

LA TECNOLOGIA A SERVIZIO DEL CUORE

ALAIDE CHIEFFO, MD

INTERVENTIONAL CARDIOLOGY UNIT

SAN RAFFAELE SCIENTIFIC INSTITUTE

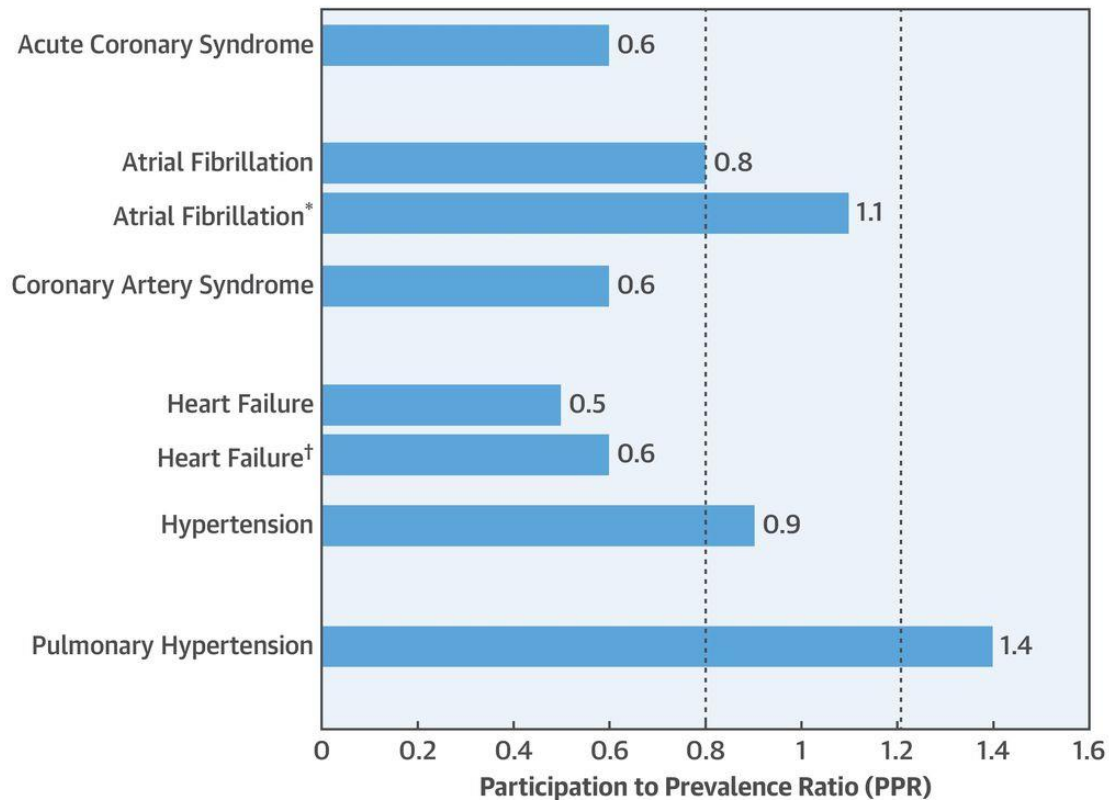
MILAN ITALY

MAJOR GAPS IN CARE IN WOMEN

1. Underrepresentation in CVD Clinical Trials
2. Female Specific Pathophysiology
3. Higher mortality in Women
4. Young Women
5. Differences in treatment and application of guidelines
6. Improvement of the results with specific protocols and treatment
7. MCS in women

1. Underepresentation in CVD Clinical Trials

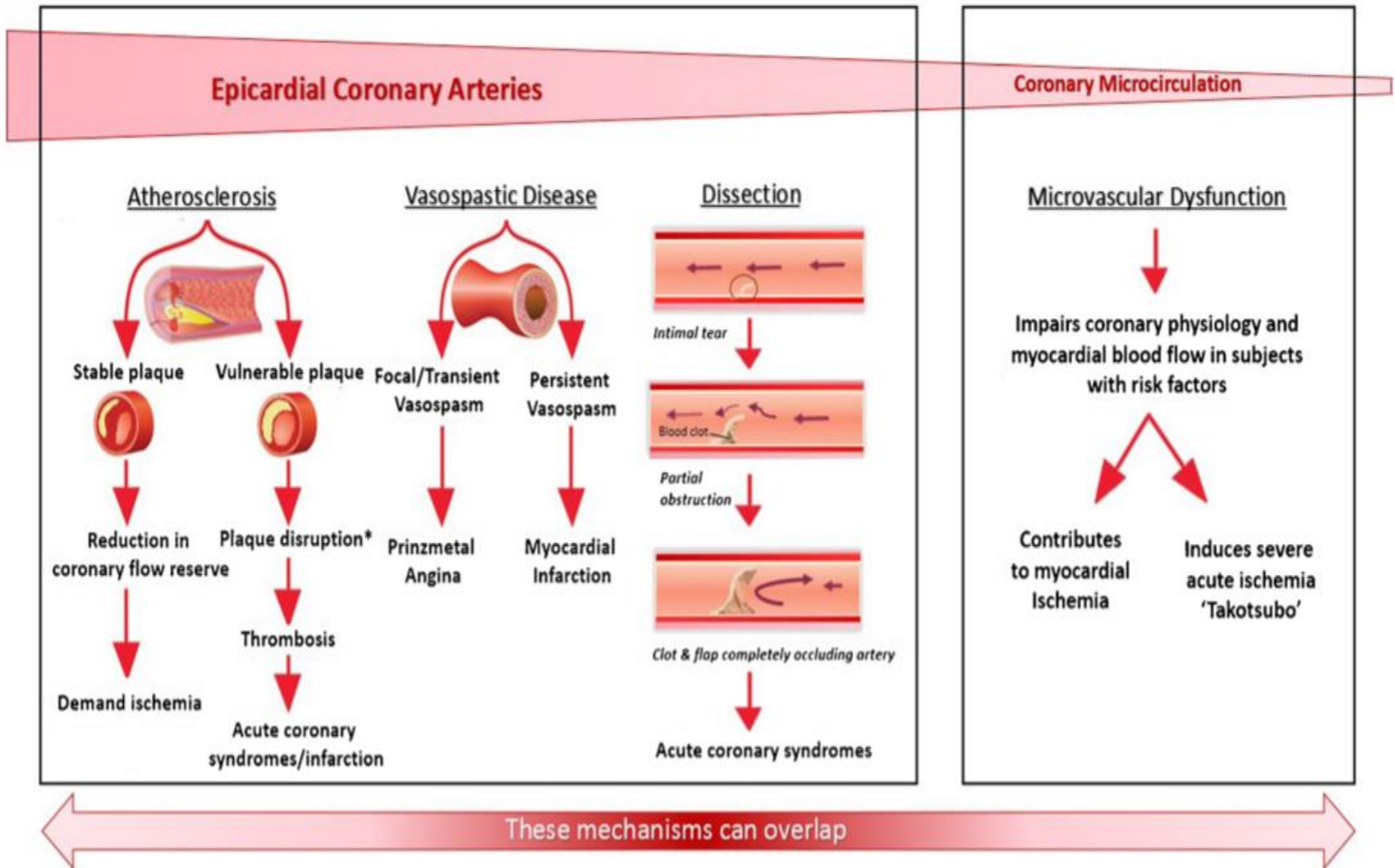
CENTRAL ILLUSTRATION: Participation of Women of CVD Clinical Trial: Prevalence-Corrected Estimate



Scott, P.E. et al. J Am Coll Cardiol. 2018;71(18):1960-9.

