the composite outcome of death from any cause, worsening of heart failure during the initial hospitalization, re-hospitalization for heart failure, or adverse left ventricular remodeling at 1 year.

Complete revascularisation versus treatment of the culprit lesion only in patients with ST-segment elevation myocardial infarction and multivessel disease (DANAMI-3—PRIMULTI): an open-label, randomised controlled trial

*Thomas Engstrøm, Henning Kelbæk, Steffen Helqvist, Dan Eik Høfsten, Lene Kløvgaard, Lene Holmvang, Erik Jørgensen, Frants Pedersen, Kari Saunamäki, Peter Clemmensen, Ole De Backer, Jan Ravkilde, Hans-Henrik Tilsted, Anton Boel Villadsen, Jens Aarøe, Svend Eggert Jensen, Bent Raungaard, Lars Køber, for the DANAMI-3—PRIMULTI Investigators**

Thomas Engstrøm et al. Lancet 2015; 386: 665–71

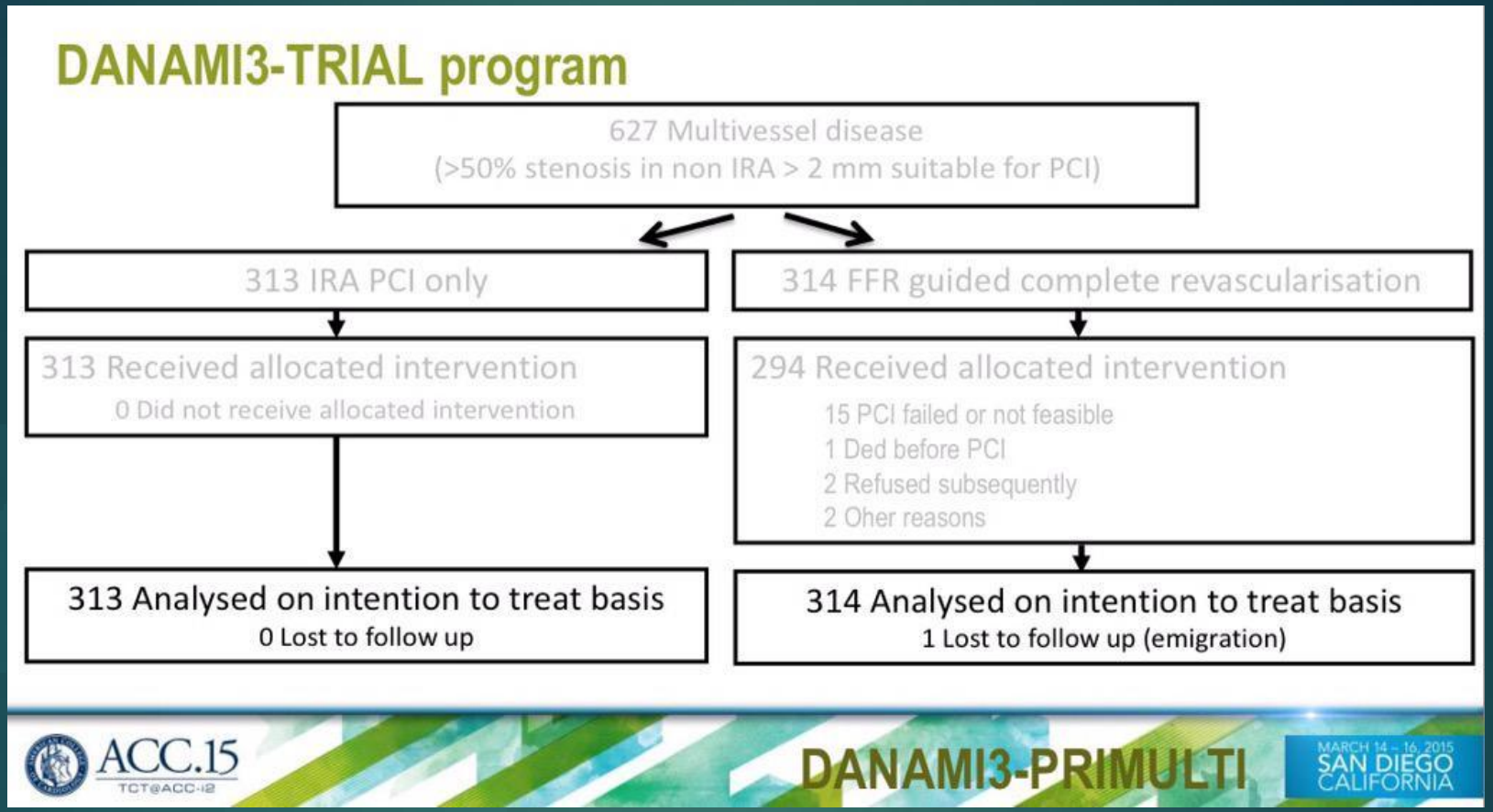
Background

- The PRAMI and CVLPRIT trials
  - angiographic assessed complete revascularization
- We aimed to study the clinical outcome of patients with STEMI treated with fractional flow reserve (FFR)-guided complete revascularization versus treatment of the infarct-related artery only.

Methods

- Procedures
  - We did additional PCI procedures—preferably with everolimus-eluting stents—2 days after the initial PCI procedure before discharge, according to local routines.
  - We judged FFR values of 0·80 or lower significant and treated those lesions, in addition to visually estimated stenosis greater than 90%.

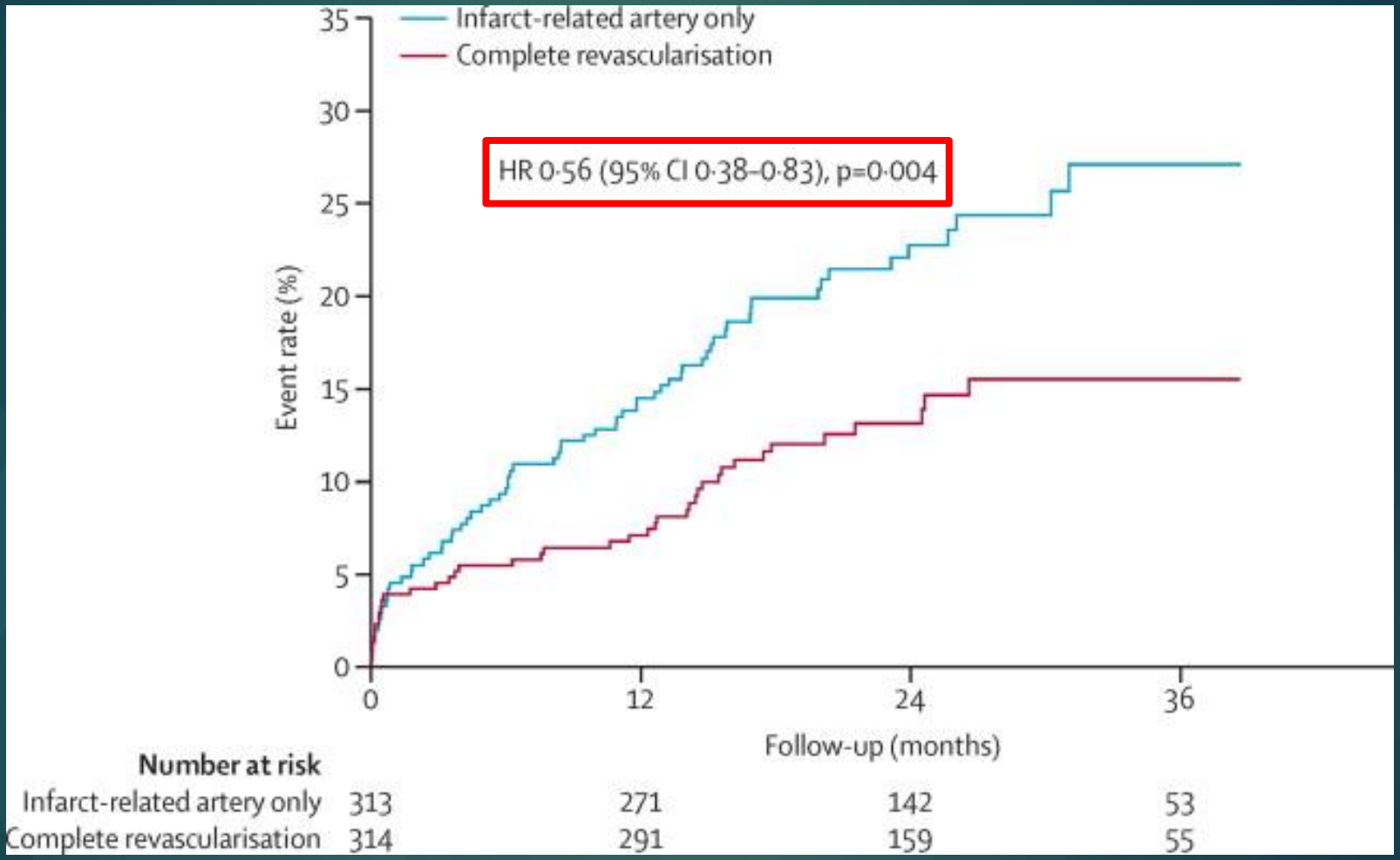
Trial profile



Results

- Of 314 patients allocated complete revascularization,
  - 97 (31%) had FFR values for lesions in non-infarct related arteries that were greater than the discrimination value of 0·80,
    - these individuals did not have any further invasive treatment.

