

# PERCUTAENOUS MECHANICAL SUPPORT DEVICES IN WOMEN

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# DISCLOSURES

- Boston Scientific
- Abbott
- Edwards
- Abiomed

# OUTLINE

- Percutaneous Mechanical Support Devices
  - Cardiogenic Shock
  - High Risk PCI
- Use of support in women –is it different?
  - Risk Factors
  - Symptoms
  - Pathophysiology
  - Treatment
  - Outcomes

# CARDIOGENIC SHOCK

## Definition of Cardiogenic Shock

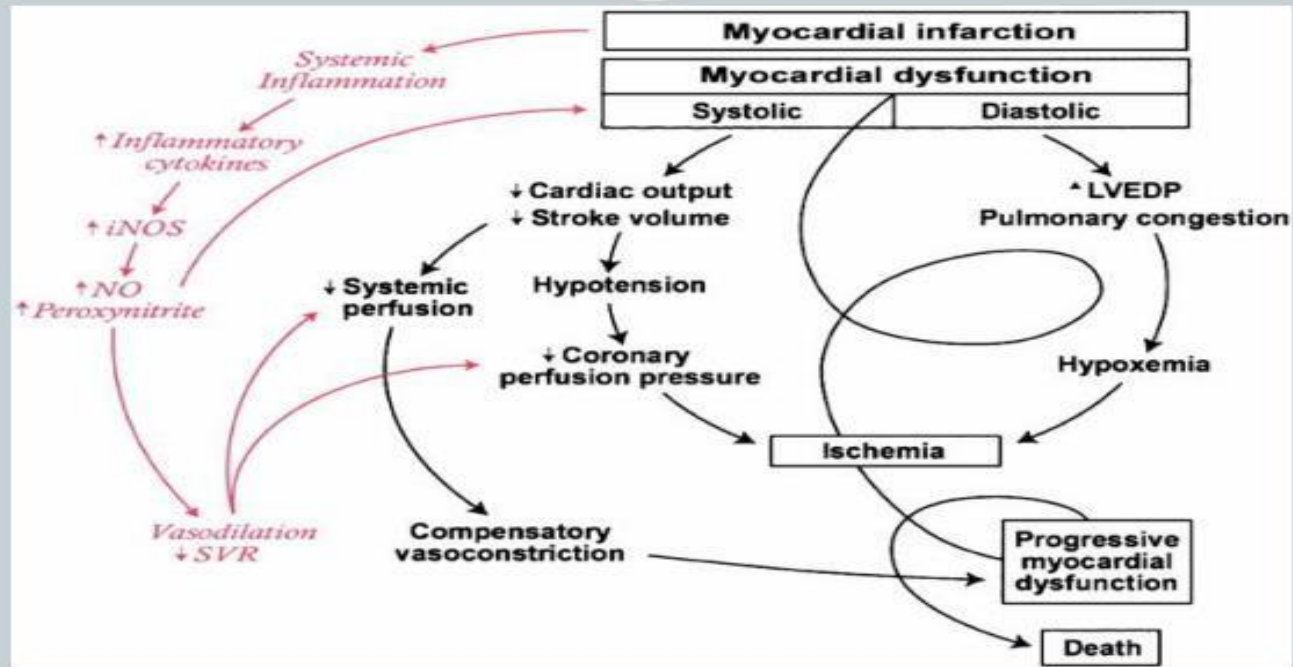


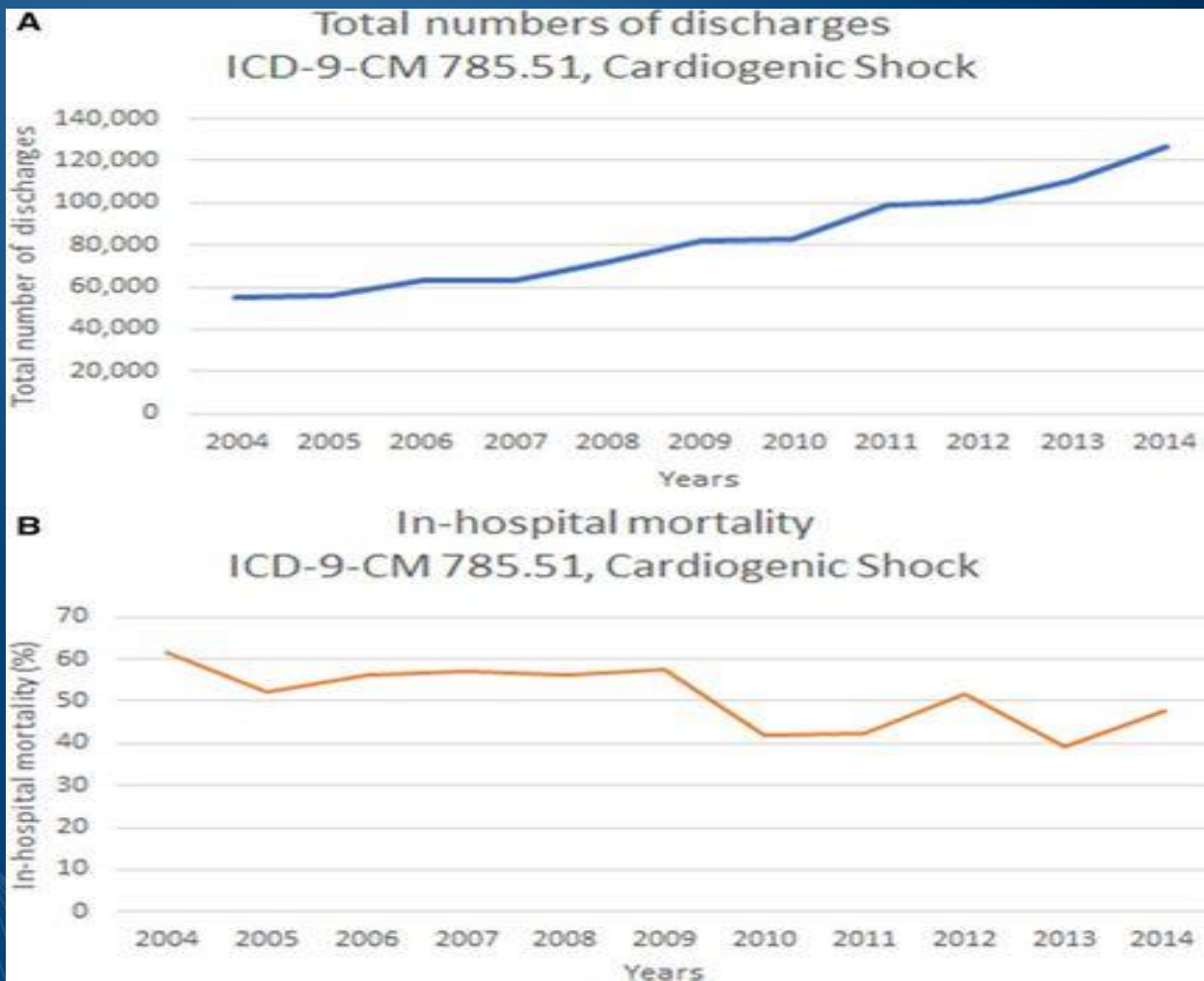
SBP < 90 mm Hg for at least 1 hour that is not responsive to fluid administration alone