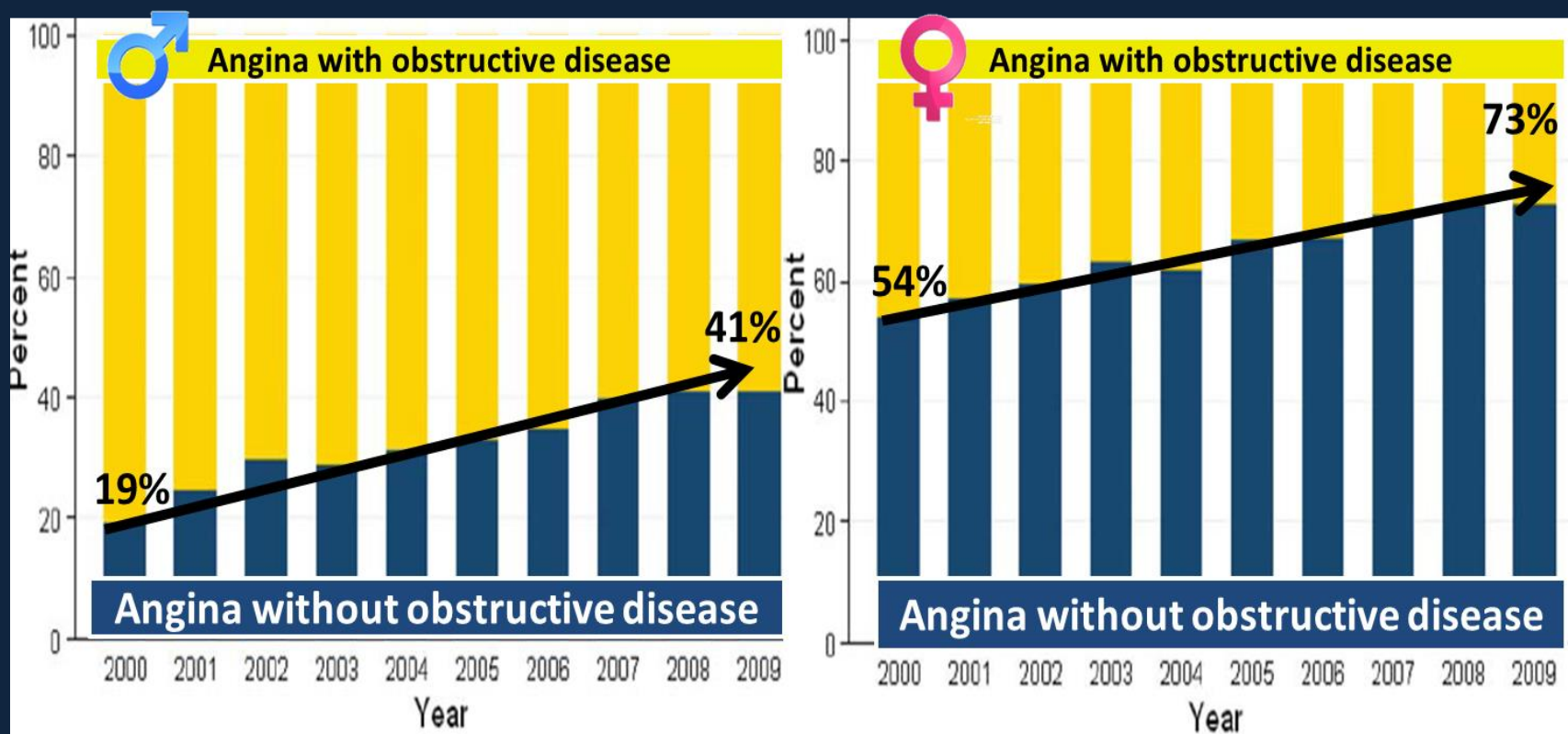
2. FEMALE SPECIFIC PATHOPHYSIOLOGY

Mechanisms of Myocardial Ischemia



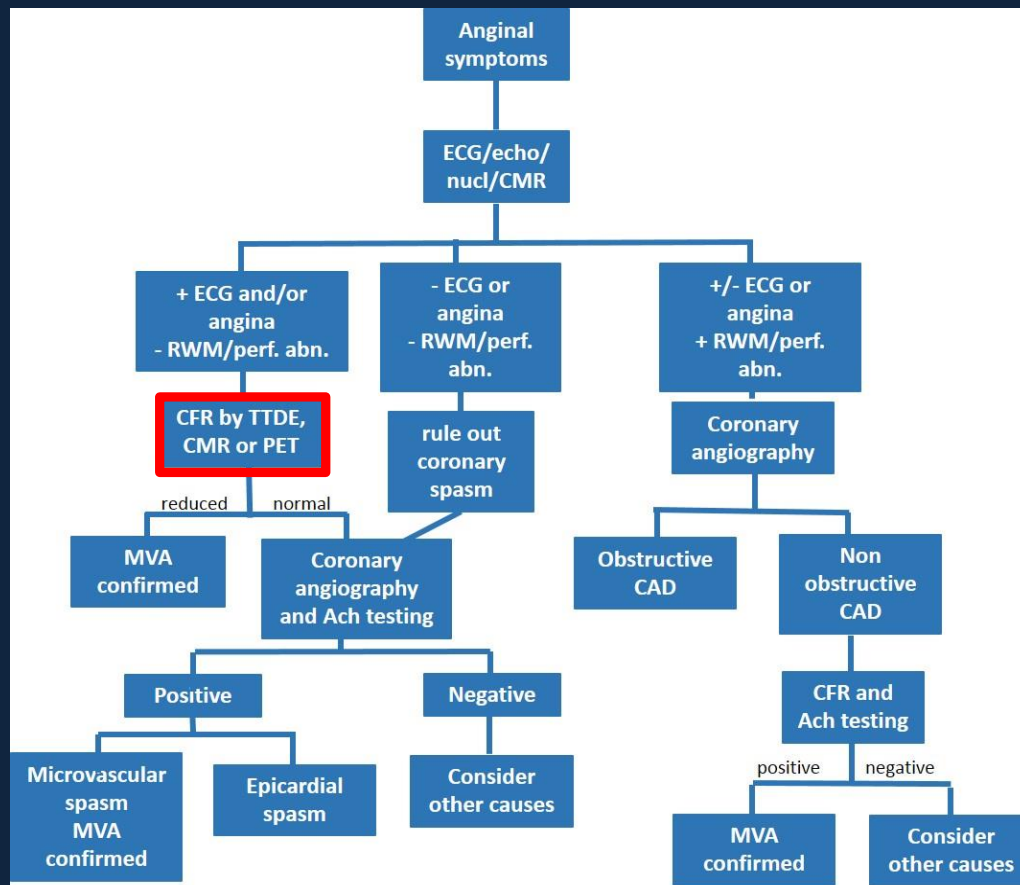
Angina exists even in the absence of obstructive disease and its prevalence is increasing

Data in 11 223 patients with stable angina pectoris



Microvascular Angina A Women's Affair?

Paolo G. Camici, MD; Filippo Crea, MD

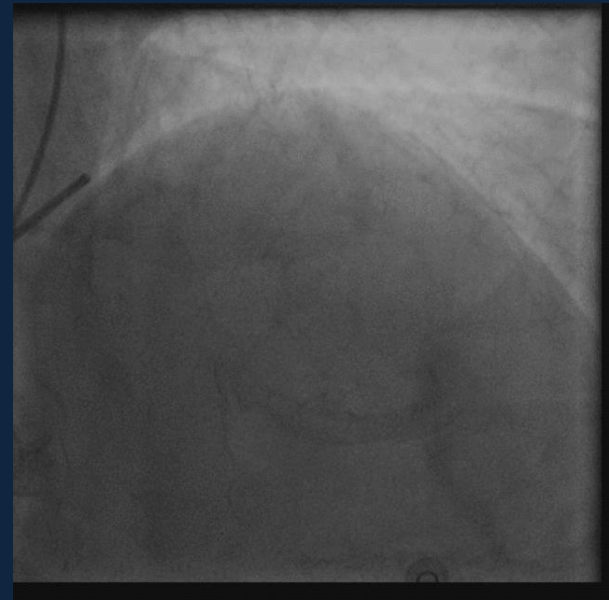
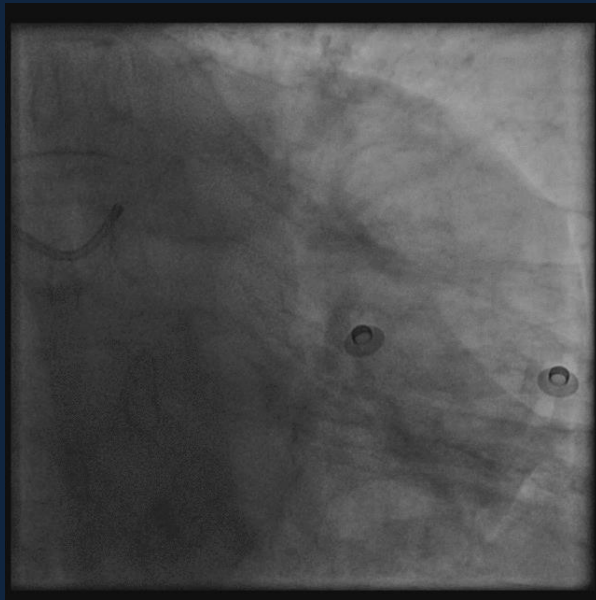
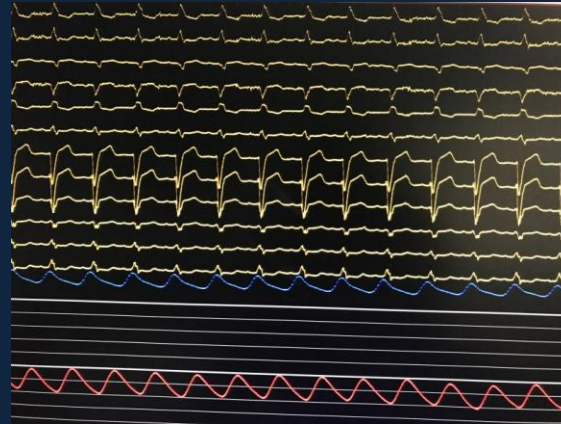