Event rates of the combined primary endpoint



Clinical outcomes

	Infarct-related artery only (n=313)	Complete revascularisation (n=314)	Hazard ratio (95% CI)	p
Primary endpoint*	68 (22%)	40 (13%)	0·56 (0·38–0·83)	0·004
All-cause mortality	11 (4%)	15 (5%)	1·40 (0·63–3·00)	0·43
Non-fatal reinfarction	16 (5%)	15 (5%)	0·94 (0·47–1·90)	0·87
Ischaemia-driven revascularisation	52 (17%)	17 (5%)	0·31 (0·18–0·53)	<0·0001
Secondary endpoints				
Cardiac death	9 (3%)	5 (2%)	0·56 (0·19–1·70)	0·29
Cardiac death or non-fatal myocardial infarction	25 (8%)	20 (6%)	0·80 (0·45–1·45)	0·47
Urgent percutaneous coronary intervention	18 (6%)	7 (2%)†	0·38 (0·16–0·92)	0·03
Non-urgent percutaneous coronary intervention	27 (9%)	8 (3%)	0·29 (0·13–0·63)	0·002
Unplanned coronary-artery bypass graft surgery	7 (2%)	3 (1%)	0·43 (0·11–1·70)	0·22

Data are number of events (%). *The first event per patient is listed. †One patient had both urgent and non-urgent percutaneous coronary intervention.

Table 3: **Clinical outcomes**

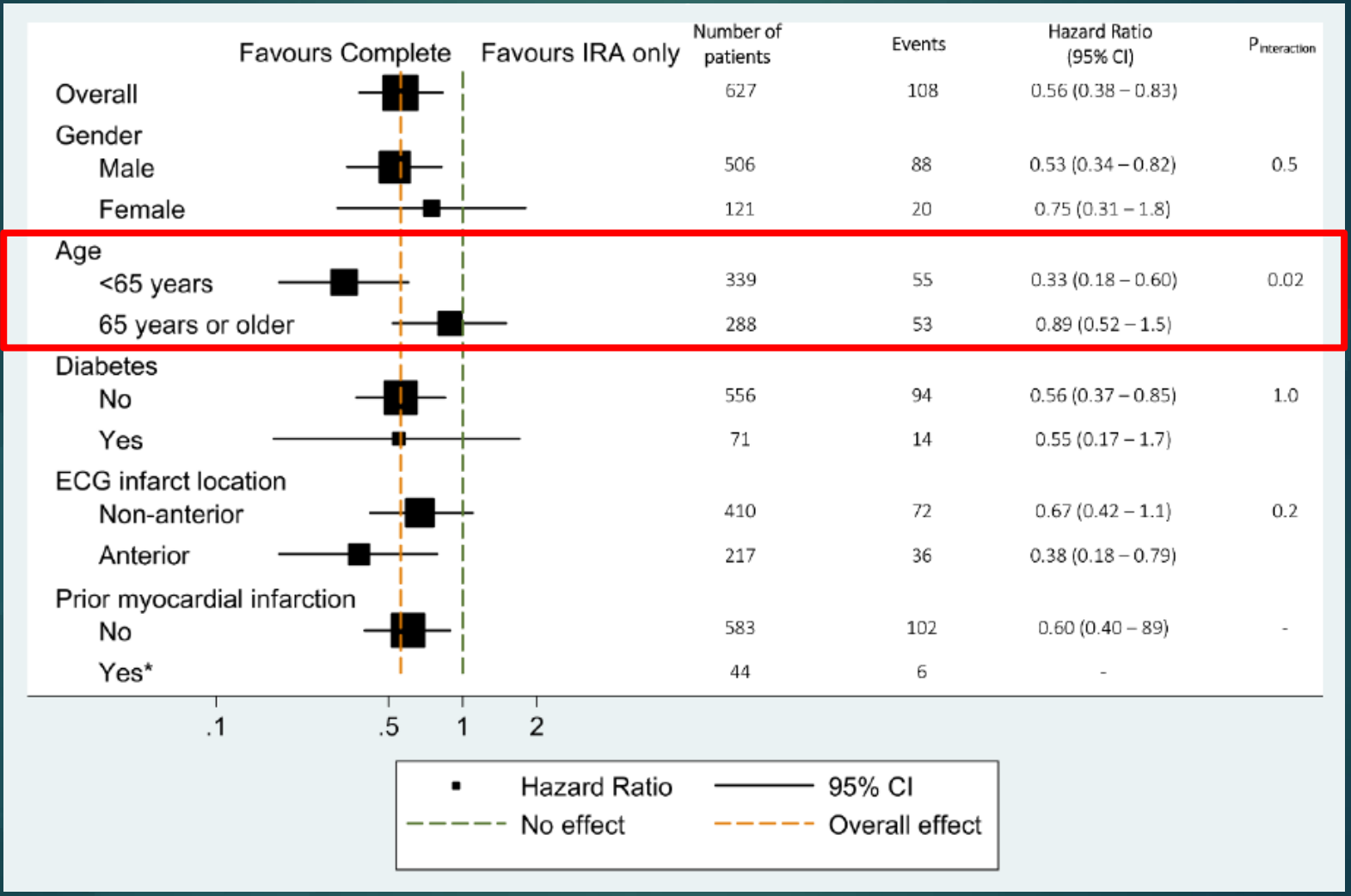
Procedure-related complications

	Infarct-related artery only (n=313)	Complete revascularisation (n=314)	p
Periprocedural myocardial infarction	0	2 (1%)	0·2
Bleeding requiring transfusion or surgery	4 (1%)	1 (<1%)	0·2
Contrast-induced nephropathy (>50% rise in plasma creatinine)	7 (2%)	6 (2%)	0·8
Stroke	1 (<1%)	4 (1%)	0·2

Data are number of events (%).

Table 4: **Procedure-related complications**

Primary endpoint in various subgroups



Results

- The 97 patients with FFR measures greater than 0·80 did not differ from the remainder of the group allocated complete revascularization (hazard ratio 1·54, 95% CI 0·82–2·90; *p*=0·18).

Discussion

- The PRAMI, CVLPRIT, and PRIMULTI trials indicate a clinical reduction in future events by complete revascularization during index admission.
- On the other hand, uncertainty remains about whether PCI of non infarct related vessels should be done.

Conclusion

- Complete revascularization during the index admission of STEMI patients with multi-vessel disease reduces the risk of future events without increasing the risk of serious adverse events.

