Joint meeting of Coronary Revascularization 2015 심혈관중재시술 국제학술회의 December 11-12, 2015 Haeundae Grand Hotel, Busan, Korea

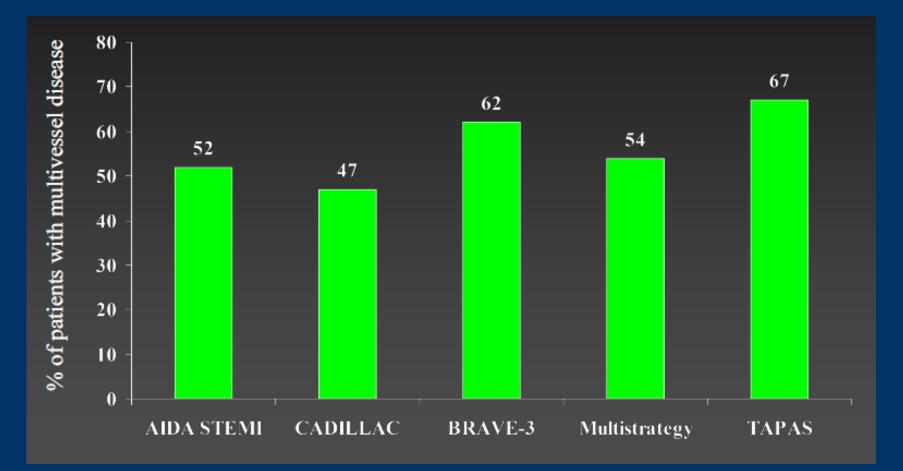
Impact of Multivessel Revascularization on Health Status Outcomes in ST-segment Elevation Myocardial Infarction Patients

2015

Jae-Sik Jang, MD, PhD Division of Cardiology, Inje University Busan Paik Hospital

Incidence of Multivessel CAD

STEMI without Shock

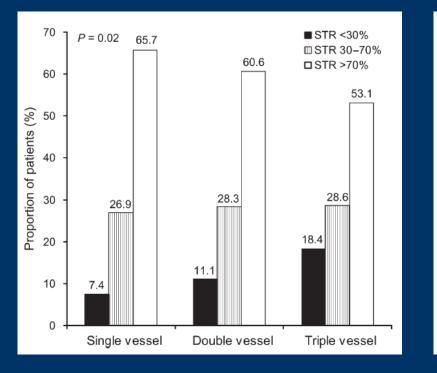


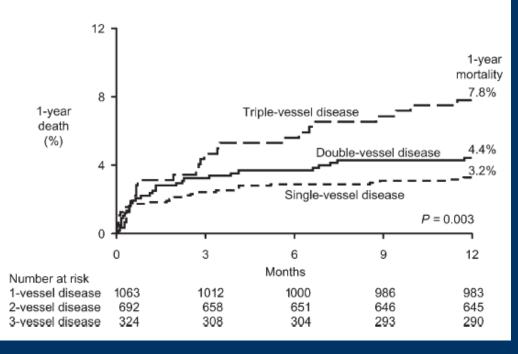
CADILAC trial

2,082 non-shock STEMI <12 h

ST-Resolution

1-Year Mortality

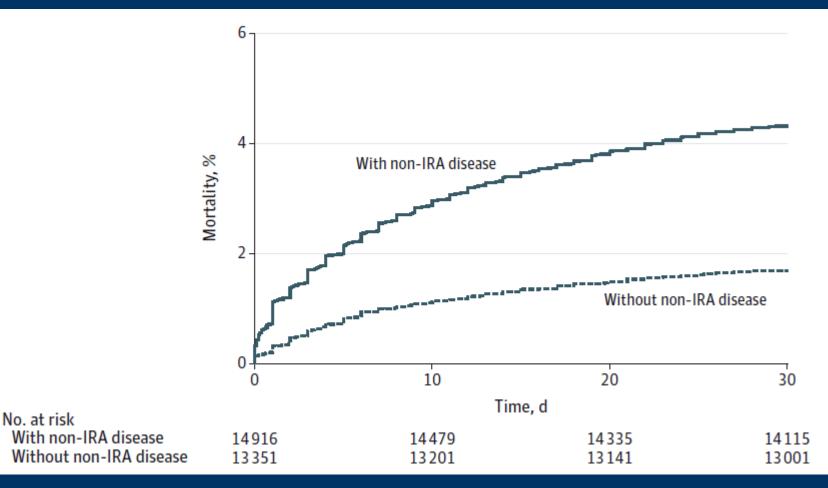




Sorajja et al. Eur Heart J 2007;28:1709

Non-Infarct-Related CAD in STEMI Pts

Pooled Analysis of 28,282 Pts from 8 RCTs 30-day Mortality: With vs. Without *non-IRA disease*



Park DW, et al. JAMA. 2014;312(19):2019-2027

2014 ESC/EACTS Guidelines on myocardial revascularization

The Task Force on Myocardial Revascularization of the European Society of Cardiology (ESC) and the European Association for Cardio-Thoracic Surgery (EACTS)

Class IIa: (Benefit > Harm)

- PCI should be limited to the culprit vessel with the exception of cardiogenic shock and persistent ischemia ater PCI of the supposed culprit lesion. (Level of Evidence: B)
- 2. Staged revascularization of non-culprit lesions should be considered in STEMI patients with multivessel disease in case of symptom or ischemia <u>within days</u> to weeks after primary PCI (Level of Evidence: B)

Class IIb: (Harm > Benefit)

1. Immediate revascularization of significant non-culprit lesions during the same procedure as primary PCI of the culprit vessel may be considered in <u>selected</u> <u>patients. (Level of Evidence: B)</u>

Eur Heart J 2014, EuroIntervention 2014 Ahead of Print

2013 ACCF/AHA Guldelines





2013 ACCF/AHA Guideline for the Management of ST-Elevation Myocardial Infarction: A Report of the American College of Cardiology Foundation/American Heart Association Task Force on Practice Guidelines

Class III: Harm

1. PCI should not be performed in a noninfarct artery at the time of primary PCI in patients with STEMI who are hemodynamically stable. (*Level of Evidence: B*)