Women with CCS 2 Angina and Positive stress test- Baseline CAG



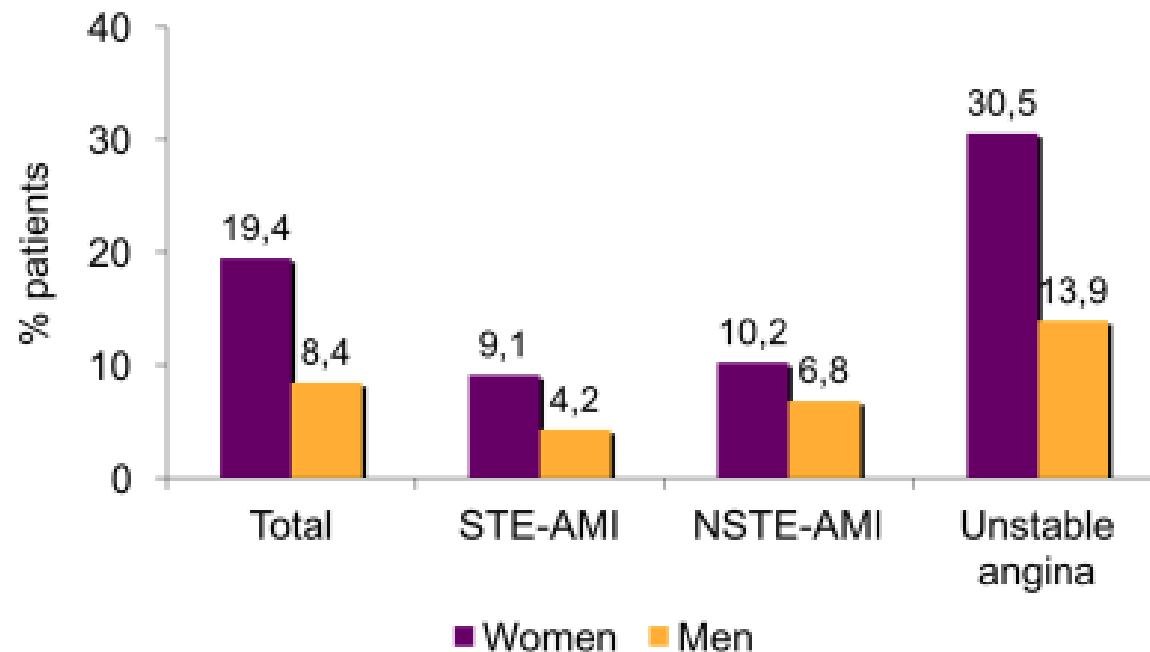
ACH - 100 μ g

Typical chest pain
LBBB



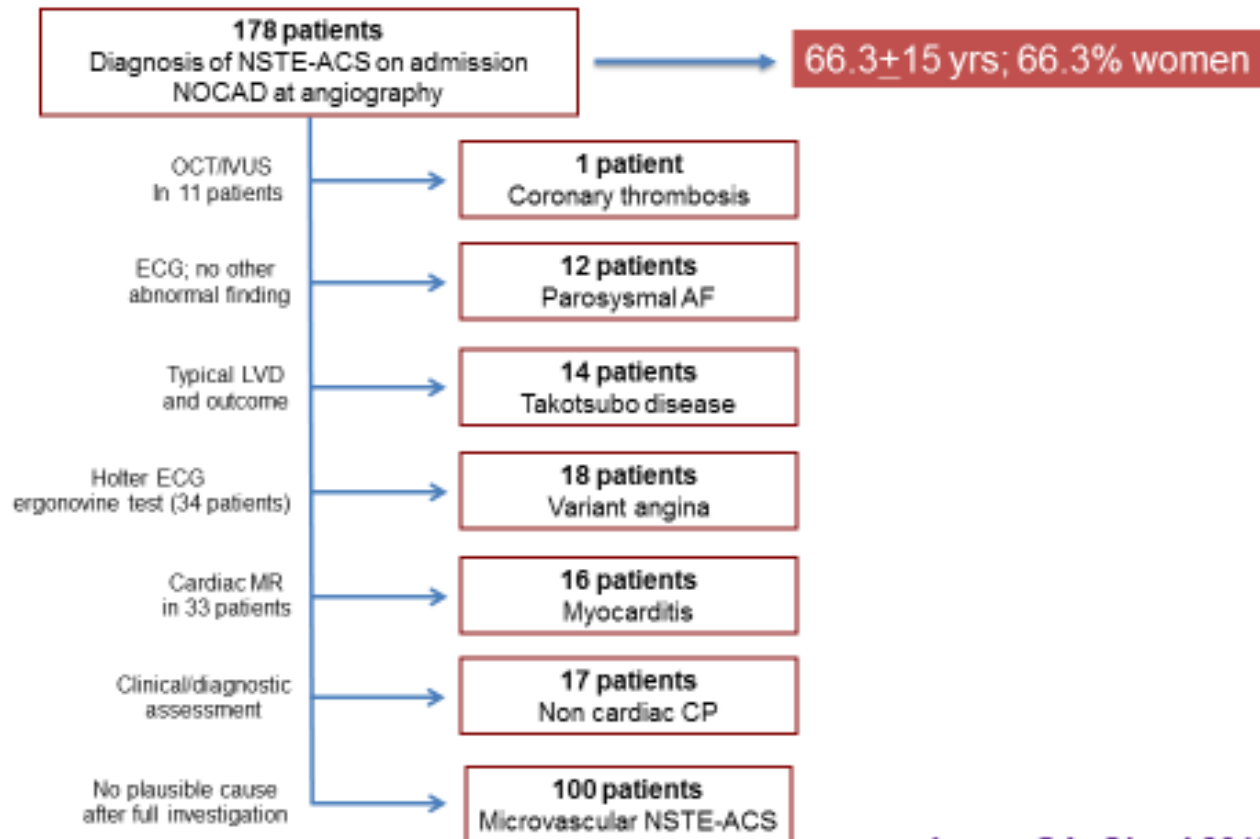
Focal Epicardial Spasm

Prevalence of non obstructive CAD in acute coronary syndromes according to sex (GUSTO-IIb)



Hochman JS, N Engl J Med 1999;341:226-32

Diagnostic spectrum of NSTEMI-ACS and NO-CAD



Lanza GA, Circ J 2016;80:1600-6

RA Pathophysiology of Takotsubo Syndrome

i-159

Circulation. 2017;135:2426–2441. DOI: 10.1161/CIRCULATIONAHA.116.027121

ABSTRACT: Originally described by Japanese authors in the 1990s, Takotsubo syndrome (TTS) generally presents as an acute myocardial infarction characterized by severe left ventricular dysfunction. TTS, however, differs from an acute coronary syndrome because patients have generally a normal coronary angiogram and left ventricular dysfunction, which extends beyond the territory subtended by a single coronary artery and recovers within days or weeks. The prognosis was initially thought to be benign, but subsequent studies have demonstrated that both short-term mortality and long-term mortality are higher than previously recognized. Indeed, mortality reported during the acute phase in hospitalized patients is ≈4% to 5%, a figure comparable to that of ST-segment-elevation myocardial infarction in the era of primary percutaneous coronary interventions. Despite extensive research, the cause and pathogenesis of

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AQ2

STATE OF THE ART

returns to normal within several weeks. This peculiarly shaped ventriculogram was originally named by Dr Sato and his colleagues as 'Takotsubo' cardiomyopathy! after the fishing pot with a round bottom and narrow neck that is used for trapping octopuses in Japan.