The Evaluating Xience and left ventricular function in PCI on occlusiOns afteR STEMI (EXPLORE) trial

The impact of PCI for concurrent CTO on left ventricular function in STEMI patients

A randomised multicenter trial

José PS Henriques, et al., TCT 2015

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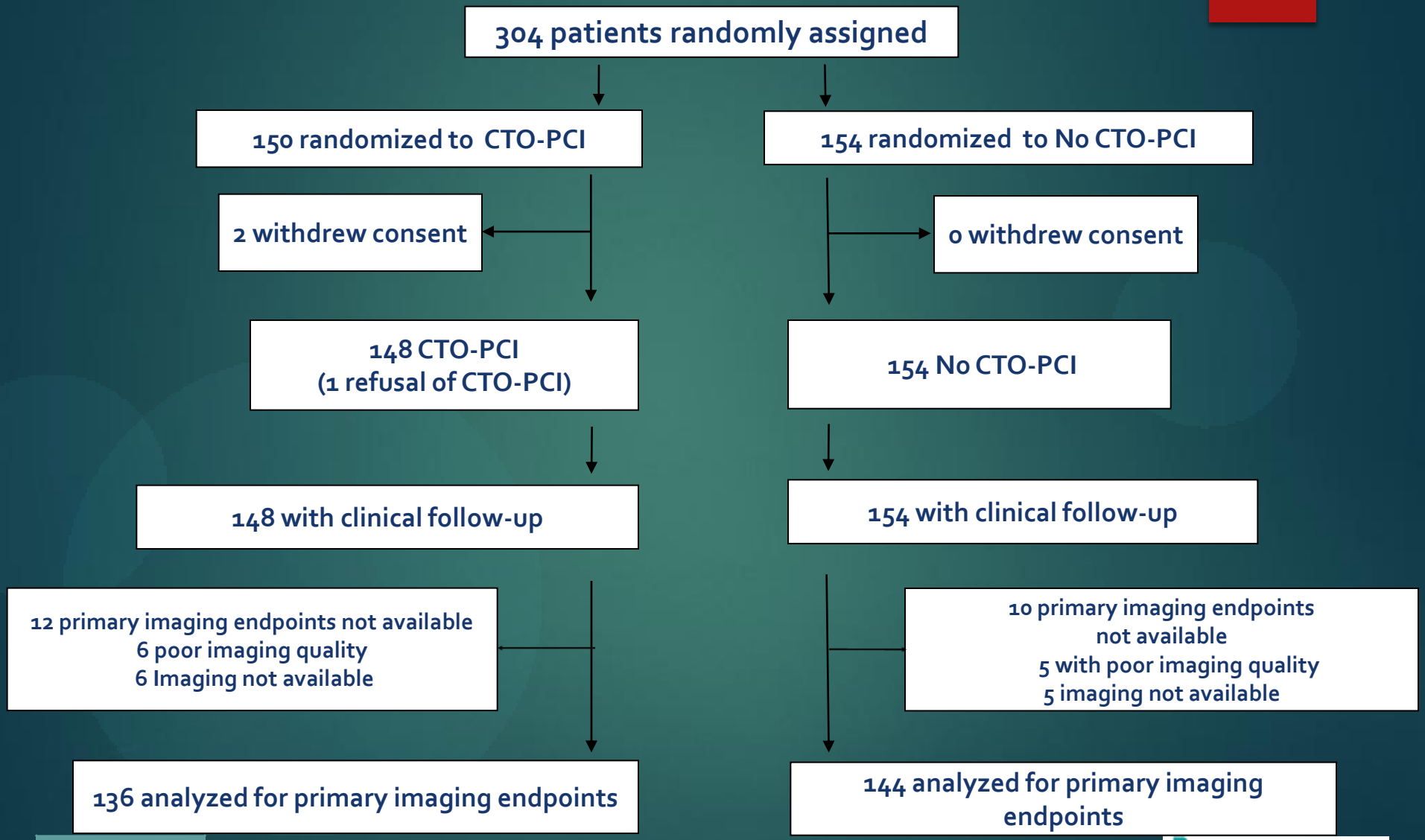
인제대학교 해운대백병원
INJE UNIVERSITY HAEUNDAE PAIK HOSPITAL

Background

- CTO in non-IRA in 10% of STEMI patients
- No randomized data on effect of CTO PCI
- EXPLORE
  - First RCT on the impact of PCI of CTO on LV function (LVEF and LVEDV) and clinical outcome in STEMI patients

Flowchart



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INJE UNIVERSITY HAEUNDAE PAIK HOSPITAL

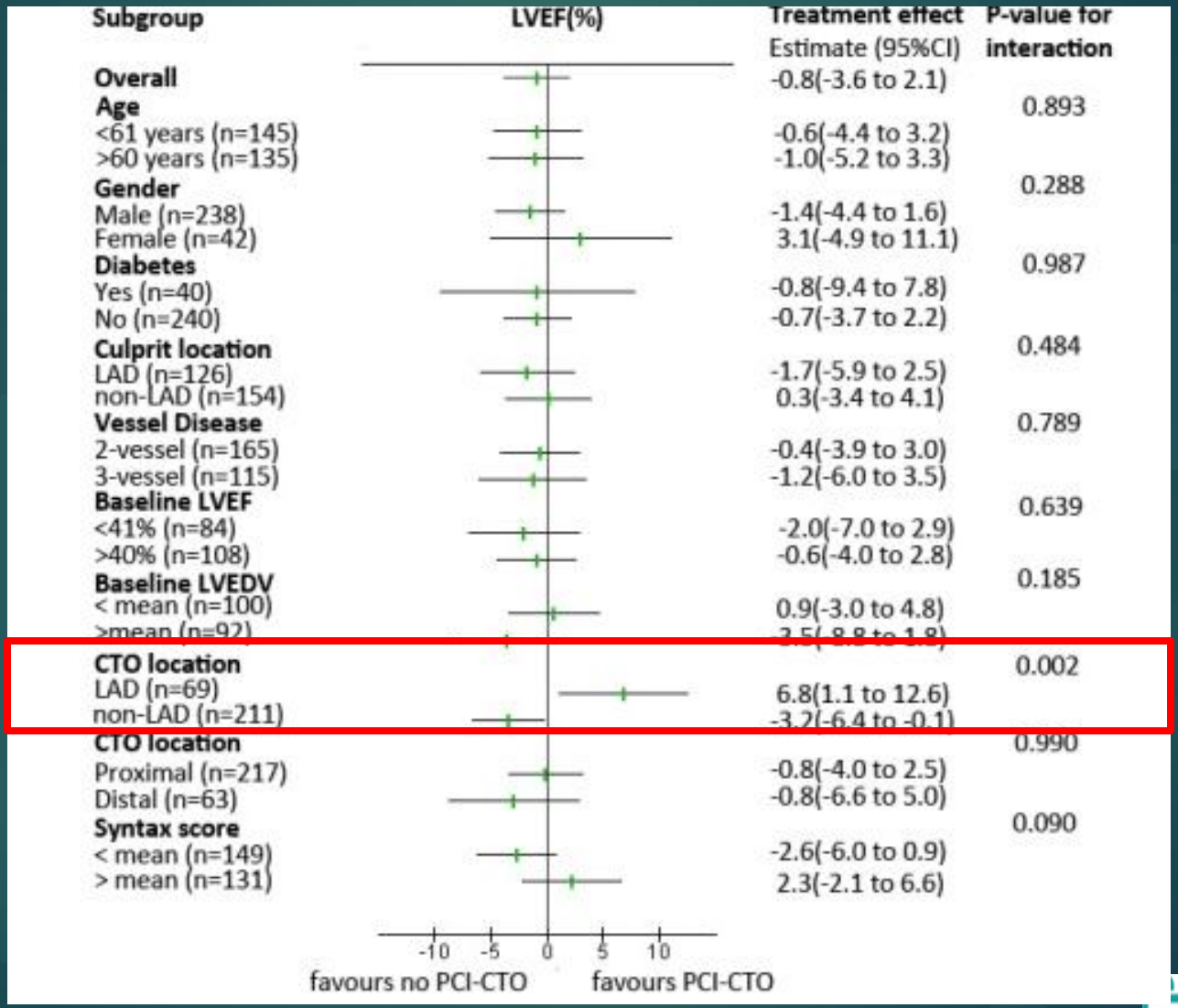
Results

	CTO PCI (n=148)	No CTO PCI (n=154)
Multiple CTOs	13 (9%)	22 (14%)
MI SYNTAX Score I	29±8	29±10
Total J-CTO Score	2±1	2±1
Multiple CTO arteries treated	6 (4%)	
Technique CTO procedure *Antegrade only* *Retrograde* *Crossboss/Stingray*	 124 (84%) 23 (16%) 5 (3%)	
PCI successful, self-reported	117 (80%)	

Primary Endpoint

	CTO PCI (n=148)	No CTO PCI (n=154)	Difference (95% CI)	p
LVEF (%)	44.1±12.2	44.8±11.9	-0.8 (-3.6to2.1)	0.597
LVEDV (mL)	215.6±62.5	121.8±60.3	2.8 (-11.6to17.2)	0.703

LVEF – Subgroup analyses



Results

	CTO PCI (n=148)	No CTO PCI (n=154)	p
Cardiac death	4 (2.7)	0 (0.0)	0.056
Myocardial infarction *Peri-procedural* *Spontaneous/Recurrent*	5 (3.4) 4 (2.7) 2 (1.4)	3 (1.9) 1 (0.6) 2 (1.3)	0.494 0.204 >0.999
CABG	0 (0.0)	1 (0.6)	>0.999
MACE	8 (5.4)	4 (2.6)	0.212