Secondary to cardiac dysfunction

Associated with signs of hypoperfusion or a CI < 2.2 L/min/m<sup>2</sup> and a PAWP > 15 mmg Hg

# Pathophysiology of CS: Downward Spiral





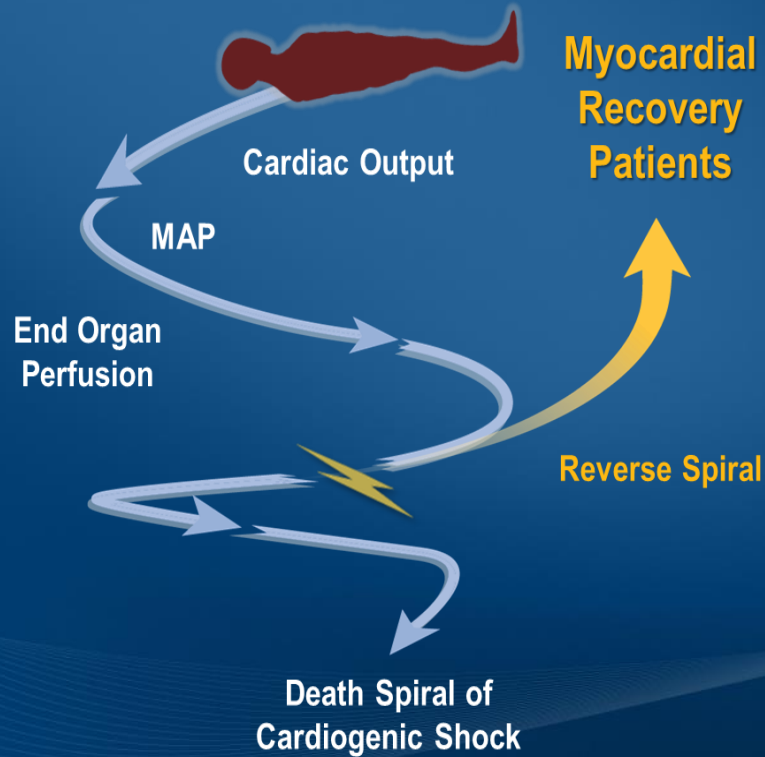
Aditya Mandawat. *Circulation: Cardiovascular Interventions*.  
Percutaneous Mechanical Circulatory Support Devices in  
Cardiogenic Shock, Volume: 10, Issue: 5, DOI:  
(10.1161/CIRCINTERVENTIONS.116.004337)

# EXPANDING CARDIOGENIC SHOCK PATIENT IDENTIFICATION

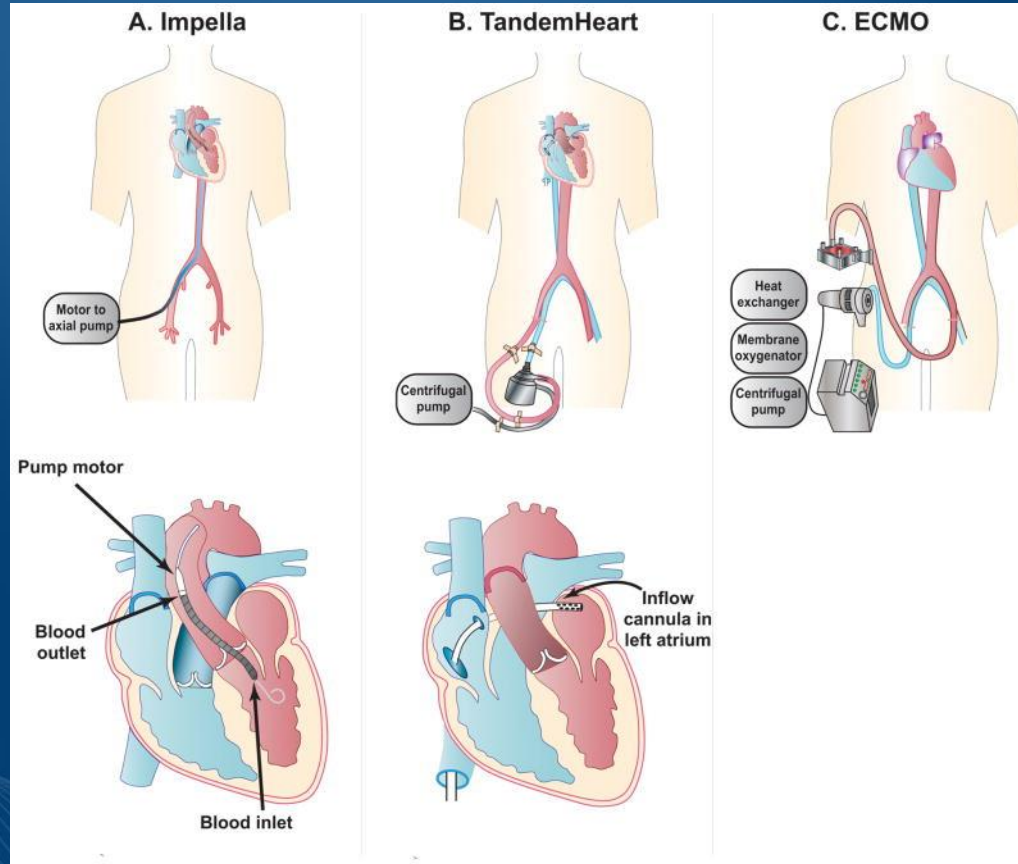
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## *Cardiogenic Shock Therapy*