CLINICAL PRESENTATION

Symptoms, clinical signs, and echocardiographic and electrocardiographic findings in patients with TTS are suggestive of an ACS.⁵ The most common symptoms at presentation are chest pain and dyspnea. TTS can also present as syncope and pulmonary edema. Cardiac arrest, cardiogenic shock, and serious ventricular arrhythmias occur more rarely in patients with TTS. Symptoms such as generalized weakness, unexplained cough, and fever have also been reported.⁶

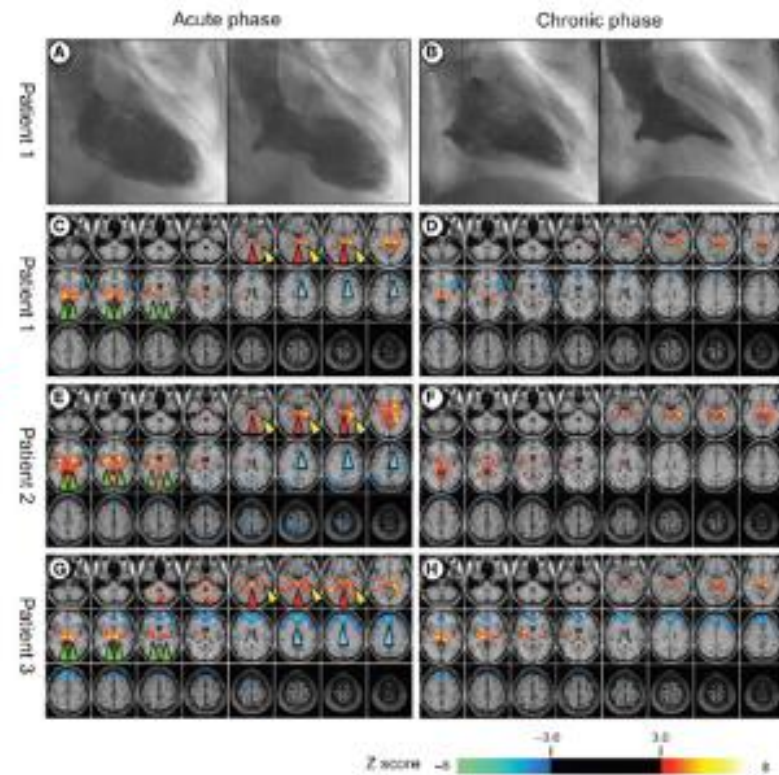
Table 1. Characteristics of the Patients at Baseline.*

Characteristic	Takotsubo Cardiomyopathy		Acute Coronary Syndrome	P Value†
	Total Cohort (N = 1750)	Matched Cohort (N = 455)	Matched Cohort (N = 455)	
Female sex — no. (%)	1571 (89.8)	411 (90.3)	411 (90.3)	1.00
Age — yr	66.4±13.1	67.7±12.5	68.7±12.3	0.19
Chest pain — no./total no. (%)	1229/1619 (75.9)	322/438 (73.5)	361/403 (89.6)	<0.001
Dyspnea — no./total no. (%)	760/1620 (46.9)	208/439 (47.4)	128/363 (35.3)	0.001
Median troponin (IQR) — factor × ULN‡	7.70 (2.22–24.00)	7.68 (2.38–24.21)	8.30 (1.80–36.40)	0.62
Median creatine kinase (IQR) — factor × ULN	0.85 (0.52–1.48)	0.87 (0.55–1.42)	1.12 (0.60–2.97)	<0.001
Median brain natriuretic peptide (IQR) — factor × ULN§	6.12 (2.12–15.70)	5.89 (1.68–13.92)	2.91 (0.88–8.26)	<0.001
ST-segment change — no./total no. (%)				
Elevation	690/1578 (43.7)	185/420 (44.0)	233/455 (51.2)	0.03
Depression	121/1578 (7.7)	35/420 (8.3)	122/392 (31.1)	<0.001
Heart rate — beats/min	87.5±21.8	87.3±21.8	76.1±18.3	<0.001
Systolic blood pressure — mm Hg	130.6±28.8	131.6±31.4	131.5±28.2	0.96
Left ventricular ejection fraction — %¶	41.1±11.8	40.7±11.2	51.5±12.3	<0.001
Left ventricular end diastolic pressure — mm Hg	21.3±8.0	22.1±7.7	20.1±7.8	0.001
Coexisting medical condition — no./total no. (%)				
Coronary artery disease	245/1597 (15.3)	96/455 (21.1)	455/455 (100.0)	<0.001
Neurologic or psychiatric disorder	714/1525 (46.8)	252/452 (55.8)	115/448 (25.7)	<0.001
Acute neurologic disorder	143/1528 (9.4)	41/452 (9.1)	4/448 (0.9)	<0.001
Past or chronic neurologic disorder	293/1512 (19.4)	98/452 (21.7)	62/448 (13.8)	0.002
Acute psychiatric disorder	149/1525 (9.8)	57/452 (1.3)	6/448 (1.3)	<0.001
Past or chronic psychiatric disorder	444/1512 (29.4)	165/451 (36.6)	61/448 (13.6)	<0.001
Treatment — no./total no. (%)				
Catecholamine	212/1735 (12.2)	53/455 (11.6)	50/455 (11.0)	0.75
Invasive or noninvasive ventilation	301/1735 (17.3)	63/455 (13.8)	41/455 (9.0)	0.02
Cardiopulmonary resuscitation	149/1735 (8.6)	40/455 (8.8)	53/455 (11.6)	0.16
In-hospital outcomes — no./total no. (%)				
Cardiogenic shock	170/1716 (9.9)	55/445 (12.4)	48/455 (10.5)	0.39
Death	72/1750 (4.1)	17/455 (3.7)	24/455 (5.3)	0.26

PATHOPHYSIOLOGY

Sympathetic Activation in TTS and Its Mechanisms

phase of TTS, Suzuki et al²⁸ have measured regional cerebral blood flow, a well-established index of brain activity, and demonstrated a significant cerebral blood flow increase in the hippocampus, brainstem, and basal ganglia, paralleled by a decrease in the prefrontal cortex. Although these changes subsided gradually, they were still present in the chronic phase of TTS even after the typical cardiac wall motion abnormalities had disappeared (Figure 2).



European Society of Cardiology: a position paper on spontaneous coronary artery dissection

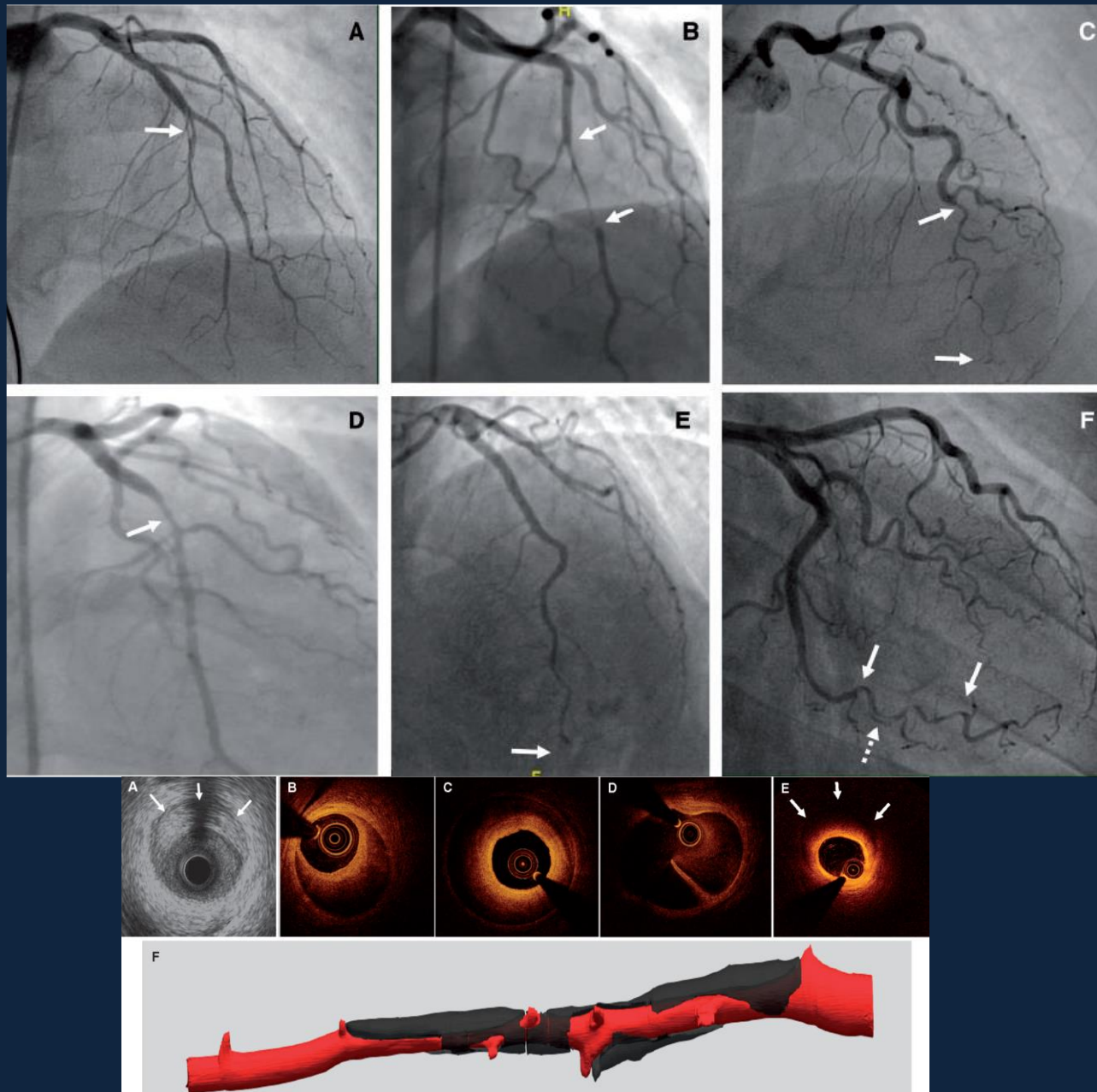
Table 1 Demographics and risk factors of patients with spontaneous coronary artery dissection (SCAD) in contemporary case series (studies with $n > 20$)