Conclusions

- CTO-PCI within one week after primary PCI is feasible and safe.
- Early CTO-PCI
  - not associated with higher LVFE at 4M
  - not associated with higher LVEDV at 4M
- In the subgroup analysis CTO-PCI of the LAD
  - associated with significantly higher LVEF at 4M

Radial versus femoral access in patients with acute coronary syndromes undergoing invasive management: a randomised multicentre trial

*Marco Valgimigli, Andrea Gagnor, Paolo Calabró, Enrico Frigoli, Sergio Leonardi, Tiziana Zaro, Paolo Rubartelli, Carlo Briguori, Giuseppe Andò, Alessandra Repetto, Ugo Limbruno, Bernardo Cortese, Paolo Sganzerla, Alessandro Lupi, Mario Galli, Salvatore Colangelo, Salvatore Ierna, Arturo Ausiello, Patrizia Presbitero, Gennaro Sardella, Ferdinando Varbella, Giovanni Esposito, Andrea Santarelli, Simone Tresoldi, Marco Nazzaro, Antonio Zingarelli, Nicoletta de Cesare, Stefano Rigattieri, Paolo Tosi, Cataldo Palmieri, Salvatore Brugaletta, Sunil V Rao, Dik Heg, Martina Rothenbühler, Pascal Vranckx, Peter Jüni, for the MATRIX Investigators**

Marco Valgimigli et al. Lancet 2015; 385: 2465–76

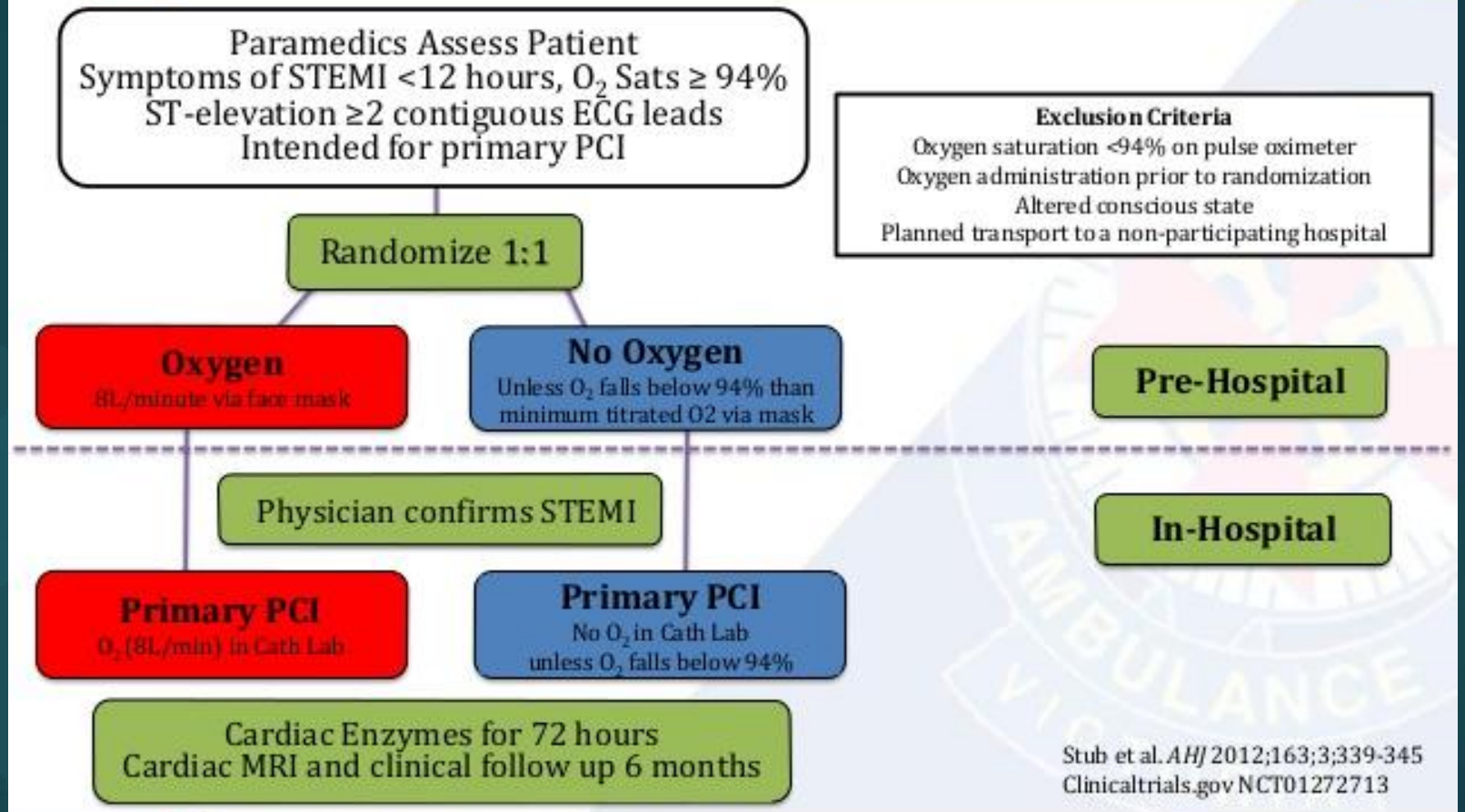
Resuscitation Science

Air Versus Oxygen in ST-Segment–Elevation Myocardial Infarction

Dion Stub, MBBS, PhD; Karen Smith, BSc, PhD; Stephen Bernard, MBBS, MD; Ziad Nehme, BEmergHlth(Pmedic); Michael Stephenson, RN, BHlthSc, Grad Dip (MICA); Janet E. Bray, RN, PhD; Peter Cameron, MBBS, MD; Bill Barger, MACAP; Andris H. Ellims, MBBS, PhD; Andrew J. Taylor, MBBS, PhD; Ian T. Meredith, BSc, MBBS, PhD; David M. Kaye, MBBS, PhD; on behalf of the AVOID Investigators*

Dion Stub et al. Circulation 2015;131:2143-2150

Trial Design



Measures of Infarct Size in Patients With Confirmed STEMI

End Point	Oxygen Arm (n=218)	No Oxygen Arm (n=223)	Ratio of means (Oxygen/No Oxygen)	*P* Value
cTnI				
Sample size, n	200	205		
Median peak (IQR), μg/L	65.7 (30.1–145.1)	62.1 (19.2–144.0)		
Geometric mean peak (95% CI), μg/L	57.4 (48.0–68.6)	48.0 (39.6–58.1)	1.20 (0.92–1.55)	0.18
Median AUC_{72} (IQR), μg/L	2336.4 (965.6–5043.1)	1995.5 (765.7–4426.0)		
Geometric mean AUC_{72} (95% CI), μg/L	2000.4 (1692.8–2363.9)	1647.9 (1380.1–1967.6)	1.21 (0.95–1.55)	0.12
Creatine kinase, U/L				
Sample size, n	217	222		
Median peak (IQR), U/L	2073 (1065–3753)	1727 (737–3598)		
Geometric mean peak (95% CI), U/L	1948 (1721–2205)	1543 (1341–1776)	1.26 (1.05–1.52)	0.01
Median AUC_{72} (IQR), U/L	64 620 (35 751–107 066)	51 757 (29–141–10 6029)		
Geometric mean AUC_{72} (95% CI), U/L	60 395 (54 185–67 316)	50 726 (44 861–57 358)	1.19 (1.01–1.40)	0.04
Infarct size on CMR*				
Sample size, n	61	66		
Median (IQR), g	20.3 (9.6–29.6)	13.1 (5.2–23.6)		0.04
Geometric mean (95% CI), g	14.6 (11.3–18.8)	10.2 (7.7–13.4)	1.43 (0.99–2.07)	0.06
Median (IQR) proportion of LV mass, %	12.6 (6.7–19.2)	9.0 (4.1–16.3)		0.08
Geometric mean (95% CI) proportion of LV mass, g	10.0 (8.1–12.5)	7.3 (5.7–9.3)	1.38 (0.99–1.92)	0.06
ECG ST-segment resolution >70%, measured 1 d after hospital admission, n (%)	132 (62.0)	149 (69.6)		0.10