*AMI, SCAD, Cardiomyopathy (Peripartum, Myocarditis), Postcardiotomy*



# Percutaneous Mechanical Support Options





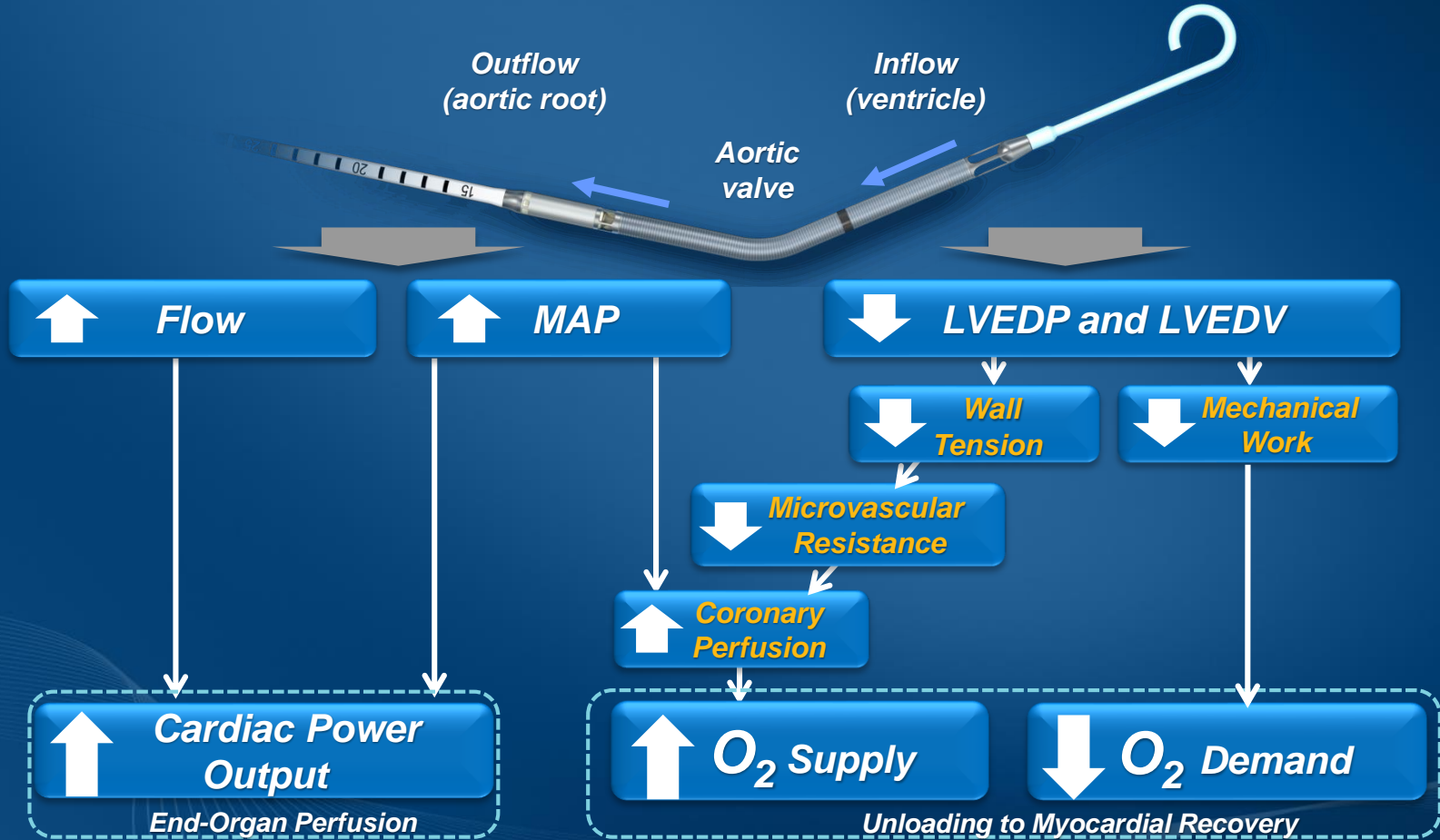
**A** TandemHeart with dual lumen cannula



**B** Impella RP



# HEMODYNAMIC EFFECTS OF IMPELLA® DEVICE SUPPORT



Suga H, et al. *Am J Physiol*. 1979;236(3):H498-H505.

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Burkhoff D, et al. *Am J Physiol Heart Circ Physiol*. 2005;289:H501-H512.

Burkhoff D, et al. *Mechanical Properties of the Heart and its Interaction with the Vascular System [white paper]*. January 2011.

Sauren LDC, et al. *Artif Organs*. 2007;31(11):839-842.

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Rimmelink M, et al. *Catheter Cardiovasc Interv*. 2007;70(4):532-537.

Agel RA, et al. *J Nucl Cardiol*. 2010;17(1):158-160.

Lam K, et al. *Clin Res Cardiol*. 2009;98(5):311-318.

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Valgimigli M, et al. *Catheter Cardiovasc Interv*. 2005;65(2):263-267.

Rimmelink M, et al. *Catheter Cardiovasc Interv*. 2010;75(2):187-194.

Weber DM, et al. *Cardiac Intervent Today*. 2009;Aug/Sept(suppl):3-16.