	Max N	Age (years)	Gender (female, %)	HTN (%)	Chol (%)	Smoking (%)	DM (%)	FH (%)	P-SCAD (%)
Mayo Clinic ³	189	44 ± 9	92	31	22	15	2	NA	15
Saw ⁴	168	52 ± 9	92	39	24	13	5	29	2
Lettieri ⁵	134	52 ± 11	81	51	33	34	2	25	NA
Faden ⁶	79	33 ± 5	100	17	18	17	11	NA	100
Rogowski ⁷	64	53 ± 11	94	45	52	28	0	19	5
Nakashima ⁸	63	46 ± 10	94	33	23	32	0	8	8
Motreff ¹³	55	50	100	27	11	22	4	22	4
McGrath-Cadell ⁹	40	45 ± 10	95	18	10	8	5	28	8
Roura ¹⁰	34	47 ± 12	94	NA	NA	NA	NA		15
Alfonso ¹¹	27	52 ± 10	85	37	33	52	4	NA	4
Ito ¹²	23	45 ± 11	100	57	22	30	4	NA	30
Vanzetto ¹⁴	23	46 ± 9	74	26	39	43	13	13	0
Mortensen ¹⁵	22	49 ± 9	81	38	NA	57	0	40	10
Rashid ¹⁶	21	53 ± 9	95	48	48	47	5	24	0

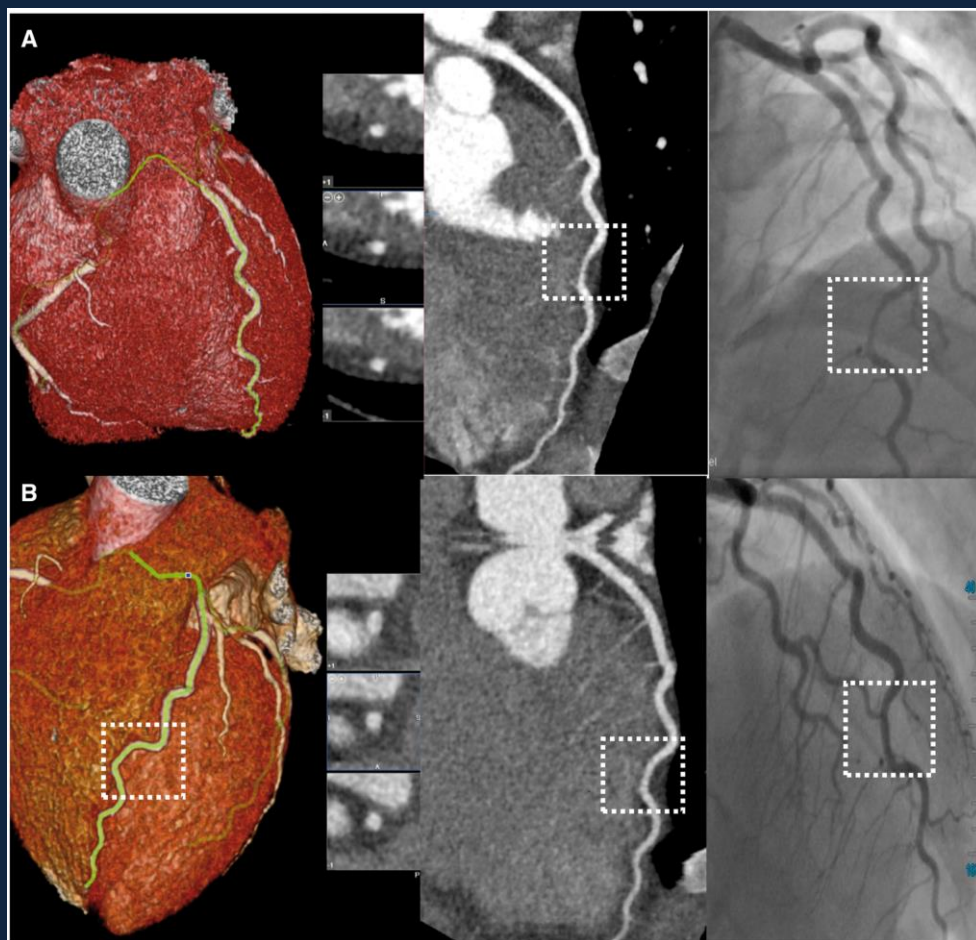
Data are given as mean ± standard deviation or percentages.

HTN, hypertension; Chol, dyslipidaemia; DM, diabetes mellitus; FH, family history of coronary artery disease; NA, not available; P-SCAD, pregnancy-associated coronary artery dissection.

SCAD:



European Society of Cardiology: a position paper on spontaneous coronary artery dissection



3. Higher mortality in Women

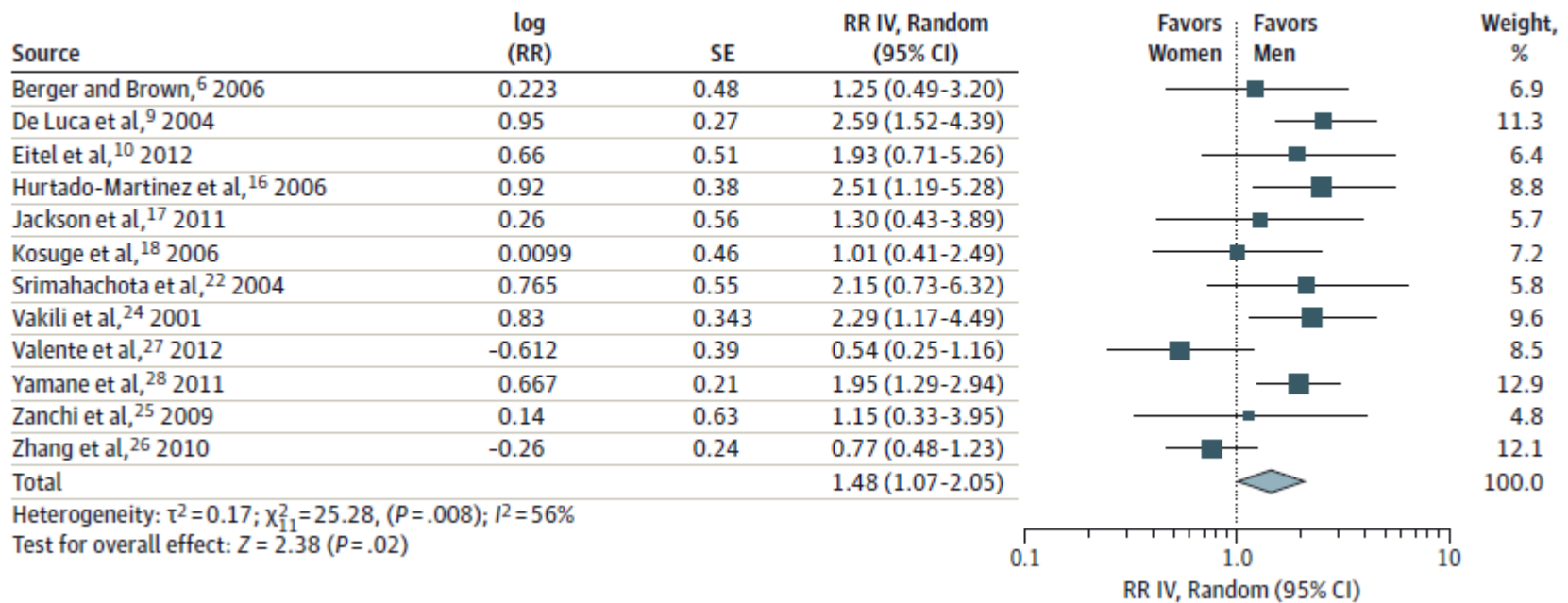
Crude in-hospital or 30 days mortality rates