Adverse Clinical End Points in Patients With Confirmed STEMI

Clinical End Point	Oxygen Arm (n=218)	No Oxygen Arm (n=223)	*P* Value
At hospital discharge, n (%)			
Mortality, any cause	4 (1.8)	10 (4.5)	0.11
Cardiac cause	4 (1.8)	7 (3.1)	…
Massive hemorrhage	0	2 (0.8)	…
Sepsis	0	1 (0.4)	…
Recurrent myocardial infarction	12 (5.5)	2 (0.9)	0.006
Stroke or transient ischemic attack	3 (1.4)	1 (0.4)	0.30
Cardiogenic shock	20 (9.2)	20 (9.0)	0.94
Coronary artery bypass grafting	5 (2.3)	9 (4.0)	0.30
Major bleeding	9 (4.1)	6 (2.7)	0.41
Arrhythmia	88 (40.4)	70 (31.4)	0.05
At the 6-mo follow-up, n (%)*			
Mortality, any cause	8 (3.8)	13 (5.9)	0.32
Cardiac cause	6 (2.9)	9 (4.1)	…
Massive hemorrhage	0	2 (0.9)	…
Sepsis	0	1 (0.5)	…
Renal failure	1 (0.5)	0	…
Cancer	0	1 (0.5)	…
Recurrent myocardial infarction	16 (7.6)	8 (3.6)	0.07
Stroke or transient ischemic attack	5 (2.4)	3 (1.4)	0.43
Repeat revascularization	23 (11.0)	16 (7.2)	0.17
MACEs	46 (21.9)	34 (15.4)	0.08

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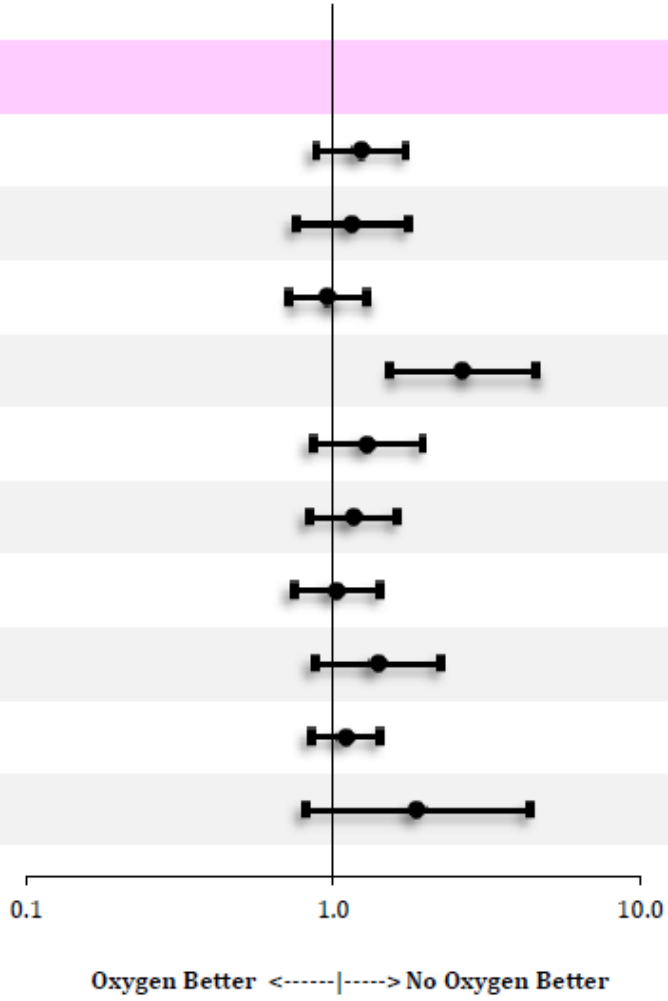
Figure S4: Ratio of geometric means (95% CI) for peak cTnI and peak CK release in patients with confirmed STEMI.

Characteristic	Sub-group	Ratio of means (Oxygen/No Oxygen)	P-value for interaction
Peak cTnI			
Age	< 65 years	1.24 (0.88 – 1.73)	0.81
	≥ 65 years	1.16 (0.76 – 1.76)	
Gender	Male	0.96 (0.72 – 1.29)	0.001
	Female	2.64 (1.52 – 4.57)	
Culprit Artery	LAD	1.30 (0.86 – 1.96)	0.69
	Non-LAD	1.17 (0.84 – 1.63)	
Symptom-to-intervention time	≤ 180 mins	1.03 (0.75 – 1.42)	0.29
	> 180 mins	1.40 (0.87 – 2.26)	
Pre-intervention TIMI flow	0 or 1	1.10 (0.85 – 1.42)	0.22
	2 or 3	1.89 (0.82 – 4.38)	



Discussion

- High-flow oxygen has been shown to reduce epicardial coronary blood flow, to increase coronary vascular resistance, and to affect the microcirculation, leading to functional oxygen shunting.
- Our study was not powered for clinical end points.

Conclusion

- Instead, the AVOID trial identified a signal for increased myocardial injury during uncomplicated acute myocardial infarction with the routine use of supplemental oxygen.
- Oxygen should be treated like all other medical therapies, balancing efficacy and side-effect profile.

Myocardial Infarction

Prospective, Multicenter, Randomized, Controlled Pilot Trial of Peritoneal Hypothermia in Patients With ST-Segment–Elevation Myocardial Infarction

Graham Nichol, MD, MPH; Warren Strickland, MD; David Shavelle, MD; Akiko Maehara, MD; Ori Ben-Yehuda, MD; Philippe Genereux, MD; Ovidiu Dressler, MD; Rupa Parvataneni, MS; Melissa Nichols, MS; John McPherson, MD; Gérald Barbeau, MD; Abhay Laddu, MD; Jo Ann Elrod, PhD; Griffeth W. Tully, MD; Russell Ivanhoe, MD; Gregg W. Stone, MD; for the VELOCITY Investigators

Graham Nichol et al. Circ Cardiovasc Interv 2015;8:e001965

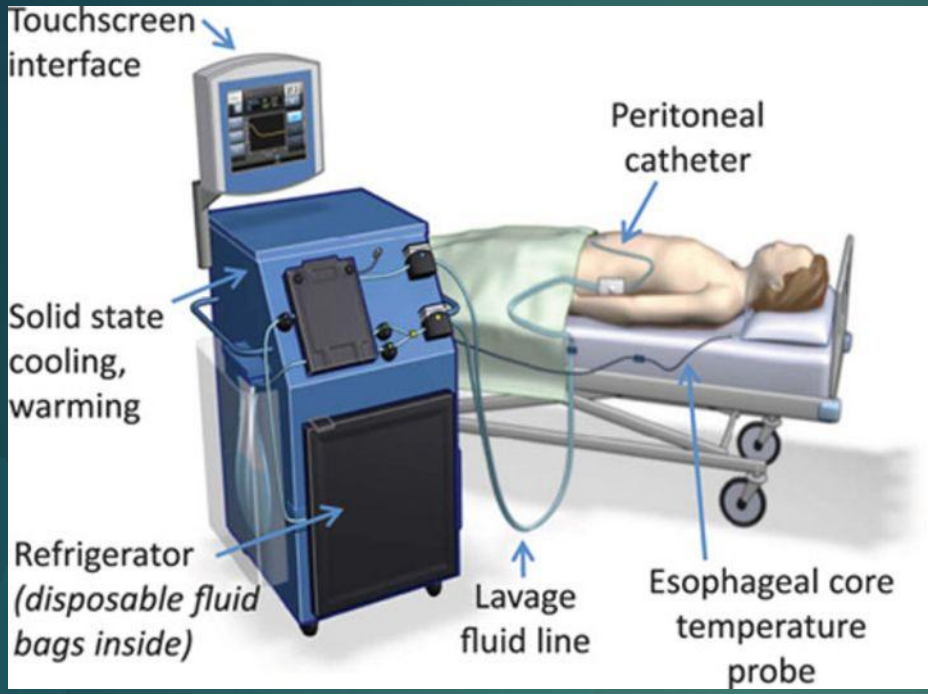
Introduction

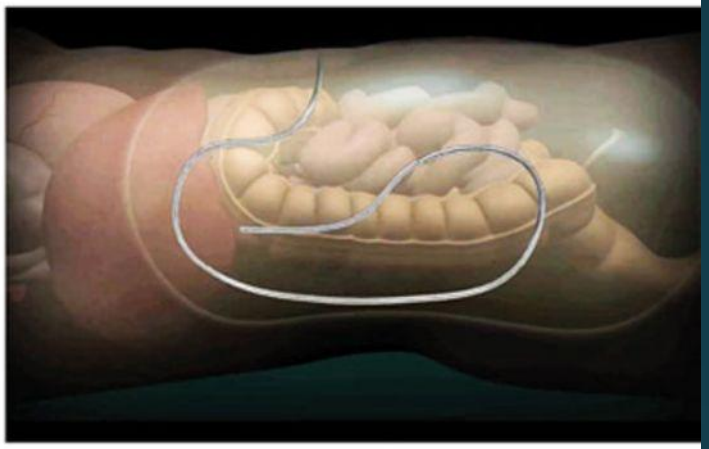
- Induction of mild hypothermia (<35°C) before reperfusion has been shown to reduce infarct size in animal models of STEMI, as well as in small randomized trials and subgroup analyses of larger randomized trials in Humans.
- But, still not fast enough to ensure adequate cooling before pPCI.