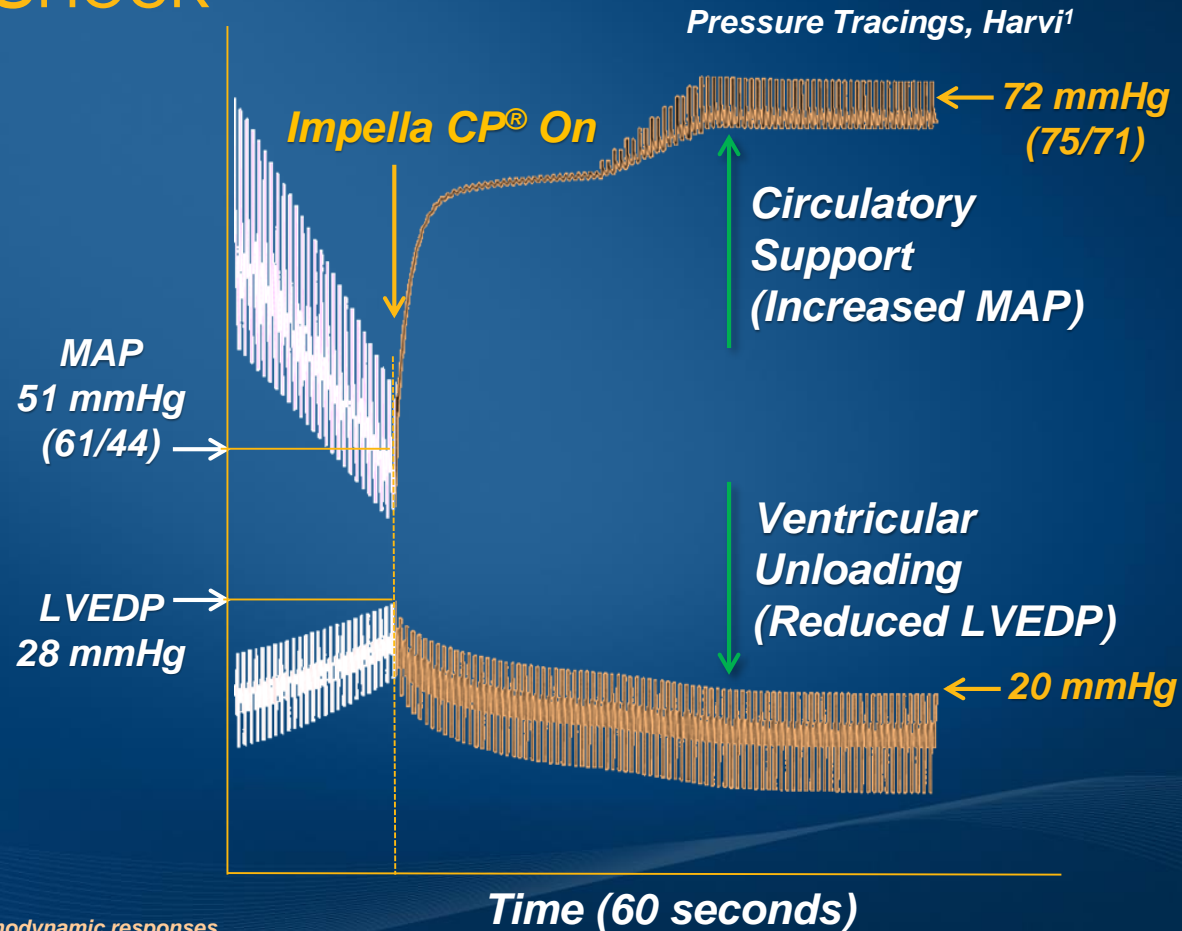
Naidu S, et al. *Circulation*. 2011;123(5):533-543.

Fincke J, et al. *J Am Coll Cardiol*. 2004;44:340-348.  
den Uil CA, et al. *Eur Heart J*. 2010;31:3032-3039.  
Mendoza DD, et al. *Am Heart J*. 2007;153(3):366-370.  
Torgersen C, et al. *Crit Care*. 2009;13(5):R157.  
Torre-Amione G, et al. *J Cardiac Fail*. 2009;15:639e644.

# HEMODYNAMICS OF IMPELLA® DEVICES IN AMI CARDIOGENIC SHOCK

## Case Example\*

- 49-year-old male
- Cold, clammy skin
- Tachycardia
- Cardiac output: 3.3 L/min
- Wedge pressure: 22 mmHg
- 75% Left main
- MAP 51 mmHg, LVEDP 28 mmHg



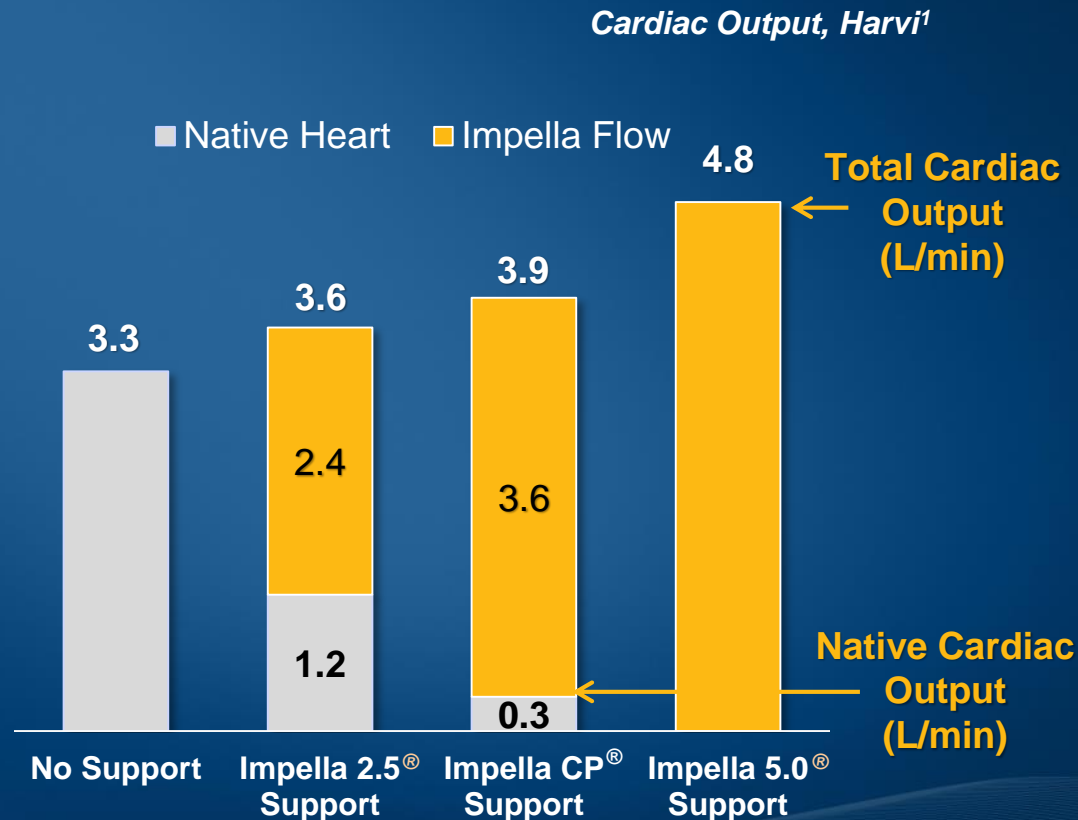
\*Not all patients will experience the same clinical outcomes or hemodynamic responses.