	N° PTS	MEN (%)	WOMEN (%)
NRMI, 1994-2006 <i>Canto JG et al, JAMA 2012</i>	1.143.513 (W 42%)	10.3	14.6
French registry, 1995 2010 (80% PCI) <i>Puymirat E et al, JAMA 2012</i>	6707 STEMI (W 26%)	9.8	23.7
		2.6	9.8
Regione Lombardia, 2000-2010 (70% PCI) <i>Ferrante, Presbitero, Am J Cardiol, 2014</i>	89,562 (W 33.%)	7.1	16.1

Sex Differences in Short-term and Long-term All-Cause Mortality Among Patients With ST-Segment Elevation Myocardial Infarction Treated by Primary Percutaneous Intervention A Meta-analysis

Forest plots showing adjusted in hospital mortality women vs men

B



4. Higher in Hosp Mortality in Young patients

In Hospital Mortality by Race and Sex among
STEMI young patients

N=230684

TABLE 4 In-Hospital Mortality (Percentages) by Race and Sex Among Patients With AMIs 30 to 54 Years of Age in the United States, 2001 to 2010

Subgroup	2001	2002	2003	2004	2005	2006	2007	2008	2009	2010
Black men	2.7	3.2	2.8	3.4	3.0	2.7	2.6	2.2	2.1	1.6
White men	2.1	1.8	1.4	2.2	1.7	1.9	1.8	1.9	1.8	1.8
Black women	4.8	5.2	5.2	4.1	2.4	2.7	2.9	1.8	3.5	2.1
White women	3.0	2.6	2.8	2.9	2.5	2.7	2.2	2.4	1.8	2.2

Hospital Mortality for MI

by Chest Pain/Discomfort on Presentation, Age, and Sex

NRMI, 1994-2006

Table 6. Hospital Mortality for Myocardial Infarction Patients, by Chest Pain/Discomfort on Presentation, Age, and Sex: NRMI, 1994-2006^a

Age, y	Men With Chest Pain	Women With Chest Pain	Men Without Chest Pain	Women Without Chest Pain	P Value
Crude rate, No. (%)					
<45 (n = 66 540)	562/44 651 (1.3)	246/12 413 (2.0)	679/6653 (10.2)	432/2823 (15.3)	<.001
45-54 (n = 132 777)	1476/85 029 (1.7)	679/25 006 (2.7)	1680/15 849 (10.6)	997/6893 (14.5)	
55-64 (n = 201 019)	3621/109 383 (3.3)	2066/43 510 (4.7)	4254/30 472 (14.0)	2974/17 654 (16.8)	
65-74 (n = 267 480)	7378/107 347 (6.9)	5746/66 942 (8.6)	9888/52 256 (18.9)	7891/40 935 (19.3)	
≥75 (n = 475 697)	15 330/112 267 (13.7)	19 962/131 554 (15.2)	23 148/98 025 (23.6)	29 147/133 851 (21.8)	
Unadjusted OR (95% CI)					C Statistic
<45	1 [Reference]	1.59 (1.36-1.85)	8.92 (7.95-10.00)	14.17 (12.42-16.17)	.74
45-54	1 [Reference]	1.58 (1.44-1.73)	6.71 (6.24-7.21)	9.57 (8.80-10.42)	.72
55-64	1 [Reference]	1.46 (1.38-1.54)	4.74 (4.52-4.96)	5.92 (5.62-6.23)	.69
65-74	1 [Reference]	1.27 (1.23-1.32)	3.16 (3.06-3.27)	3.24 (3.13-3.35)	.64
≥75	1 [Reference]	1.13 (1.11-1.16)	1.95 (1.91-2.00)	1.76 (1.72-1.80)	.57
Adjusted OR (95% CI)					

5. Differences in Treatment

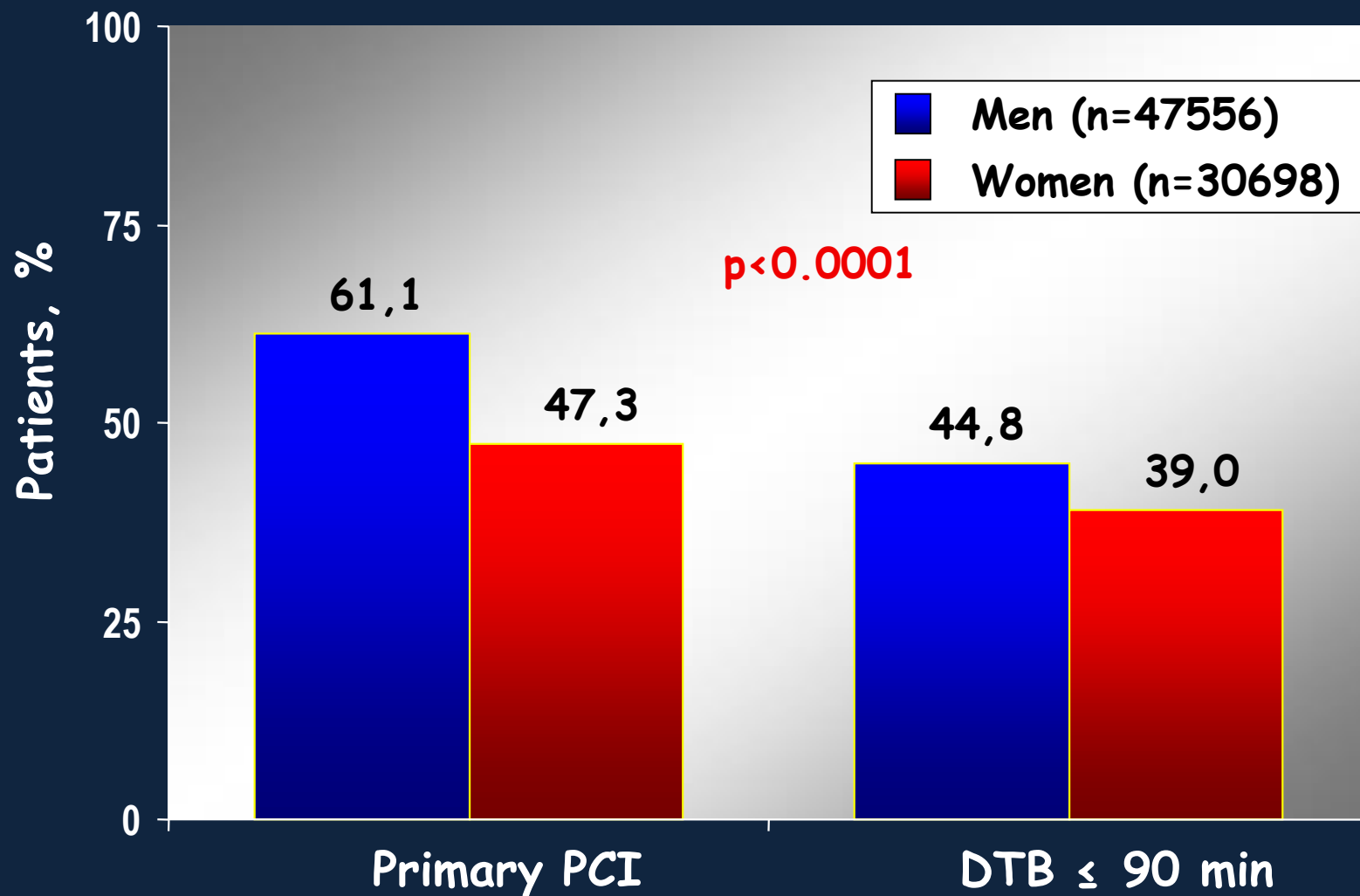
“Get with the Guidelines” registry database

- Underutilization of evidence-based treatments for women
- Delayed reperfusion among women (STEMI)

Measure/Treatment	Men (n=47 556), % (n)	Women (n=30 698), % (n)	P
Early medical therapy			
Aspirin within <24 h	93.3 (40 332)	91.0 (24 686)	<0.0001
β-Blockers within <24 h	87.2 (34 653)	84.7 (21 124)	<0.0001
Invasive procedures			
Cardiac catheterization	56.2 (26 733)	45.6 (14 012)	<0.0001
PCI	52.3 (22 253)	36.1 (10 070)	<0.0001
CABG	9.2 (3893)	5.4 (1501)	<0.0001
Revascularization	60.2 (25 614)	40.9 (11 409)	<0.0001
Timeliness of reperfusion			
DTN time, median (25 th -75 th), min	39.0 (24.0-66.0)	47.0 (27.0-83.0)	<0.0001
DTB time, median (25 th -75 th), min	95.0 (69.0-135.0)	103.0 (74.0-154.0)	<0.0001