Procedure

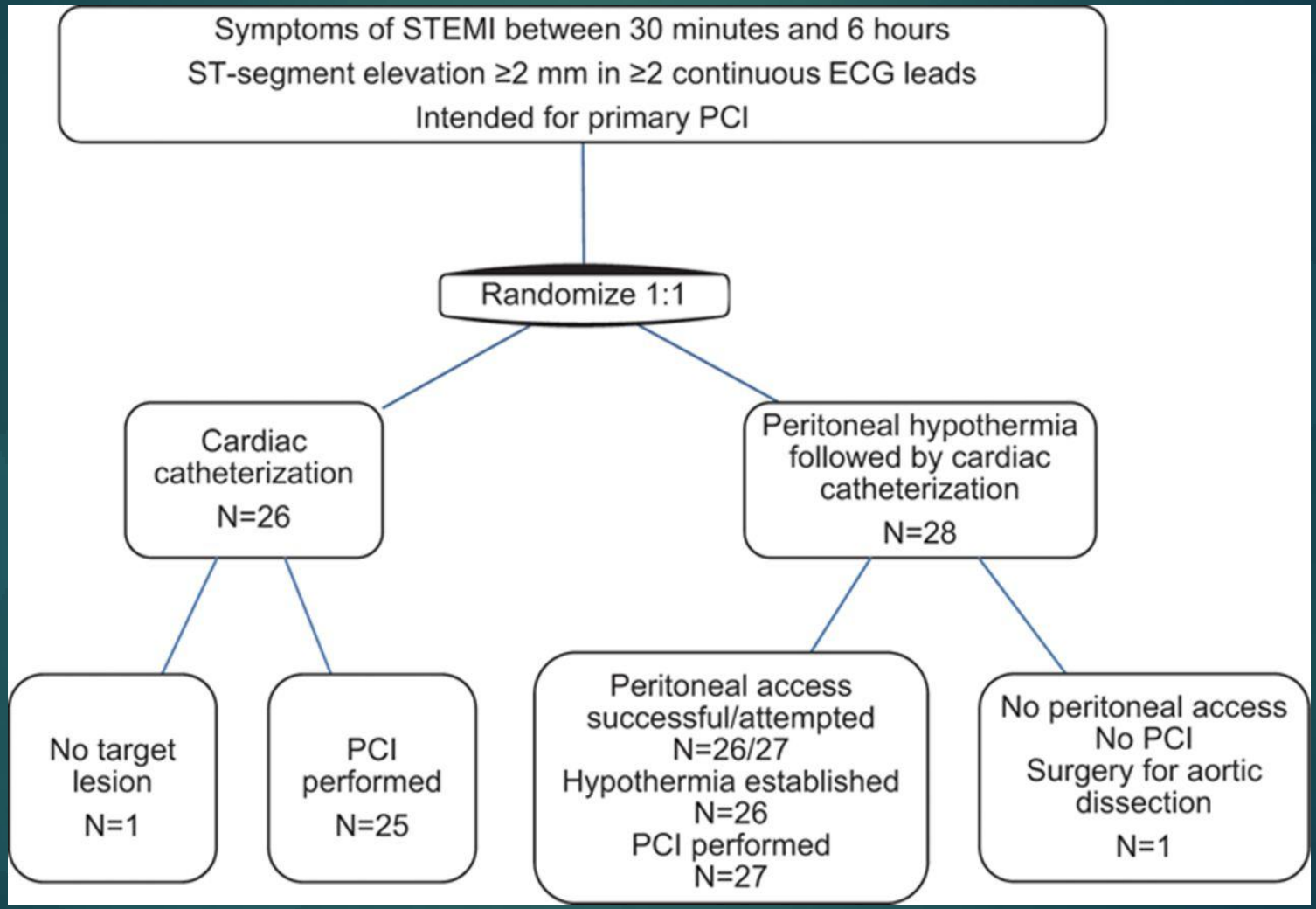
- In the intervention group, hypothermia to ≤34.9°C was induced before PCI by lavaging the peritoneal cavity with temperature-controlled lactated Ringer's solution using the Velomedix Automated Peritoneal Lavage System (Velomedix Inc, Menlo Park, CA), consisting of a peritoneal lavage kit and controller console (Figure 1).

The peritoneal hypothermia system





Patient flow diagram



Temperature and Time Measures

	Control (N=26)	Hypothermia (N=28)	*P* Value
Temperature measures, °C*			
Emergency room arrival	36.4 [36.1, 36.7]	36.5 [36.3, 36.9]	0.17
At time of first balloon inflation	36.2 [35.9, 36.7]	34.7 [34.0, 34.9]	<0.0001
Minimum temperature (PCI patients, n=27)	-	34.0 [33.2, 34.8]	-
<35°C		25 (92.6%)	
<34°C		12 (44.4%)	
<33°C		6 (22.2%)	
<32°C		1 (3.7%)	
3 h post hospital arrival	36.6 [36.5, 36.8]	34.7 [33.4, 35.7]	<0.0001
6 h post hospital arrival	36.8 [36.6, 37.1]	36.2 [36.0, 36.4]	<0.0001
12 h post hospital arrival	36.8 [36.6, 37.0]	36.6 [36.4, 36.9]	0.12
Time intervals (minutes)			
Symptom onset-to-hospital arrival	118 [52, 164]	102 [80, 165]	0.72
Hospital arrival-to-catheterization laboratory	19 [1, 29]	12 [1, 40]	0.51
Catheterization laboratory-to-arterial access	13 [11, 17]	27 [17, 31]	<0.0001
Door-to-balloon	47 [37, 55]	62 [51, 81]	0.007
Symptom onset-to-balloon	167 [104, 217]	172.5 [152, 247]	0.17
PCI procedure duration	33 [25, 48]	32 [24, 58]	0.56