Circulation. 2013;127:e362-e425

2015 ACC/AHA/SCAI Focused Update on Primary Percutaneous Coronary Intervention for Patients With ST-Elevation Myocardial Infarction: An Update of the 2011 ACCF/AHA/SCAI Guideline for Percutaneous Coronary Intervention and the 2013 ACCF/AHA Guideline for the Management of ST-Elevation Myocardial Infarction

Class IIb

PCI of a noninfarct artery may be considered in selected patients with STEMI and multivessel disease who are hemodynamically stable, either at the time of primary PCI or as a planned staged procedure. (Level of Evidence: B-R)

• Not endorsing *routine* MV PCI in all patients with STEMI and MVD

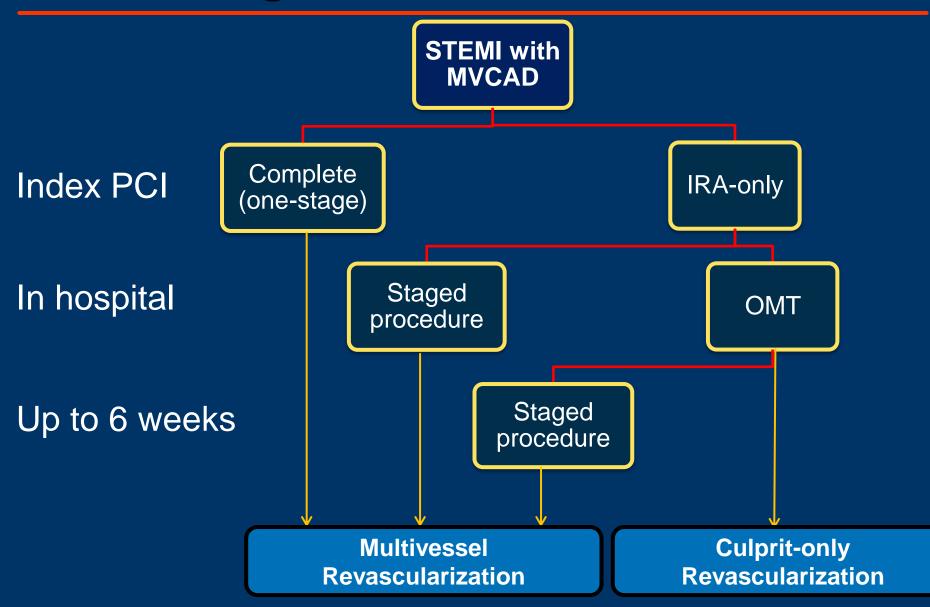
• Integrate clinical data, lesion severity/complexity, and risk of CIN.

Levine GN, et al. 2015 ACC/AHA/SCAI Focused Update on Primary PCI. JACC 2015

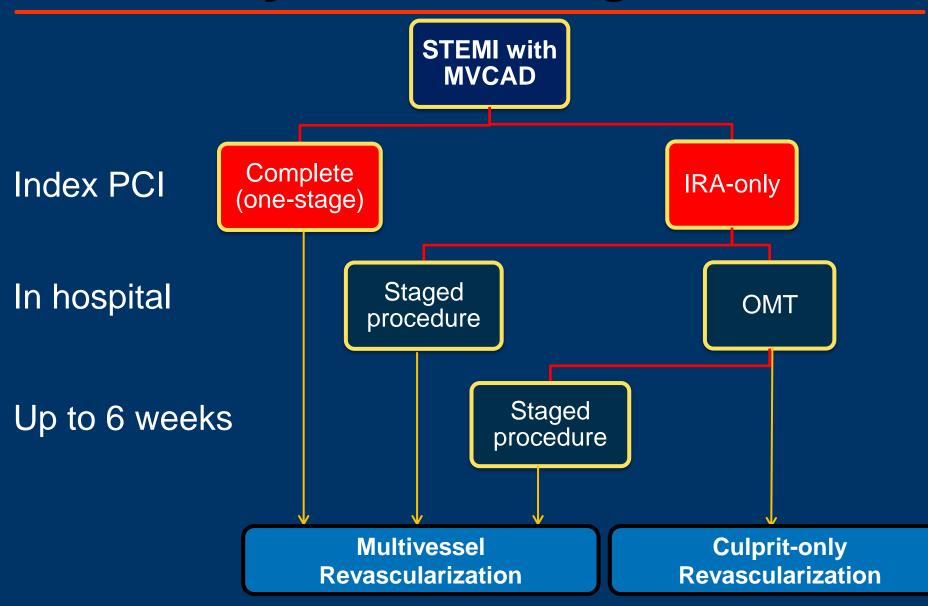
Strategies for STEMI Pts with MV CAD

Culprit Only	PCI to IRA only
One-stage	 PCI to IRA and other significant non-IRA at
Multivessel PCI	primary PCI
Staged PCI	 PCI to IRA and other significant non-IRA in
within 1 st stay	a later session during index hospital stay
Staged PCI	 PCI to IRA and other significant non-IRA
within 2 nd stay	during 2nd admission

Timing of Revascularization



IRA-only vs. One Stage MV PCI



Intervention of the non-culprit vessels during primary PCI

ADVANTAGES

- Reduction of total ischemic burden
 ; Better LVEF
- Treatment of all unstable plaque by treating nonculprit vessel
 - ; less future MACE
- Less future hospitalizations and procedures
 - ; cost saving

DISADVANTAGES

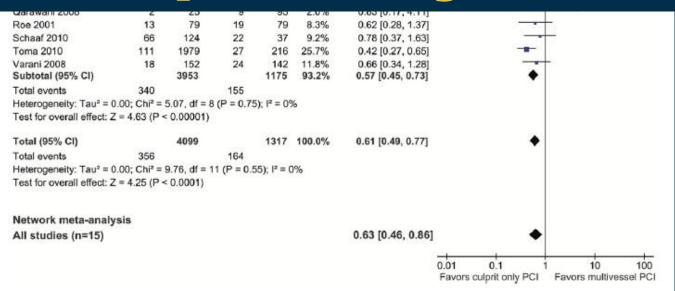
- Extension of infarcted m.
 ; acute complications (dissection, thrombosis)
- Lesion severity in non-IRA overestimated (vasoconstriction and endothelial dysfunction)
- Hemodynamic compromise
- Contrast load