Sex differences in STEMI Primary PCI

Get With the Guidelines-Coronary Artery Disease Registry



Sex Differences in Outcomes After STEMI Effect Modification by Treatment Strategy and Age

Variable	Age <60 Years (n = 3806)		Age ≥60 to 74 Years (n = 3556)		Age ≥75 Years (n = 1472)	
	OR (95% CI)	P Value	OR (95% CI)	P Value	OR (95% CI)	P Value
Women	1.88 (1.08-3.26)	.02	1.28 (0.88-1.88)	.19	1.17 (0.80-1.73)	.40
Age, y	1.04 (0.99-1.08)	.05	1.08 (1.04-1.13)	<.001	1.06 (1.02-1.11)	.002
Diabetes mellitus	2.04 (1.18-3.54)	.01	1.18 (0.80-1.75)	.39	1.24 (0.83-1.87)	.28
Hypertension	0.66 (0.39-1.13)	.13	0.60 (0.40-0.90)	.02	0.76 (0.50-1.14)	.20
Current smoking	0.52 (0.31-0.89)	.02	1.01 (0.66-1.55)	.93	0.66 (0.33-1.32)	.25
Prior angina pectoris	0.49 (0.21-1.13)	.10	0.62 (0.35-1.08)	.10	0.65 (0.39-1.08)	.10
Prior MI	0.81 (0.38-1.72)	.59	1.90 (1.19-3.03)	.007	0.76 (0.41-1.38)	.37
Prior PCI	2.97 (1.51-5.83)	.002	1.08 (0.62-1.86)	.77	1.26 (0.67-2.40)	.46
Prior CABG	0.74 (0.07-7.47)	.80	1.28 (0.44-3.71)	.64	1.02 (0.20-5.23)	.98
Prior stroke	1.04 (0.27-3.87)	.95	1.72 (0.96-3.08)	.07	2.26 (1.28-3.98)	.004
Prior HF	1.10 (0.41-2.95)	.84	0.45 (0.19-1.06)	.07	0.77 (0.40-1.48)	.45
Killip class ≥2	11.25 (6.54-19.35)	<.001	7.72 (5.21-11.44)	<.001	3.46 (2.33-5.15)	<.001
HR at admission (SD increment) ^a	1.43 (1.17-1.75)	.001	1.08 (0.93-1.25)	.26	1.01 (0.87-1.18)	.82
SBP at admission (SD increment) ^a	0.76 (0.61-0.94)	.01	0.70 (0.61-0.80)	<.001	0.71 (0.60-0.83)	<.001
Time to admission ≤2 h	1.15 (0.66-2.00)	.61	0.94 (0.59-1.50)	.82	0.57 (0.31-1.02)	.06

Abbreviations: CABG, coronary artery bypass graft; HF, heart failure; HR, heart rate; MI, myocardial infarction; PCI, percutaneous coronary intervention; SBP, systolic blood pressure; SD, standard deviation.

^a Standard deviations for heart rate and systolic blood pressure in the overall population were 16.6 bpm and 23.8 mm Hg.

6. Improvement of the results with specific protocols and treatment

Four-Step Protocol for Disparities in STEMI Care and Outcomes in Women

1,272 patients (32% women) treated at Cleveland Clinic before and after implementation of a protocol to standardize STEMI care.

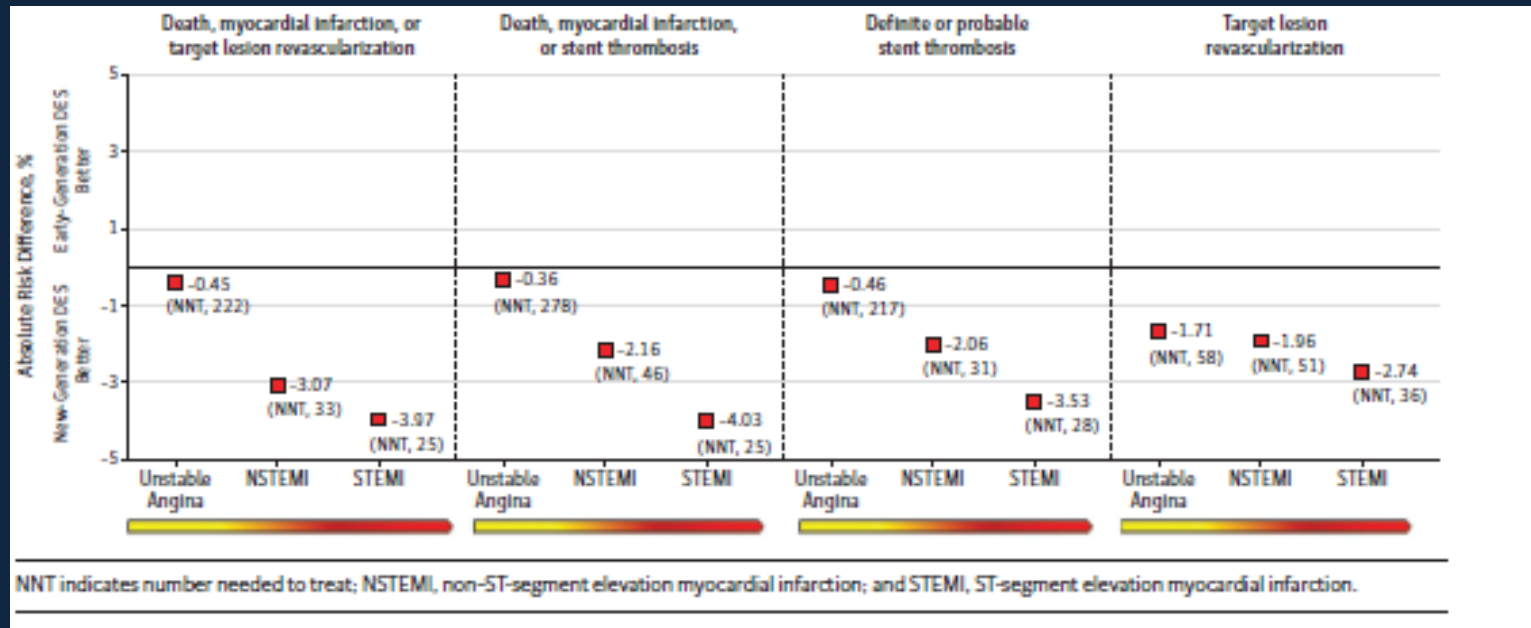
- Before the new protocol, women had longer door-to-balloon times, less use of guideline-directed medical therapy, and worse in-hospital outcomes compared with men
- After implementation of the protocol, those sex differences in processes and in-hospital outcomes disappeared
- The gap in 30-day mortality (higher in women) grew smaller from the earlier to the later time period

Conclusion: A Cleveland Clinic protocol designed to improve STEMI care processes for all patients also had the benefit of mitigating the suboptimal care and outcomes seen in women.

Huded CP, et al. *J Am Coll Cardiol.*
2018;71:2122-2132.

Long-term Safety and Efficacy of New-Generation DES in Women With AMI From the Women in Innovation and Drug-Eluting Stents (WIN-DES) Collaboration

Absolute risk differences between new vs early generation DES across the spectrum of ACS



7. MCS in Women

- High prevalence of women presenting with AMI-CGS¹
- Higher risk profile (vs men) with advanced age and worse hemodynamics (lower CI, lower bp)^{1,2}, higher STS mortality risk scores³, more likely to have sustained cardiac arrest³
- Greater survival benefit (vs men) to hospital discharge with early LV unloading prior to PCI³
- However women are less likely to receive acute MCS devices even when in Cardiogenic Shock

1. Wong et al. JACC 2011;38: 1395-401

2. Fengler et al. Clin Res Cardiology 2014

3. Joseph et al J Interven Cardiol 2016; 29:248-256

Women with Cardiogenic Shock

Clin Res Cardiol (2015) 104:71–78
DOI 10.1007/s00392-014-0767-2

ORIGINAL PAPER

Gender differences in patients with cardiogenic shock complicating myocardial infarction: a substudy of the IABP-SHOCK II-trial

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Abstract

Background Cardiogenic shock (CS) complicating acute myocardial infarction (AMI) is associated with high mortality. Previous studies regarding gender-specific differences in CS are conflicting and there are insufficient data for the presence of gender-associated differences in the contemporary percutaneous coronary intervention era. Aim of this study was therefore to investigate gender-specific differences in a large cohort of AMI patients with CS undergoing contemporary treatment.