1. Santamore WP, Burkhoff D. Am J Physiol. 1991;260(1 Pt 2):H146-H157.

# HEMODYNAMICS OF IMPELLA® DEVICES IN CARDIOGENIC SHOCK

## Case Example\*

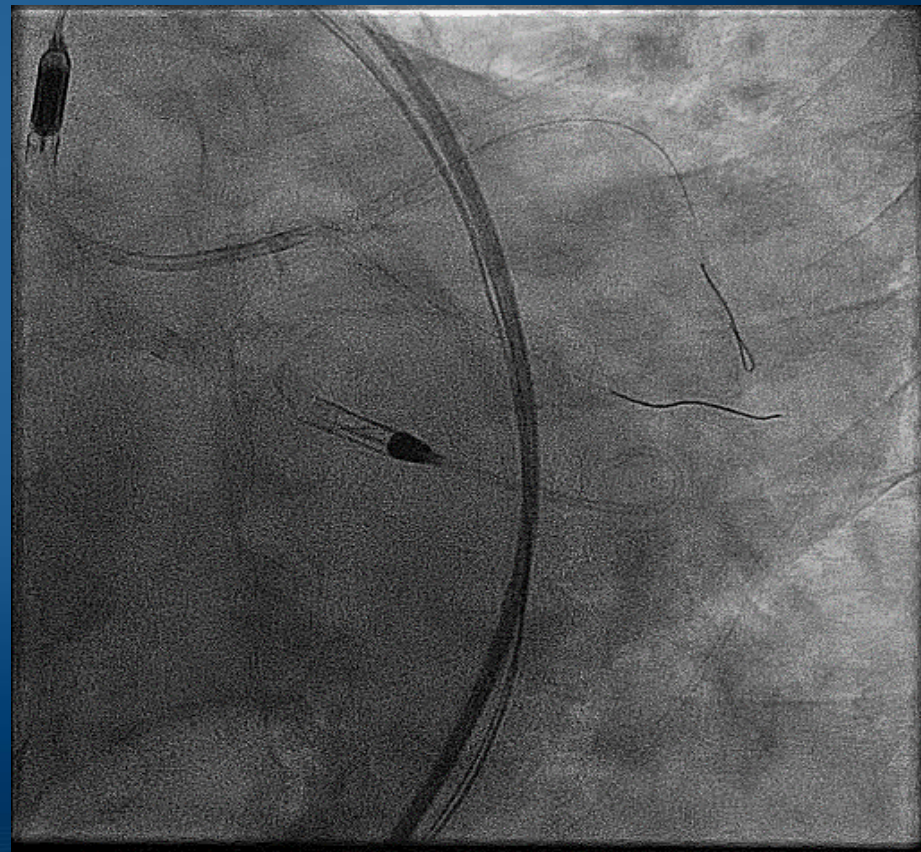
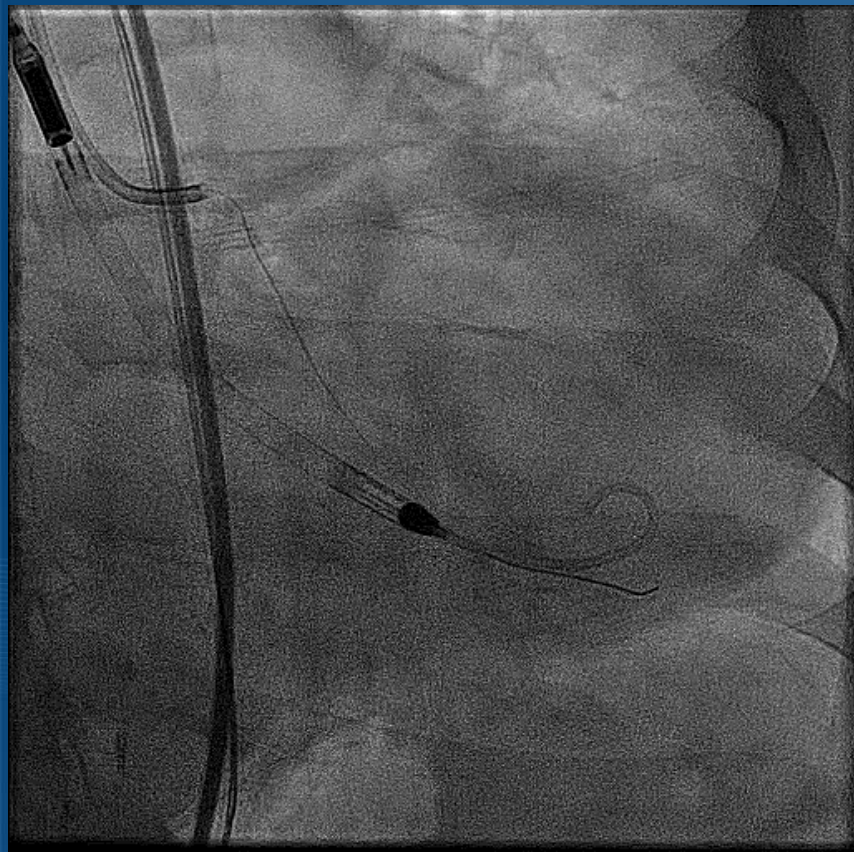
- Heart rate: 122
- Ejection fraction: 13%
- Cardiac output: 3.3 L/min
- Wedge pressure: 22 mmHg
- 75% Left main
- MAP: 62 mmHg (declining)
- LVEDP: 25 mmHg (climbing)