Culprit only PCI vs. MV-PCI

Pairwise and Network Meta-Analysis



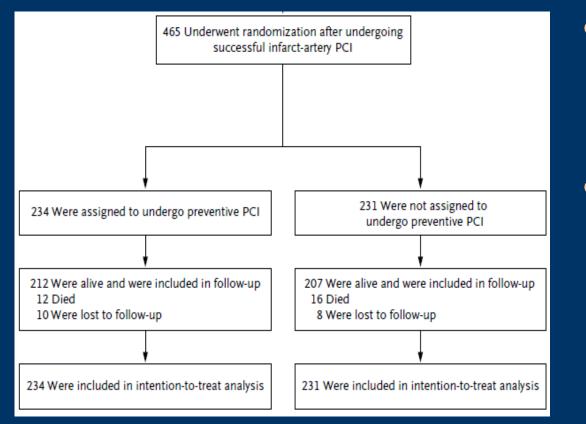
Long-term mortality favors Culprit Only PCI



Vlaar et al. J Am Coll Cardiol 2011;58:692-7

PRAMI: "Preventative" PCI of Non-culprit Lesions after Culprit Lesion Primary PCI in STEMI

465 non-shock STEMI pts with MVD at 5 UK sites



 Staged PCI in patients without angina was <u>discouraged</u>

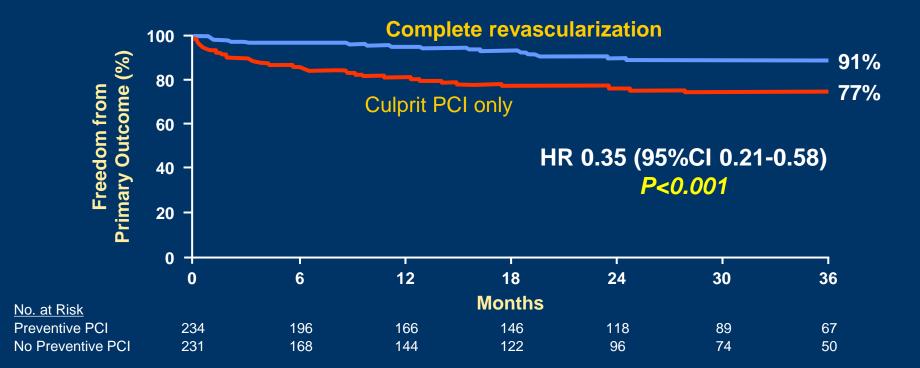
 Further PCI only in cases of refractory angina

Primary endpoint: Cardiac death, MI or refractory angina

Wald DS et al. NEJM 2013

PRAMI: "Preventative" PCI of Non-culprit Lesions after Culprit Lesion Primary PCI in STEMI

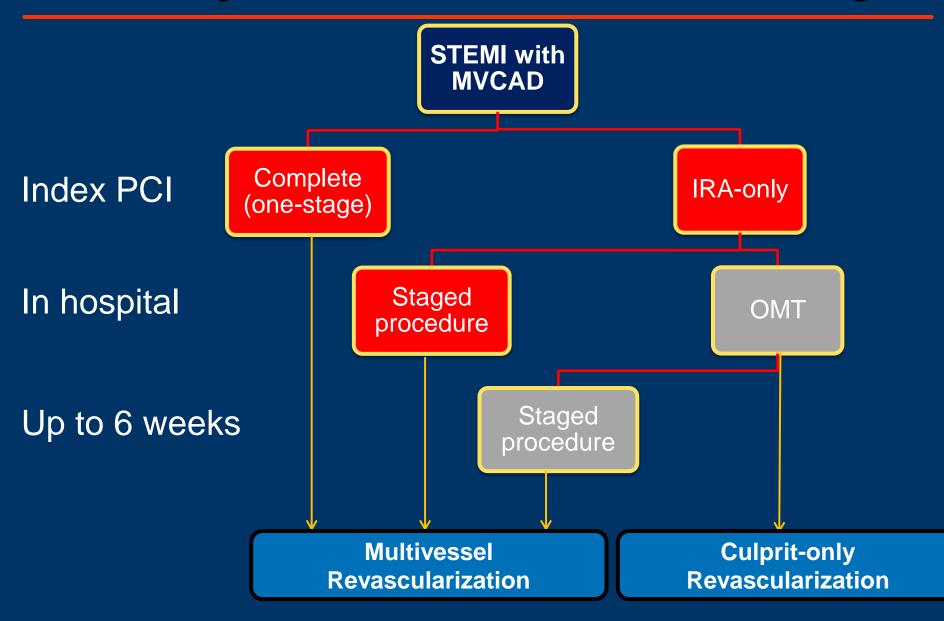
465 non-shock STEMI pts with MVD at 5 UK sites



600 pts planned; DSMB stopped trial early after 465 pts enrolled (2008-2013)

Wald DS et al. NEJM 2013

IRA-only vs. MV PCI before discharge



Should we intervene the non-culprit vessels as a Staged-PCI?

ADVANTAGES

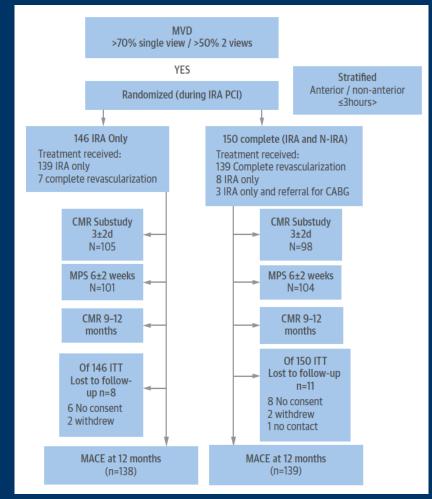
- Reduction of total ischemic burden ; Better LVEF
- Treatment of all unstable plaque by treating nonculprit vessel
 - ; less future MACE
- Increased safety in stabilized patients

DISADVANTAGES

- Increased cost by additional admission
- No proven benefit if patients are asymptomatic
- Expose patients to further complication of PCI
- Uncertain timing of 2nd PCI/admission