Methods In the randomized Intra-aortic Balloon Pump in Cardiogenic Shock II (IABP-SHOCK II) trial, 600 patients with CS complicating AMI undergoing early revasculari-

zation were assigned to therapy with or without intra-aortic balloon pump. We compared sex-specific differences in these patients with regard to baseline and procedural characteristics as well as short- and long-term clinical outcome.

Results Of 600 patients 187 (31 %) were female. Women were significantly older than men and had a significantly lower systolic and diastolic blood pressure at presentation ($p < 0.05$ for all). Diabetes mellitus and hypertension were more frequent in women, whereas smoking was more frequent in men ($p < 0.05$ for all). Women showed a higher mortality within the first day after randomization ($p = 0.004$). However, after multivariable adjustment this numerical difference was no longer statistically significant. No gender-related differences in clinical outcome were observed after 1, 6 and 12 months of follow-up.

K. Fengler and G. Fuernau contributed equally to this study.

Clinicaltrials.gov: NCT00491036.

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Absence of Gender Differences in Clinical Outcomes in Patients With Cardiogenic Shock Complicating Acute Myocardial Infarction

A Report From the SHOCK Trial Registry

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New York, New York; Watertown and Boston, Massachusetts; and Toronto, Canada

- OBJECTIVES** The aim of this study was to assess the impact of gender on clinical course and in-hospital mortality in patients with cardiogenic shock (CS) complicating acute myocardial infarction (AMI).
- BACKGROUND** Previous studies have demonstrated higher mortality for women compared with men with ST elevation myocardial infarctions and higher rates of CS after AMI. The influence of gender and its interaction with various treatment strategies on clinical outcomes once CS develops is unclear.
- METHODS** Using the SHOCK Registry database of 1,190 patients with suspected CS in the setting of AMI, we examined shock etiologies by gender. Among the 884 patients with predominant left ventricular (LV) failure, we compared the patient demographics, angiographic and hemodynamic findings, treatment approaches as well as the clinical outcomes of women versus men. This study had a 97% power to detect a 10% absolute difference in mortality by gender.
- RESULTS** Left ventricular failure was the most frequent cause of CS for both gender groups. Women in the SHOCK Registry had a significantly higher incidence of mechanical complications including ventricular septal rupture and acute severe mitral regurgitation. Among patients with predominant LV failure, women were, on average, 4.6 years older, had a higher incidence of hypertension, diabetes and a lower cardiac index. The overall mortality rate for women was higher (41.0%). After adjustment for differences in patient demographics and treatment approaches, there was no significant difference in in-hospital mortality between the two gender groups (odds ratio = 1.03, 95% confidence interval of 0.73 to 1.43, $p = 0.88$). Mortality was also similar for women and men who were selected for revascularization (44% vs. 38%, $p = 0.244$).
- CONCLUSIONS** Women with CS complicating AMI had more frequent adverse clinical characteristics and mechanical complications. Women derived the same benefit as men from revascularization, and gender was not independently associated with in-hospital mortality in the SHOCK Registry. (J Am Coll Cardiol 2001;38:1395–401) © 2001 by the American College of Cardiology

Myocardial infarction (MI) strikes close to one million Americans annually (1) and accounted for one of every 4.8 deaths in 1995 (2,3). With the establishment of coronary care units, advances made in early detection and treatment of obstructive coronary artery disease and the application of thrombolytic treatment strategies in acute MI (AMI), the mortality rate in patients admitted to hospitals with MI has declined in recent years (2,3). Despite these advances, mortality associated with cardiogenic shock (CS) complicating MI remains unacceptably high (4,5). Conventional

treatment with intravenous thrombolytic therapy has had limited impact on 30-day mortality in patients with MI after pump failure is diagnosed (6). Importantly, women may have a higher incidence of CS and mortality, complicating acute ST elevation MI, than that seen in men (4,7–20). However, whether there are gender differences in treatment approaches and clinical outcomes in patients with CS is less clear.

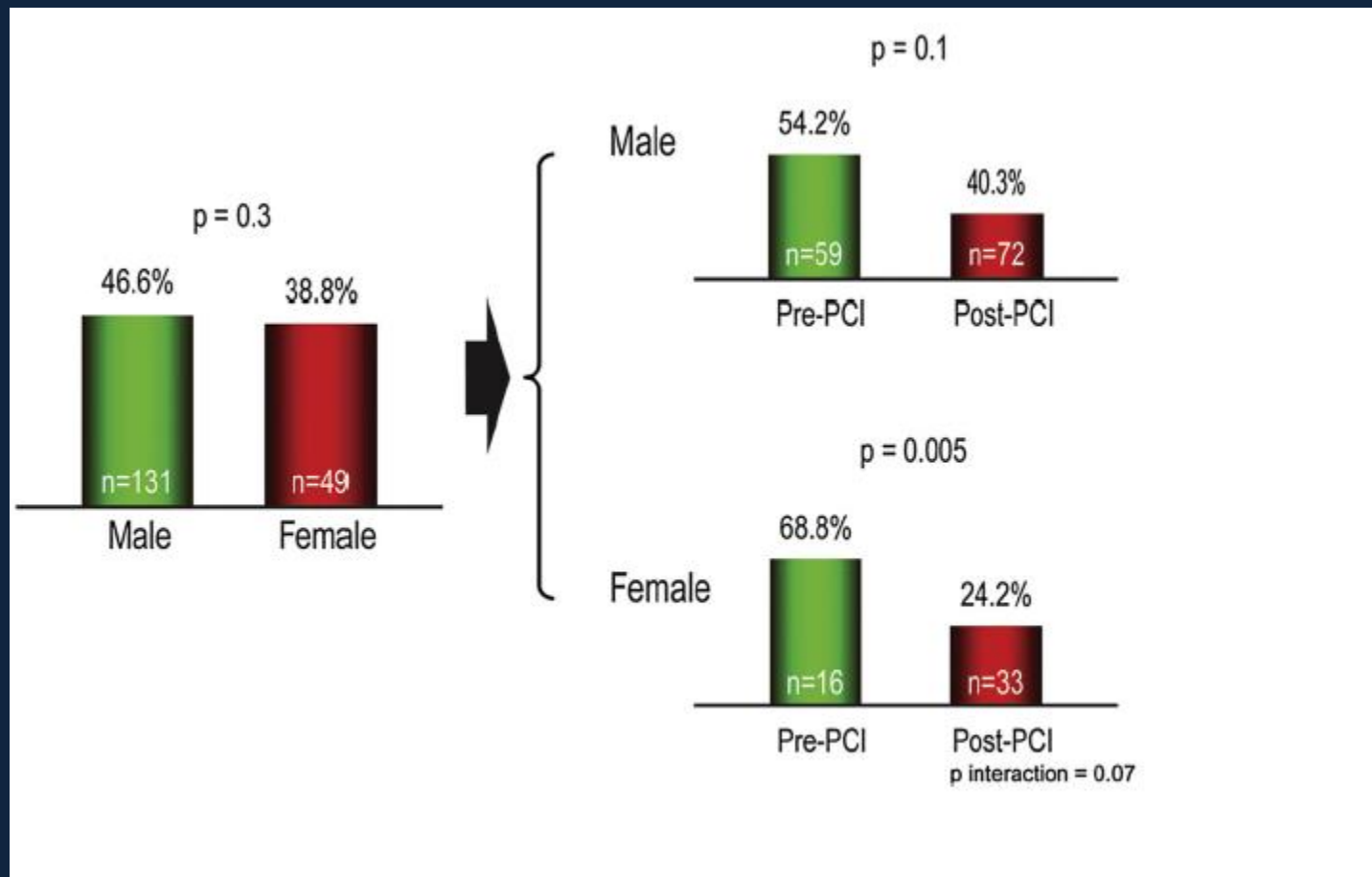
The SHOCK we emergently revascularize Occluded Coronaries for cardiogenic Shock (SHOCK) trial was a National Heart, Lung, and Blood Institute-sponsored multicenter study designed to assess the impact of a direct invasive strategy including emergent coronary angiography and revascularization on 30-day mortality in patients with AMI complicated by CS. In an effort to ensure that all potentially eligible patients were screened for the study, patients with any clinical or hemodynamic evidence of CS complicating an AMI who were not enrolled in the ran-

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Women With Cardiogenic Shock Derive Greater Benefit From Early Mechanical Circulatory Support: An Update From the cVAD Registry

Survival to Discharge stratified by sex and timing of Impella insertion



Key recommendations/future directions

- Still need to improve women participation in clinical trials
- Need to improve awareness of the patients, community and also health care providers especially in young women - public campaigns, patient focus educational meetings, etc
- Need to further investigate no atherosclerotic ACS and their diagnosis and treatment
- Need to provide specific protocols for women presenting with STEMI and ACS - think out of the box for young women
- Improve early recognition and treatment of MCS