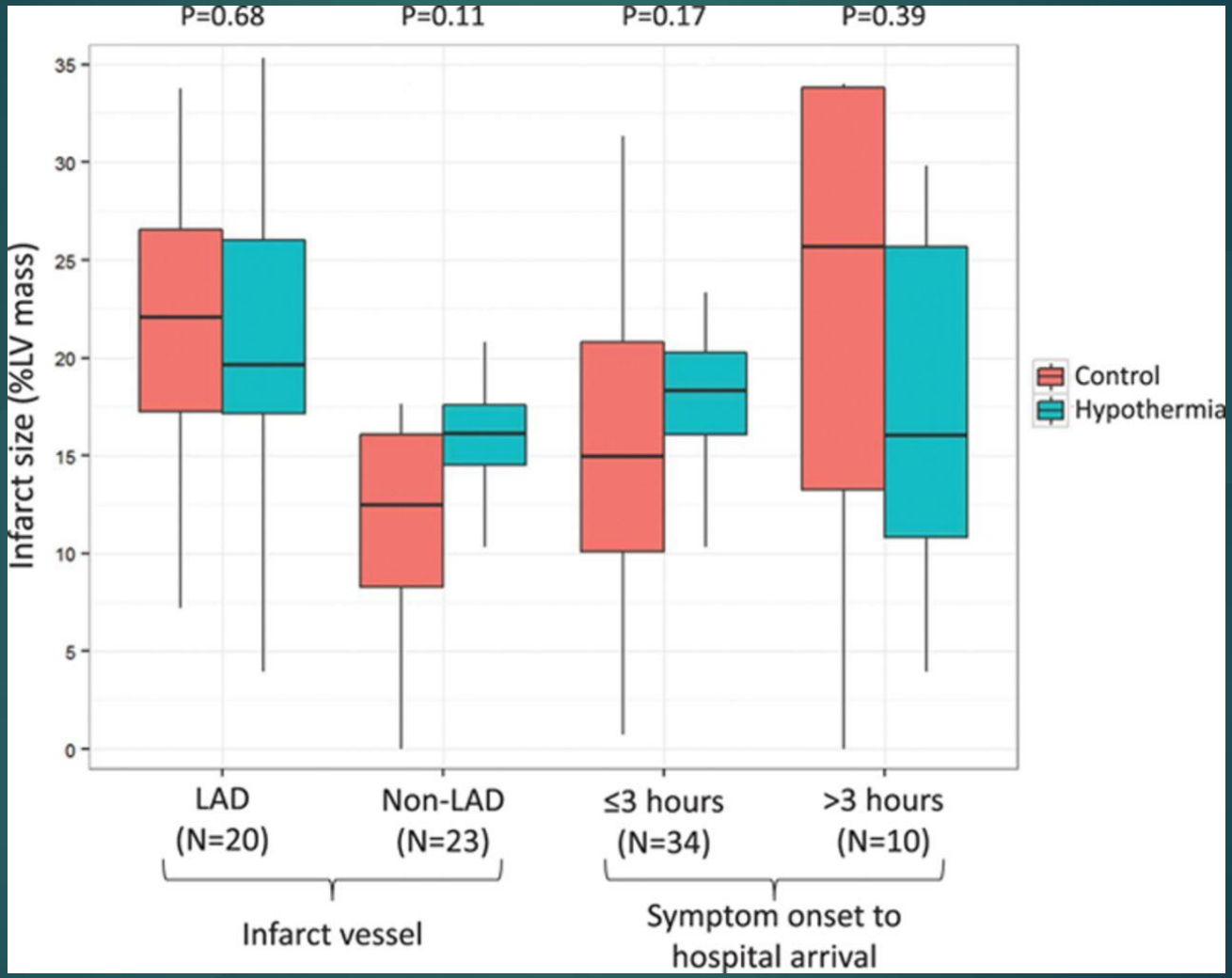
Clinical Event Rates Within 30 Days

	Control (N=26)	Hypothermia (N=28)	*P* Value
Primary composite safety end point	0% (0)	21.4% (6)	0.01
Cardiac death	0% (0)	3.6% (1)	0.34
Noncardiac death	0% (0)	0% (0)	…
Reinfarction	0% (0)	3.6% (1)	0.34
Ischemia-driven target vessel revascularization	0% (0)	11.0% (3)	0.09
Major bleeding	0% (0)	3.6% (1)	0.34
Ventricular tachycardia or fibrillation	0% (0)	3.6% (1)	0.34
Sepsis	0% (0)	3.6% (1)	0.34
Pneumonia	0% (0)	0% (0)	…
Renal failure	0% (0)	0% (0)	…
Peritonitis	0% (0)	0% (0)	…
Major adverse cardiac events	0% (0)	14.3% (4)	0.047
Stent thrombosis	0% (0)	11.0% (3)	0.09
Acute (≤24 h)	0% (0)	7.1% (2)	0.17
Subacute (1–30 days)	0% (0)	3.6% (1)	0.34
Definite	0% (0)	11.0% (3)	0.09
Probable	0% (0)	0% (0)	…

Results From Cardiac MRI

	Day 3–5 Study			Day 23–37 Study		
	Control (N=20)	Hypothermia (N=26)	*P* Value	Control (N=18)	Hypothermia (N=24)	*P* Value
Time from index procedure, days	4 (3, 4)	4 (3, 5)	0.53	32 (28, 33)	32 (29, 37)	0.39
LV myocardial mass, g	125.5 (109.5, 135,5)	123 (107, 142)	0.80	114 (102, 131)	110.5 (98, 127)	0.76
Area at risk, g	35.1 (20.4, 50.5)	34.2 (26, 51.6)	0.56	…	…	…
Area at risk (% total LV mass)	26.8 (16.7, 40.6)	26.1 (22.7, 34.4)	0.69	…	…	…
Infarct mass, g	20.8 (10.9, 27.6)	22.2 (15.6, 30.1)	0.44	12.0 (6.0, 17.4)	13.7 (10.6, 18.1)	0.036
Infarct mass/area at risk, %	55.8 (43.8, 67.2)	67.3 (48.9, 73.3)	0.36	…	…	…
Myocardial salvage, %	44.2 (32.8, 56.2)	32.7 (26.7, 51.1)	0.36	…	…	…
Infarct size (% total LV mass)*	16.1 (10.0, 22.2)	17.2 (15.1, 20.6)	0.54	11.8 (6.9, 13.2)	12.5 (8.6, 14.5)	0.43
Microvascular obstruction, g	0 (0, 0.2)	0 (0, 0.7)	0.57	…	…	…
Microvascular obstruction (% total LV mass)	0 (0, 0.2)	0 (0, 0.5)	0.64	…	…	…
Left ventricular end-diastolic volume, mL	161 (137.5, 172)	159 (125, 191)	0.80	157 (139, 183)	152 (126, 175)	0.65
Left ventricular end-systolic volume, mL	83.3 (66.8, 102)	81.9 (71, 119)	0.63	78.3 (63.2, 90.5)	74.9 (59.4, 96.3)	0.50
Left ventricular stroke volume, mL	75.2 (61.4, 81.5)	75.4 (61.1, 84)	0.78	77.1 (67.5, 85.6)	80.8 (66.3, 89.0)	0.87
Left ventricular ejection fraction, %	46.3 (42.6, 50.6)	43.3 (37.4, 52)	0.37	48.4 (44.1, 55.1)	50.6 (43.7, 55.4)	0.89
Total abnormal wall motion score	8 (4, 11.5)	8 (6, 10)	0.52	3.5 (3, 9)	5.5 (3, 7.5)	0.46

Subgroup analysis for the primary efficacy end point



P values for interaction =0.35 and 0.25, respectively

Discussion

- It is possible that the prolonged door-to-balloon time in the hypothermia group may have attenuated the effect of hypothermia on infarct size.
- Stent thrombosis
  - Hypothermia increases platelet activation.
  - may attenuate the efficacy of ADP antagonists.
  - may delay gastric absorption and reduce the bioavailability of oral antiplatelet agents.

Conclusion

- Peritoneal hypothermia was associated with an increased rate of adverse events (including stent thrombosis) without reducing infarct size.

Coronary Interventions

Mesh-Covered Embolic Protection Stent Implantation in ST-Segment–Elevation Myocardial Infarction

Final 1-Year Clinical and Angiographic Results From the MGUARD for Acute ST Elevation Reperfusion Trial

Dariusz Dudek, MD, PhD; Artur Dziewierz, MD, PhD; Sorin J. Brener, MD; Alexandre Abizaid, MD, PhD; Béla Merkely, MD, PhD; Ricardo A. Costa, MD, PhD; Eli Bar, BSc; Tomasz Rakowski, MD, PhD; Ran Kornowski, MD; Ovidiu Dressler, MD; Andrea Abizaid, MD; Sigmund Silber, MD, PhD; Gregg W. Stone, MD

Dariusz Dudek et al. Circ Cardiovasc Interv 2015;8:e001484

European Heart Journal Advance Access published September 23, 2015

European Heart Journal
doi:10.1093/eurheartj/ehv500

FASTTRACK
ESC Hot Line

Acute coronary syndromes

Everolimus-eluting bioresorbable stent vs. durable polymer everolimus-eluting metallic stent in patients with ST-segment elevation myocardial infarction: results of the randomized ABSORB ST-segment elevation myocardial infarction—TROFI II trial