CvLPRIT: Complete vs. Lesion-Only Primary PCI trial

296 STEMI pts at 7 UK Centers



• CR Group

Treat IRA first
CR recommended at same setting
Staged procedure during the index admission

Gershlick et al. J Am Coll Cardiol2015;65:963-72

CvLPRIT: Complete vs. Lesion-Only Primary PCI trial

296 STEMI pts at 7 UK Centers Clinical Outcomes at 12 Months

Variable	IRA only	Complete	HR (95% CI)	P value
	(N=146)	Revascularisation (N=150)		
Time to First Event				
MACE N= (%)	31 (21.2)	15 (10.0)	0.45 (0.24, 0.84)	0.009
Components N=(%)				
All-cause mortality	6 (4.1)	2 (1.3)	0.32 (0.06, 1.60)	0.14
Recurrent MI	4 (2.7)	2 (1.3)	0.48 (0.09, 2.62)	0.39
Heart failure	9 (6.2)	4 (2.7)	0.43 (0.13, 1.39)	0.14
Repeat	12 (8.2)	7 (4.7)	0.55 (0.22, 1.39)	0.2
Revascularisation				

55% reduced hazards of MACE by complete revascularization

Gershlick et al. J Am Coll Cardiol2015;65:963–72

MV-PCI vs. Staged PCI Pairwise and Network Meta-Analysis

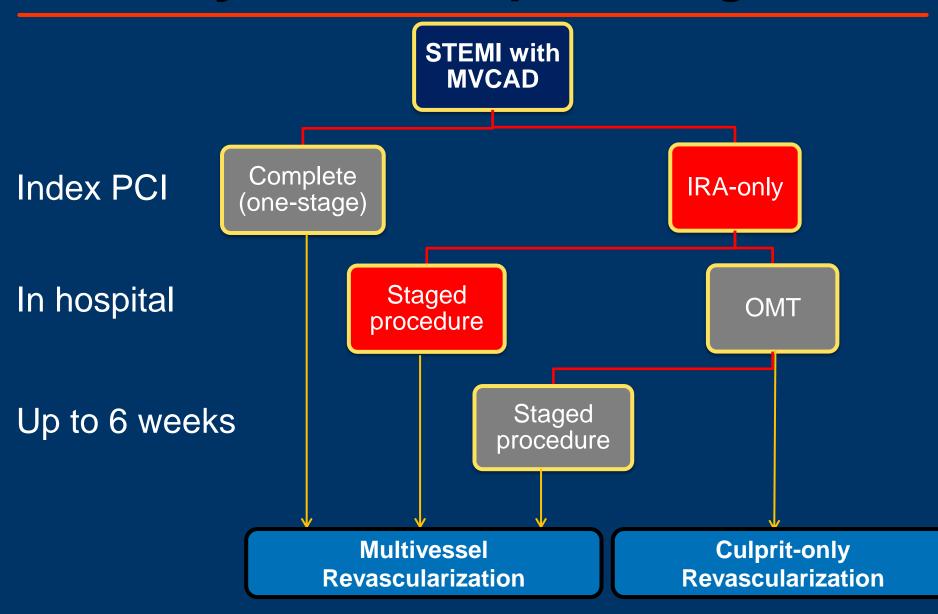
2	Multivess	el PCI	Staged	PCI		Odds Ratio	Odds Ratio
Study or Subgroup	Events	Total	Events	Total	Weight	IV, Random, 95% CI	IV, Random, 95% Cl
Prospective studies							
Ochala 2004	0	48	0	44		Not estimable	
Politi 2010	6	65	4	65	14.0%	1.55 [0.42, 5.78]	
Subtotal (95% CI)		113		109	14.0%	1.55 [0.42, 5.78]	
Total events	6		4				

Long-term mortality favors Staged PCI

Heterogeneity: Tau² = 0.00; Chi² = 2.19, df = 3 (P = 0.53); l² = 0% Test for overall effect: Z = 3.28 (P = 0.001) Total (95% CI) 2.28 [1.39, 3.72] 791 591 100.0% Total events 73 31 Heterogeneity: Tau² = 0.00; Chi² = 2.57, df = 4 (P = 0.63); l² = 0% Test for overall effect: Z = 3.29 (P = 0.001) Network meta-analysis All studies (n=15) 2.88 [1.73, 4.89] 0.01 0.1 10 100 Favors multivessel PCI Favors staged PCI

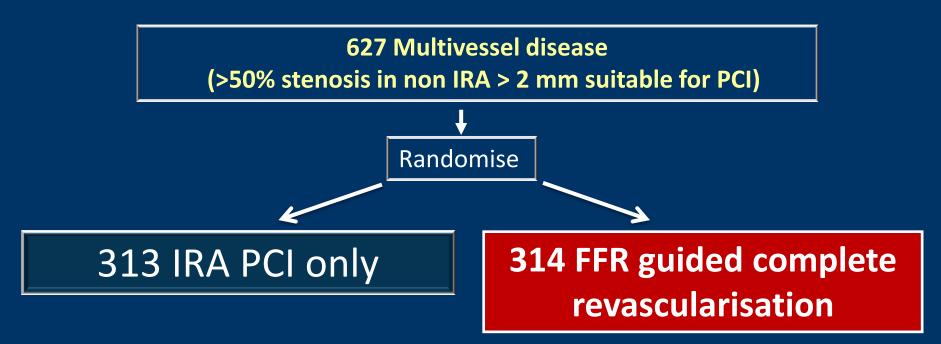
Vlaar et al. J Am Coll Cardiol 2011;58:692-7