\*Not all patients will experience the same clinical outcomes or hemodynamic responses.

1. Santamore WP, Burkhoff D. Am J Physiol. 1991;260(1 Pt 2):H146-H157.





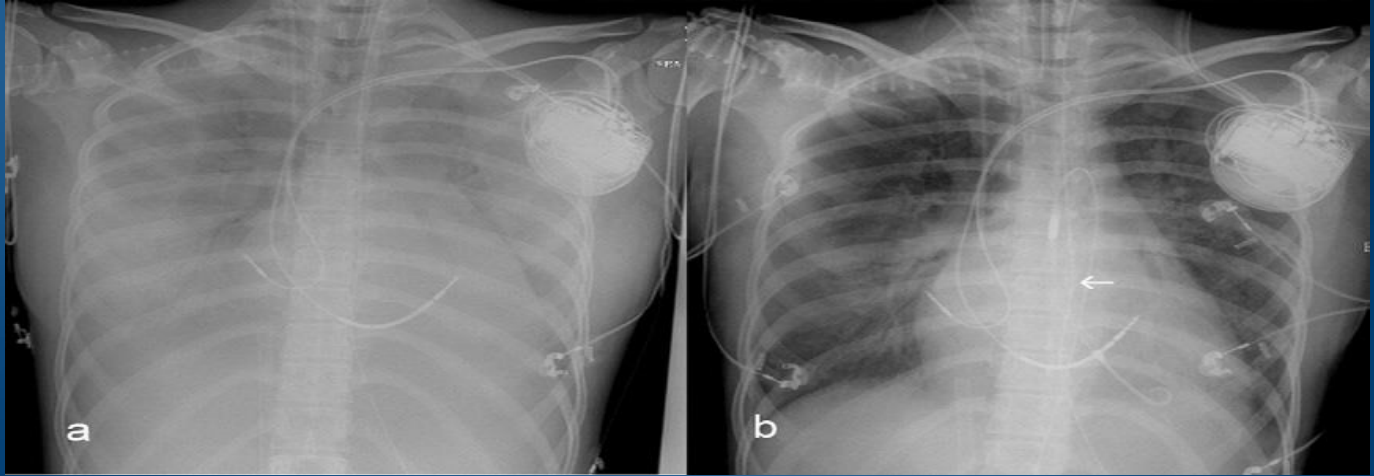
# WHY HEART/LUNG INJURY WITH ECMO?



- *ECMO results in LV loading from residual RV flow and bronchial flow (up to 15 to 20% CO)*
- *LV must eject or pulmonary hemorrhage ensues*
- *LV ejection often maintained through use of inotropes*