The INNOVATION Trial

Cheol Woong Yu, et al., TCT 2015

KSC 2015

인제대학교 해운대백병원
INJE UNIVERSITY HAEUNDAE PAIK HOSPITAL

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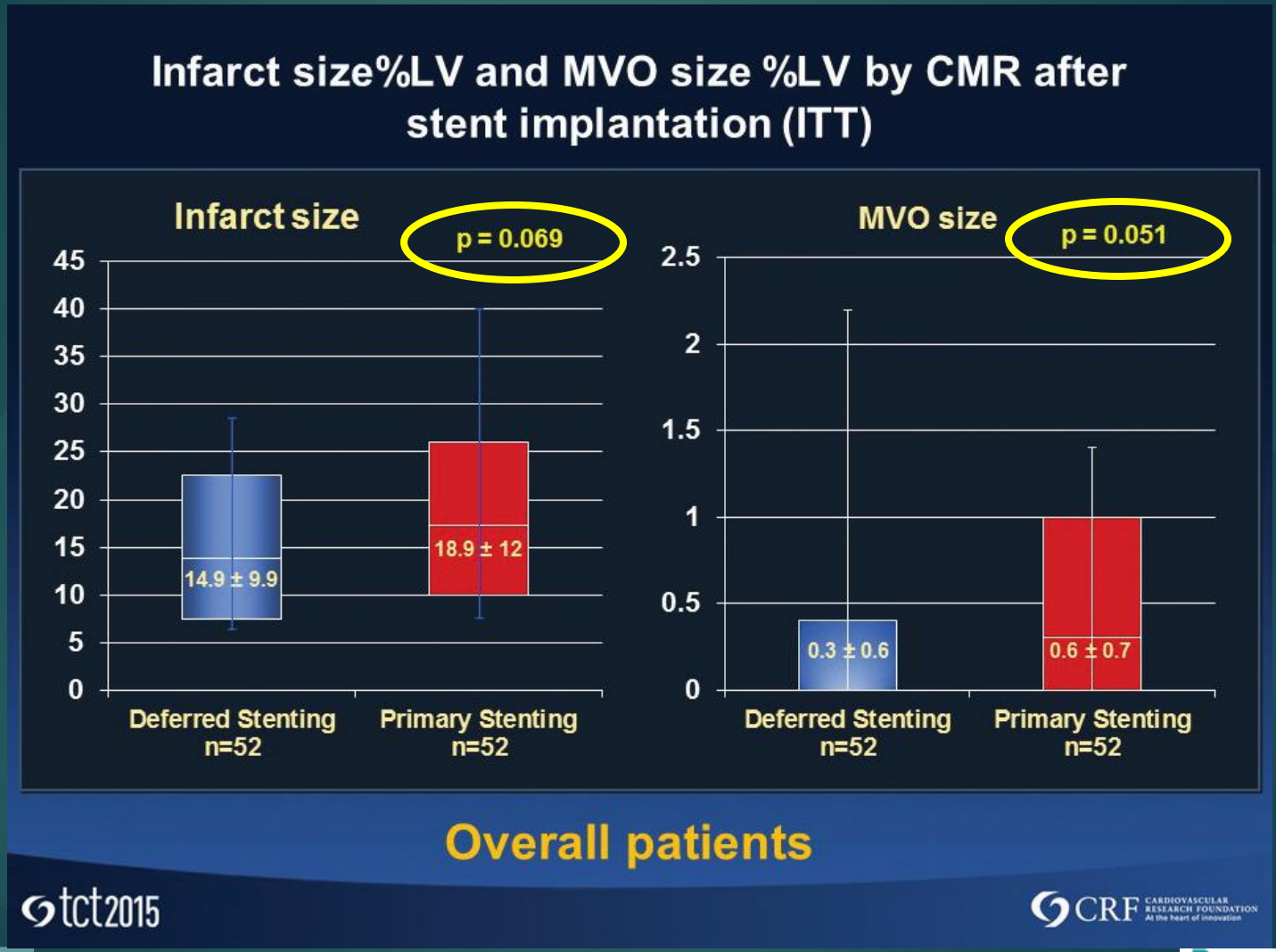
CLINICAL RESEARCH **Interventional Cardiology**

A Randomized Trial of Deferred Stenting Versus Immediate Stenting to Prevent No- or Slow-Reflow in Acute ST-Segment Elevation Myocardial Infarction (DEFER-STEMI)

Methods

- STEMI patients presenting at two centers in Korea within 12 hours of symptom onset.
- After achieving TIMI 3 flow, patients were randomized to receive either immediate (n = 52) or deferred stenting with intent to stent 3 to 7 days later (n = 52).
- For the primary endpoint of infarct size as percentage of left ventricular volume at 30 to 35 days after primary reperfusion as assessed by cardiac MRI.

Results



Results

- Differences between groups were more pronounced among patients with anterior wall MI for all parameters, favoring the deferred strategy (P = .025 for infarct size; P = .013 for microvascular obstruction size).
- Mean peak CK-MB measurements were smaller in the deferred vs. the immediate stenting group (199 vs. 260; P = .039), and more deferred than immediate stenting patients reached myocardial brush grade 3 (39 vs. 28; P = .057) and TIMI myocardial perfusion grade 3 (28 vs. 18; P = .085).

Results

- Aggravation of residual stenosis and dissection over time in the deferred stenting group was not significant between the beginning of the second procedure and the first procedure.
- No urgent PCI was required in the deferred stenting group.

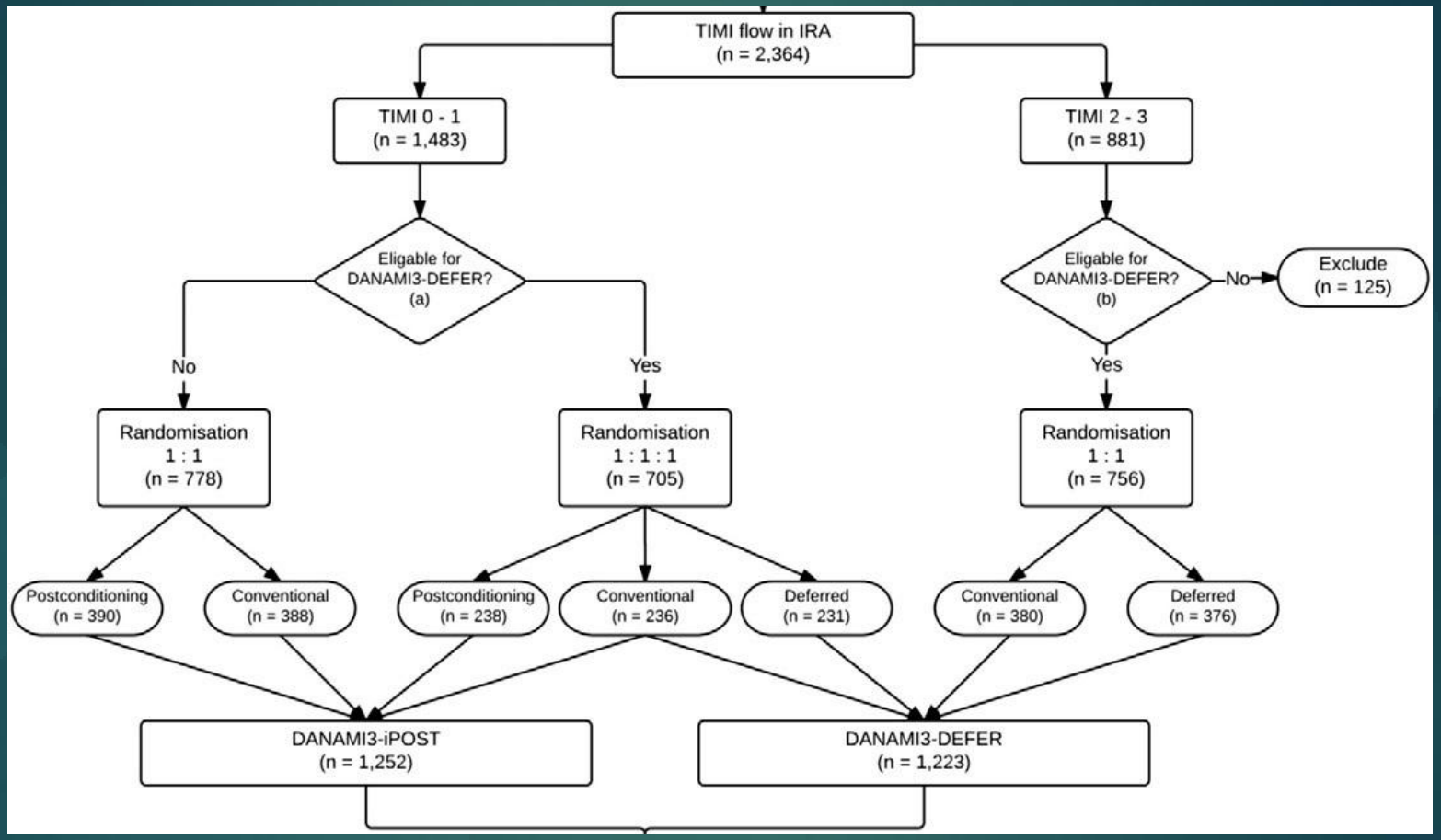
Discussion

- The small sample size meant the study was not powered to demonstrate efficacy of deferred stenting.
- Furthermore, six patients originally assigned to deferred stenting crossed over to the immediate procedure group, which may have contributed to the absence of urgent revascularization.

Conclusion

- Deferred stenting could be performed without additional risk of adverse events with meticulous monitoring during the initial procedure, compared with immediate stenting.

Design of the DANAMI 3 trial program



Dan Eik Høfsten, et al., Am Heart J 2015;169:613-21

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KSC 2015

인제대학교 해운대백병원
INJE UNIVERSITY HAEUNDAE PAIK HOSPITAL