IRA-only vs. In-hospital Staged PCI



DANAMI3-PRIMULTI

627 STEMI Pts with MVD from 2011 to 2014



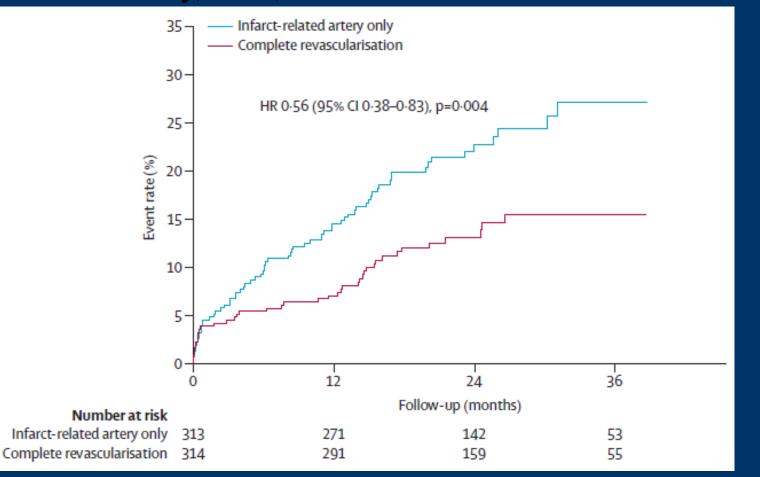
* Additional PCI procedures 2 days after the initial PCI before discharge

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

DANAMI3-PRIMULTI

627 STEMI Pts with MVD from 2011 to 2014

All-cause mortality, NFMI, and Ischemia-driven revascularization



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

Updated Meta-Analysis All-cause death

All-ca <u>Study</u> 1.2<u>.1</u>

> Corpu Varar Han e Rigat

Politi Hann Moha HORI Subto

Total Heter Test f 1.2.2 Roe e Poyer

Di Ma ljssel Corpu Chen Kong Qarav Khatt

Varar Cavel EUR APEX Hann Politi

Moha EHS-KAMI PRAM Caver Myole CVLP ICAS. Yang Subto Total Heter Testf 1.2.3 Corpu Ocha Varar Hann Politi Moha Subto Total Heter Test f

Test f

- Culprit only PCI < Staged</p>
- One-time < Culprit only PCI</p>
- One-time < Staged PCI</p>

Song YJ, Jang JS, et al. J Interven Cardiol 2015;28:1-13

ause mortality	experim	ental	cont	rol		Odds Ratio		Odds Ratio
ly or Subgroup	Events	Total	Events	Total	Weight	M-H, Random, 95% Cl	Year	M-H, Random, 95% Cl
1 Staged PCI vers	us Culprit	t only PC	3					
ous et al.	12	126	42	354	20.4%	0.78 [0.40, 1.54]	2004	
ni et al.	3	85	18	152	11.4%	0.27 [0.08, 0.95]	2008	
et al.	3	93	4	149	8.8%	1.21 [0.26, 5.52]	2008	
attieri et al.	1	64	7	46	5.2%	0.09 [0.01, 0.75]	2008	
i et al.	4	65	13	84	12.3%	0.36 [0.11, 1.16]	2010	
nan et al.	10	259	14	259	17.5%	0.70 [0.31, 1.61]	2010	
amad et al.	2	12	3	30	6.1%	1.80 [0.26, 12.41]	2011	
RIZONS-AMI	9	393	25	275	18.4%	0.23 [0.11, 0.51]	2011	
total (95% CI)		1097		1349	100.0%	0.48 [0.28, 0.82]		-
l events	44		126					
erogeneity: Tau* =				P = 0.08	; P = 45%	6		
for overall effect:	Z=2.67 (P = 0.00	8)					
2 Single Multivess	sel PCI ver	rsus Cul	lprit only	PCI				
et al.	19	79	13	79	4.5%	1.61 [0.73, 3.53]	2001	
en et al.	1	86	2	81	0.8%	0.46 [0.04, 5.23]	2003	
ario et al.	1	52	0	17	0.5%	1.02 [0.04, 26.19]		
elmuiden et al.	8	104	3	109	2.2%	2.94 [0.76, 11.42]		
ous et al.	5	26	42	354	3.3%	1.77 [0.63, 4.94]		<u>+</u>
n et al.	26	239	112	1145	6.9%	1.13 [0.72, 1.77]		- - -
a et al.	5	632	31	1350	3.7%	0.34 [0.13, 0.88]		
awani et al.	9	95	2	25	1.7%	1.20 [0.24, 5.96]	2008	
ttab et al.	2	25	3	45	1.3%	1.22 [0.19, 7.82]	2008	
nietal.	24	142	18	152	5.3%	1.51 [0.78, 2.93]		+
ender et al.	246	3134	1321	25802	8.9%	1.58 [1.37, 1.82]		-
OTRANSFER	11	70	57	707	5.1%	2.13 [1.06, 4.27]		
X-AMI	27	217	111	1984	6.9%	2.40 [1.53, 3.75]		
nan et al.	36	503	28	503	6.4%	1.31 [0.79, 2.18]		+
i et al.	6	65	13	84	3.3%	0.56 [0.20, 1.55]		
amad et al.	2	7	3	30	1.2%	3.60 [0.47, 27.35]		
-PCI	40	82	95	254	6.5%	1.59 [0.96, 2.63]		
IR	9	538	25	1106	4.6%	0.74 [0.34, 1.59]		
MI	12	234	16	231	4.6%	0.73 [0.34, 1.57]		-+-
ender et al. (2)	32	43	101	156	4.7%	1.58 [0.74, 3.39]		+
ette et al.	37	66	82	103	5.2%	0.33 [0.17, 0.65]		
PRIT	2	150	6	146	1.7%	0.32 [0.06, 1.59]		
3	17	54	24	220	5.0%	3.75 [1.84, 7.66]		→
a et al.	21	60	85	278	5.8%	1.22 [0.68, 2.20]		
total (95% CI)		6703		34961		1.26 [1.00, 1.59]	2011	•
l events	598		2193			• • •		
erogeneity: Tau ² =	0.15; Chi ^a	e = 59.69	, df = 23	(P < 0.0	001); I² =	61%		
for overall effect:	Z=1.92 (f	P = 0.05))					
3 Single Multivess	sel PCI ver	rsus Sta	iged PCI	_				
ous et al.	5	26	12	126	18.5%	2.26 [0.72, 7.09]	2004	
ala et al.	0	48	0	44		Not estimable		
ni et al.	24	142	3	85	15.9%	5.56 [1.62, 19.07]		
nan et al.	36	503	10	259	46.9%	1.92 [0.94, 3.93]		⊢ ■−
i et al.	6	65	4	65		1.55 [0.42, 5.78]		
amad et al.	2	7	2	12	4.8%	2.00 [0.21, 18.69]		
total (95% CI)		791			100.0%	2.28 [1.39, 3.72]		●
l events	73		31					
erogeneity: Tau² = for overall effect: :				= 0.62);	I ² = 0%			
								0.01 0.1 1 10 1
for subaroup diffe	erences: (Chi² = 17	.82. df=	2 (P = 0	0001). IP	= 88.8%	ŀ	avours experimental Favours control