# WHY HEART/LUNG INJURY WITH ECMO?

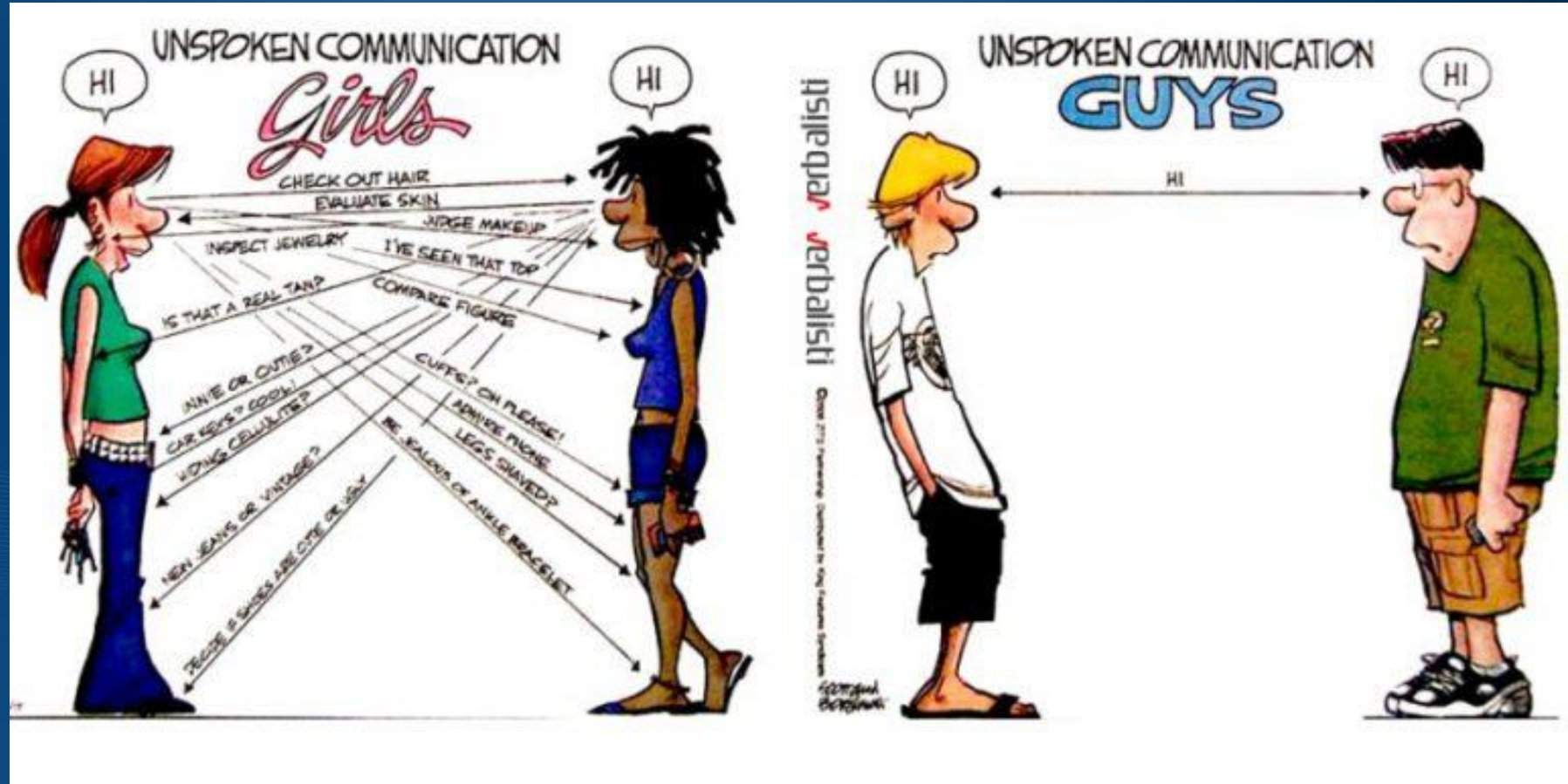


**VA ECMO**

**After Impella®  
Device  
Decompression**



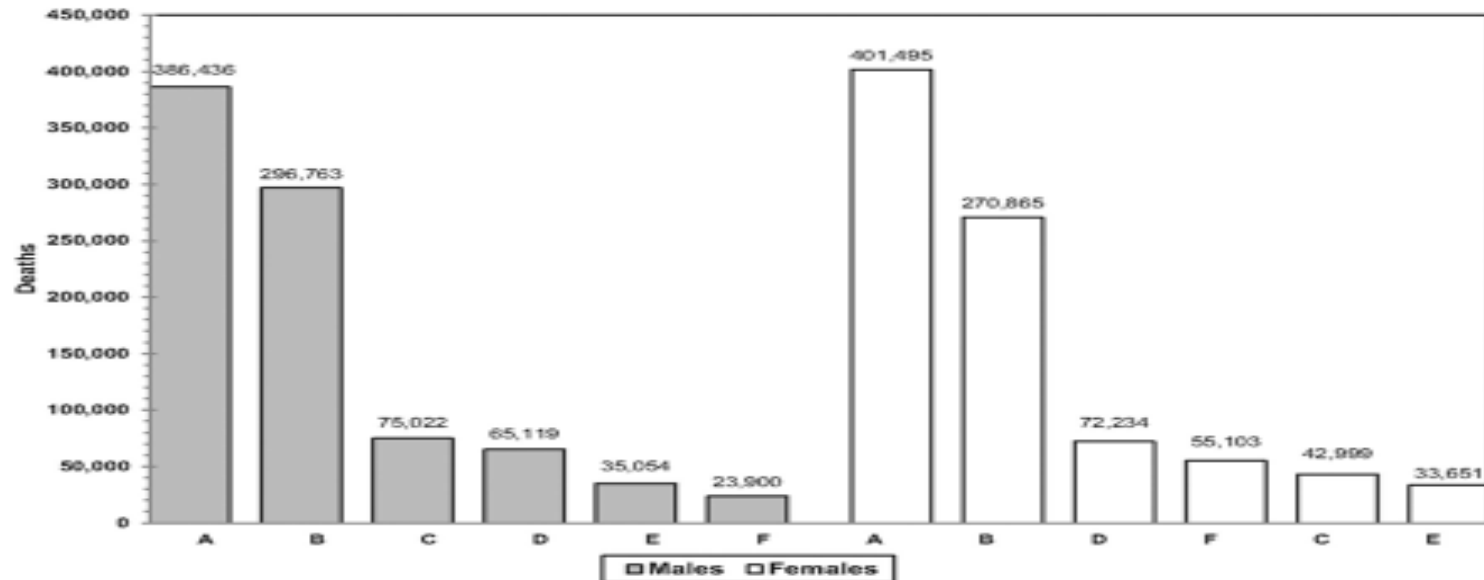
# ARE THERE GENDER DIFFERENCES?





# CARDIOVASCULAR Dz REMAINS THE #1 CAUSE OF DEATH FOR BOTH MALES AND FEMALES

Cardiovascular disease and other major causes of death for all males and females (United States: 2009).