100

Background

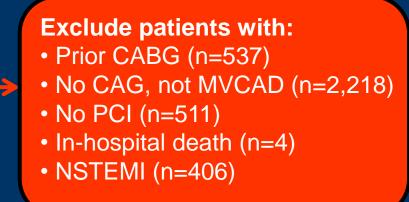
 Previous studies have focused upon mortality and no insights into the long-term health status of STEMI patients managed with culprit-only or complete revascularization have been reported.

Aims & Objectives

- To define the potential patient-centered benefits of complete revascularization
 - The patterns of treating non-infarct vessels
 - patient characteristics associated with multivessel revascularization
 - variation in practice across hospitals
 - independent association of multivessel revascularization with 1-year health-related QoL and mortality

Methods

TRIUMPH patients (All AMI patients, April 2005-December 2008), N = 4,340



Final Study Population 664, STEMI patients with multivessel CAD

QoL Outcomes

Seattle Angina Questionnaire (baseline/1-year);

- 19-item patient-reported health status instrument
- recall period of 4 weeks
- Angina Frequency (SAQ AF)
- Quality of Life (SAQ QoL)
- Physical Limitation
- Treatment Satisfaction

Clinical Outcomes

- All-cause mortality: phone follow-up and the Social Security death master index
- Myocardial infarction
- Repeat revascularization procedures: PCI or CABG
- Severe angina: having more than 3 episodes of angina per week as defined by a SAQ AF score of ≤40

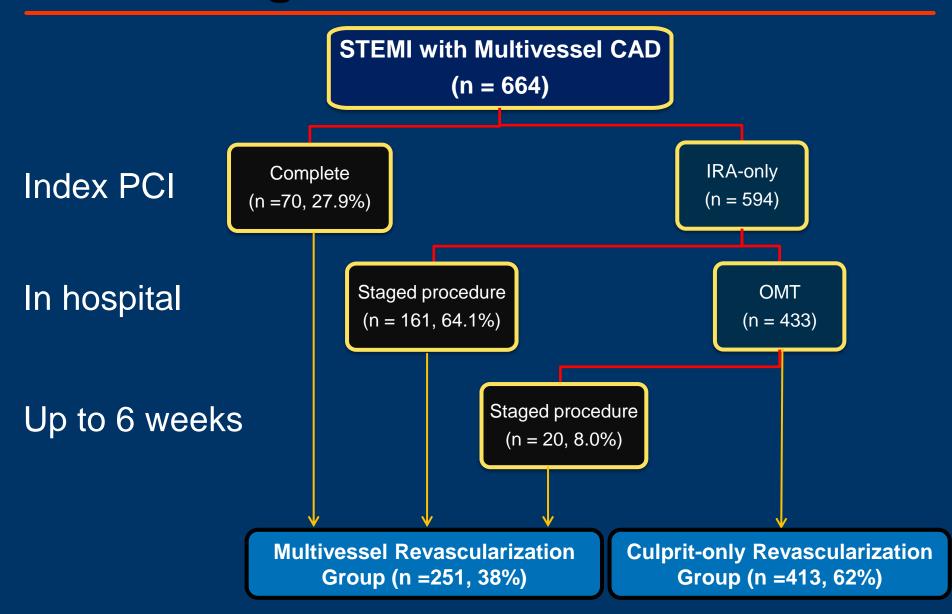
Statistical Analysis (1)

- Baseline clinical and demographic characteristics using t-test or Mann-Whitney U tests for continuous variables and chi-square or Fisher's exact test for categorical variables
- Multivariable, hierarchical (adjusting for site as a random effect) modified Poisson regression model to identify factors associated with multivessel revascularization
- Median rate ratio (MRR) to assess variation in the practice of multivessel revascularization across the study sites

Statistical Analysis (2)

- Hierarchical (adjusting for site as a random effect) multivariable linear regression models for each health status outcome (SAQ AF and SAQ QoL) to evaluate the association of multivessel revascularization with 1-year health status outcomes
- Kaplan-Meier survival analysis and the log-rank test to assess the associations of multivessel revascularization with 1-year mortality, myocardial infarction, and repeat revascularization
- Sensitivity analysis excluding patients undergoing CABG to determine whether our results were comparable in the PCI-only patients

Timing of Revascularization



Baseline Demographics

	Multivessel	Culprit-only	
	n = 251 (38%)	n = 413 (62%)	P-Value
Age	56.4 ± 10.0	58.7 ± 12.1	0.012
Caucasian	197 (79.4%)	299 (72.7%)	0.053
Female gender	62 (24.7%)	108 (26.2%)	0.678
Insurance: None/Self-Pay	58 (23.7%)	92 (22.9%)	0.830
Diabetes	59 (23.5%)	106 (25.7%)	0.532
Hypertension	144 (57.4%)	242 (58.6%)	0.756
Dyslipidemia	115 (45.8%)	190 (46.0%)	0.962
Prior PCI	29 (11.6%)	78 (18.9%)	0.012
Chronic heart failure	5 (2.0%)	8 (1.9%)	1.000
Peripheral vascular disease	5 (2.0%)	16 (3.9%)	0.179
Smoking	156 (62.2%)	252 (61.0%)	0.770
In-hospital heart failure	15 (6.0%)	15 (3.6%)	0.158
LV dysfunction (EF < 40%)	43 (18.4%)	79 (21.0%)	0.438
Peak troponin I/T (ng/dL): (Median)	23.8	13.7	< 0.001
Hemoglobin (g/dL): Initial (Median)	15.0	14.7	0.035
Systolic BP (mmHg): Initial (Median)	142.0	140.0	0.443

Baseline Demographics

	Multivessel	Culprit-only	D Volue
	n = 251 (38%)	n = 413 (62%)	P-Value
Number of diseased vessels	2.5 ± 0.7	2.4 ± 0.6	< 0.001
Number of vessels treated	1.9 ± 0.6	1.0 ± 0.0	< 0.001
Distribution of culprit vessels			< 0.001
Left main coronary artery	1 (0.4%)	3 (0.7%)	
Proximal LAD artery	45 (17.9%)	31 (7.5%)	
Mid to distal LAD artery	42 (16.7%)	116 (28.1%)	
Left circumflex artery	23 (9.2%)	50 (12.1%)	
Right coronary artery	109 (43.4%)	181 (43.8)	
LAD artery culprit	87 (34.7%)	147 (35.6%)	0.807
Distribution of non-culprit vessels			
Left main coronary artery	10 (4.0%)	18 (4.4%)	0.815
Proximal LAD artery	25 (10.0%)	12 (2.9%)	< 0.001
Mid to distal LAD artery	119 (47.4%)	169 (40.9%)	0.101
Left circumflex artery	112 (44.6%)	206 (49.9%)	0.188
Right coronary artery	74 (29.5%)	134 (32.4%)	0.424
Number of bare-metal stents	0.8 ± 1.2	0.7 ± 0.9	0.556
Number of drug-eluting stents	1.6 ± 1.6	0.7 ± 0.9	< 0.001

Baseline and 1-year Health Status

	Multivessel n = 251 (38%)	Culprit-only n = 413 (62%)	P-Value
SAQ AF score (baseline)	89.6 ± 17.1	89.2 ± 16.8	0.77
SAQ AF score (1 year)	94.8 ± 14.2	92.8 ± 17.4	0.20
Mean changes in SAQ AF	5.2 ± 22.4	3.2 ± 20.8	0.34
SAQ QoL score (baseline)	62.3 ± 20.9	68.5 ± 22.9	< 0.001
SAQ QoL score (1 year)	85.0 ± 18.3	81.5 ± 20.7	0.07
Mean changes in SAQ QoL	22.3 ± 24.9	12.7 ± 26.5	< 0.001

Independent Correlates of MV Revascularization

Age

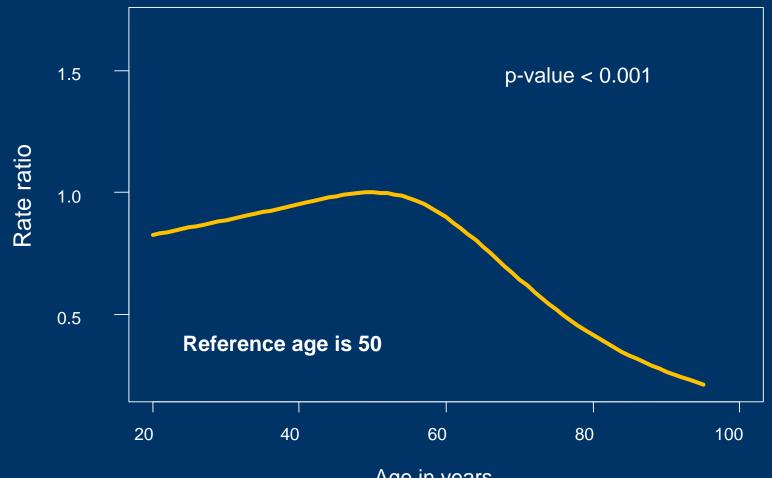
- 40 vs. 50
- 60 vs. 50
- 70 vs. 50
- 80 vs. 50

Female

Caucasian

Avoid care due to costs **Disease vessels (per 1 increment)** Non-LAD culprit vessel History of CHF In-hospital heart failure History of atrial fibrillation History of diabetes mellitus LV systolic dysfunction (moderate or severe) Initial creatinine (per 5 units increment) Initial hemoglobin (per 5 units incement) SF-12 PCS (per 5 units incement) Angina at baseline Hospital site (median rate ratio) 0.95 (0.78, 1.16) 0.90 (0.83, 0.97) 0.64 (0.54, 0.77) 0.41 (0.27, 0.64) 1.12 (0.93, 1.35) 1.08 (0.88, 1.34) 1.04 (0.84, 1.29) 1.31 (1.17, 1.46) 1.02 (0.77, 1.37) 1.33 (0.79, 2.23) 1.44 (0.95, 2.19) 0.63 (0.29, 1.35) 0.91 (0.67, 1.25) 0.90 (0.65, 1.26) 0.78 (0.39, 1.54) 1.08 (0.82, 1.42) 0.98 (0.95, 1.02) 0.90 (0.77, 1.05) 1.30 (1.18, 1.97)

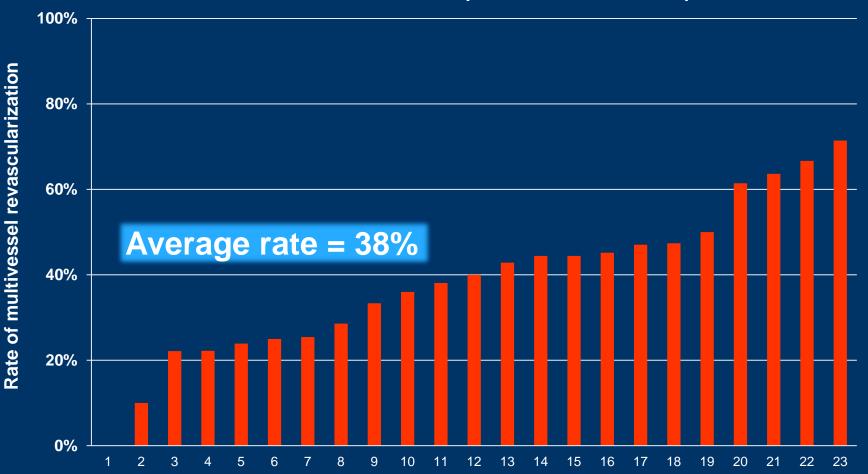
Age and Likelihood of MV Revascularization



Age in years

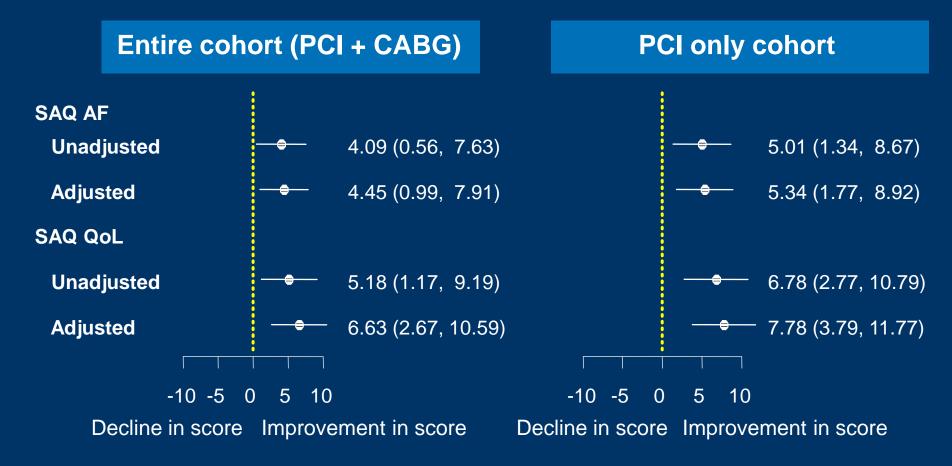
Hospital Variation of MV Revascularization

Median Rate Ratio = 1.30 (95% CI 1.18 to 1.97)



Health status outcomes

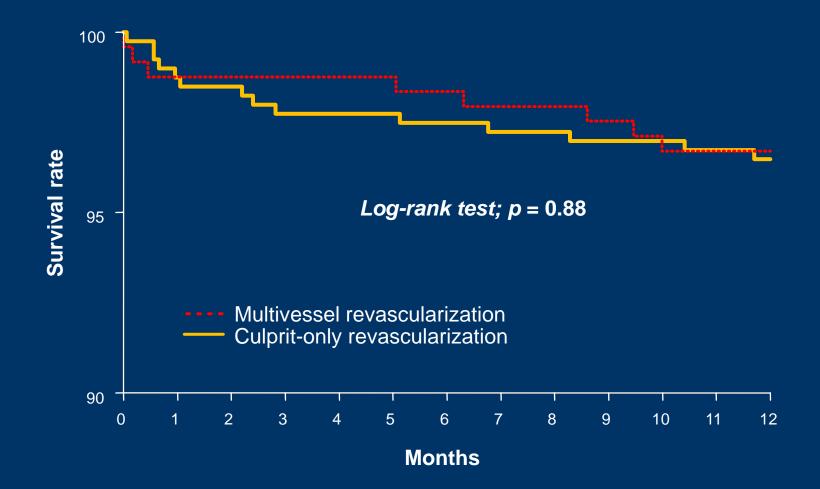
Multivessel vs. culprit-only revascularization



Clinical Outcomes at 1 year

	Multivessel n = 251	Culprit-only n = 413	P-Value
Mortality	8 (3.6%)	14 (3.4%)	0.88
Recurrent MI	7 (3.5%)	4 (1.4%)	0.12
Repeat revascularization	17 (7.5%)	32 (9.1%)	0.50
Severe angina	10 (4.4%)	22 (6.3%)	0.34

K-M Curves of 1-year Mortality



Study Limitations

- Potential for unmeasured confounding or selection bias
- No query to the clinicians as to why complete or culprit-only revascularization was performed
- Missing SAQ data in 1/3 of patients at 1 year
- No angiographic core laboratory assessing the severity of CAD
- Excluded in-hospital death. Cannot be extrapolated to extremely sick patients

Conclusions

- In a large, multicenter AMI registry,
 Multivessel, complete revascularization in STEMI setting;
- common (n=251, 38% among 664 patients)
- varied by patient characteristics and the treating hospital
- improved both angina and QoL at 1 year

 Future studies of the potential benefits and harms of multivessel revascularization in STEMI patients should include both symptoms and health-related QoL outcomes so that more complete insights into the benefits of multivessel revascularization can be assessed JOURNAL OF THE AMERICAN COLLEGE OF CARDIOLOGY © 2015 BY THE AMERICAN COLLEGE OF CARDIOLOGY FOUNDATION PUBLISHED BY ELSEVIER INC.

Impact of Multivessel Revascularization on Health Status Outcomes in Patients With ST-Segment Elevation Myocardial Infarction and Multivessel Coronary Artery Disease

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ABSTRACT

BACKGROUND Up to 65% of patients with ST-segment elevation myocardial infarction (STEMI) have multivessel coronary artery disease (MVCAD). Long-term health status of STEMI patients after multivessel revascularization is unknown.

OBJECTIVES This study investigated the relationship between multivessel revascularization and health status outcomes (symptoms and quality of life [QoL]) in STEMI patients with MVCAD.

METHODS Using a U.S. myocardial infarction registry and the Seattle Angina Questionnaire (SAQ), we determined the health status of patients with STEMI and MVCAD at the time of STEMI and 1 year later. We assessed the association of multivessel revascularization during index hospitalization with 1-year health status using multivariable linear regression analysis, and also examined demographic, clinical, and angiographic factors associated with multivessel revascularization.

RESULTS Among 664 STEMI patients with MVCAD, 251 (38%) underwent multivessel revascularization. Most revascularizations were staged during the index hospitalization (64.1%), and 8.0% were staged after discharge, with 27.9% performed during primary percutaneous coronary intervention. Multivessel revascularization was associated with age and more diseased vessels. At 1 year, multivessel revascularization was independently associated with improved symptoms (4.5 points higher SAQ angina frequency score; 95% confidence interval [CI]: 1.0 to 7.9) and QoL (6.6 points higher SAQ QoL score; 95% CI: 2.7 to 10.6). One-year mortality was not different between those who did and did not undergo multivessel revascularization (3.6% vs. 3.4%; log-rank test p = 0.88).

CONCLUSIONS Multivessel revascularization improved angina and QoL in STEMI patients with MVCAD. Patient-centered outcomes should be considered in future trials of multivessel revascularization. (J Am Coll Cardiol 2015;66:2104-13) © 2015 by the American College of Cardiology Foundation.

Thank you for your attention!