Alan S. Go et al. Circulation. 2013;127:e6-e245



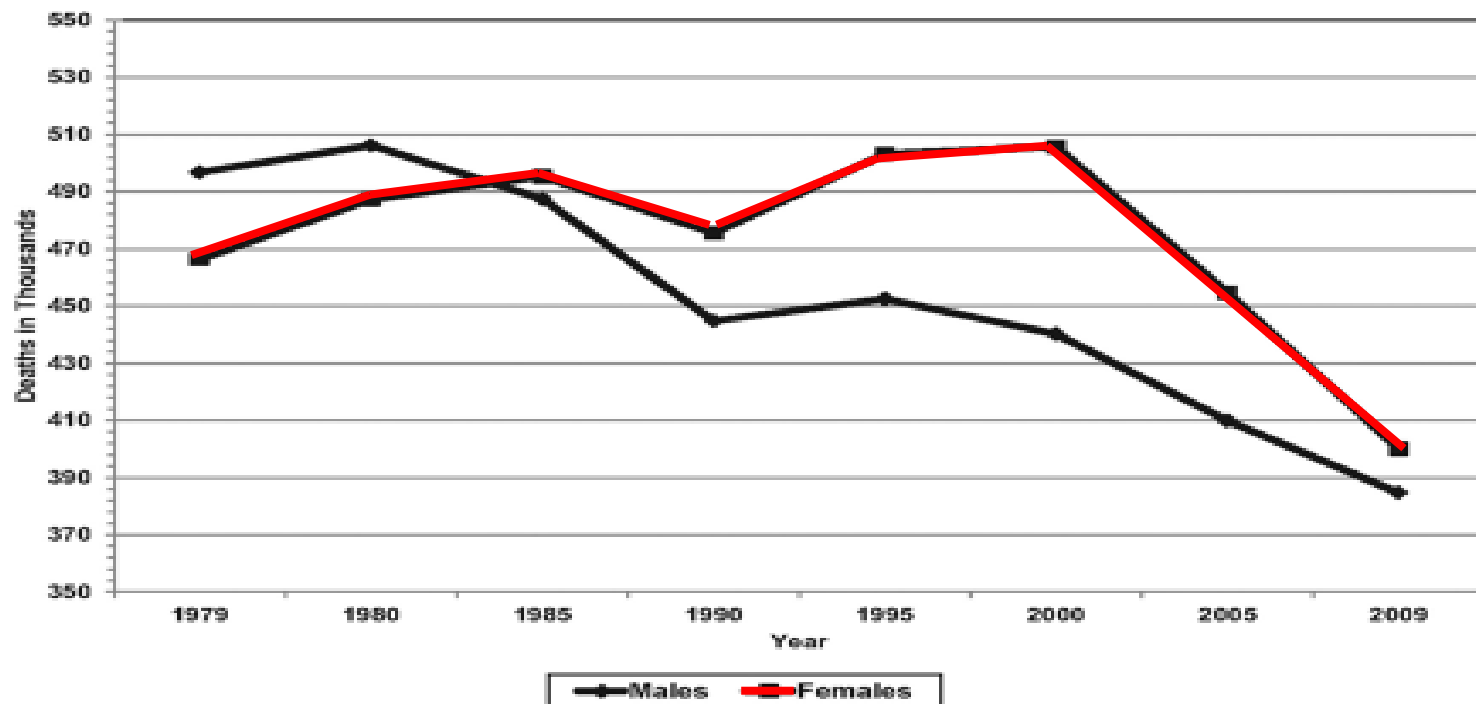
Copyright © American Heart Association, Inc. All rights reserved.

- A: Cardiovascular Disease
- B: Cancer
- C: Accidents

- D: Chronic Lower Respiratory Dz
- E: Diabetes
- F: Alzheimer's Dz

# SINCE 1984, CVD DEATHS FOR FEMALES HAS EXCEEDED THOSE FOR MALES

Cardiovascular disease mortality trends for males and females (United States: 1979–2009).



Alan S. Go et al. *Circulation*. 2013;127:e6-e245

# SO THERE ARE DIFFERENCES.....



**1 in 3** women die from cardiovascular diseases each year.



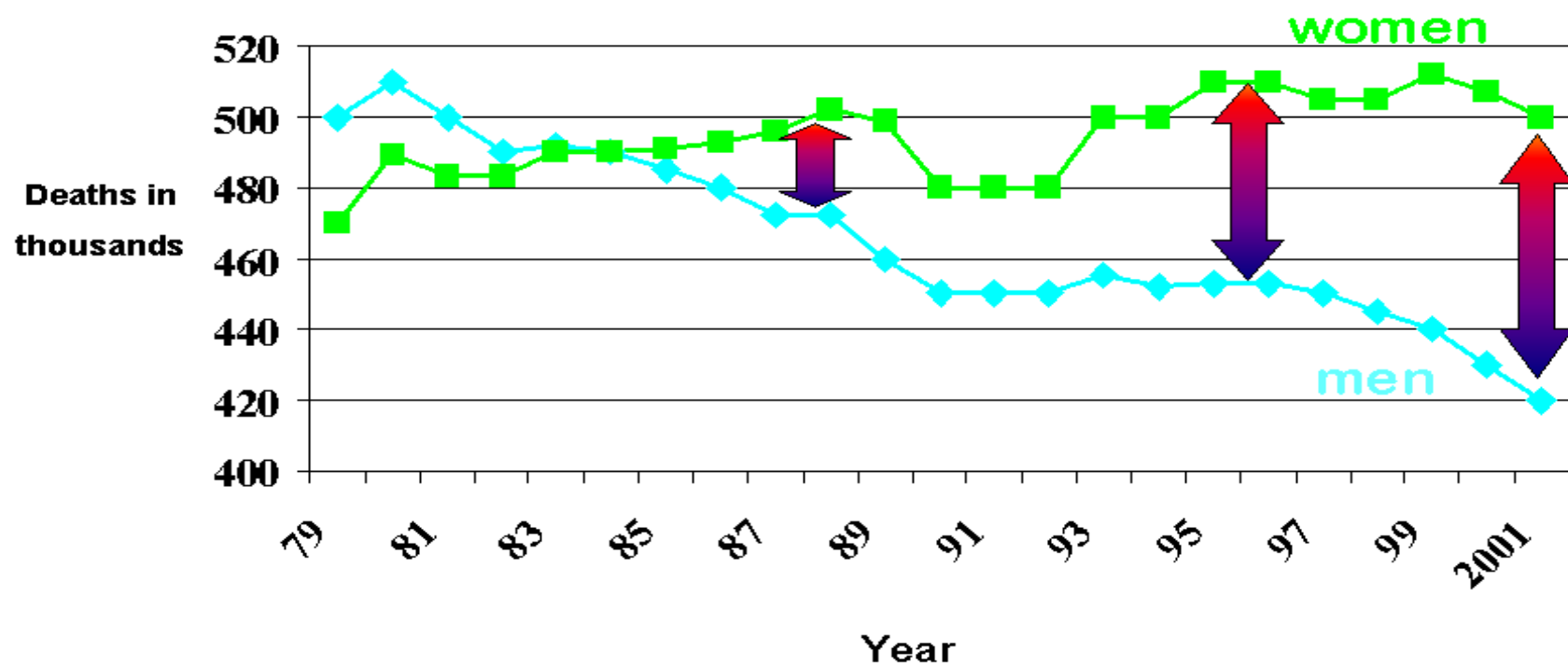
Heart disease is the  
**#1 killer**  
of women

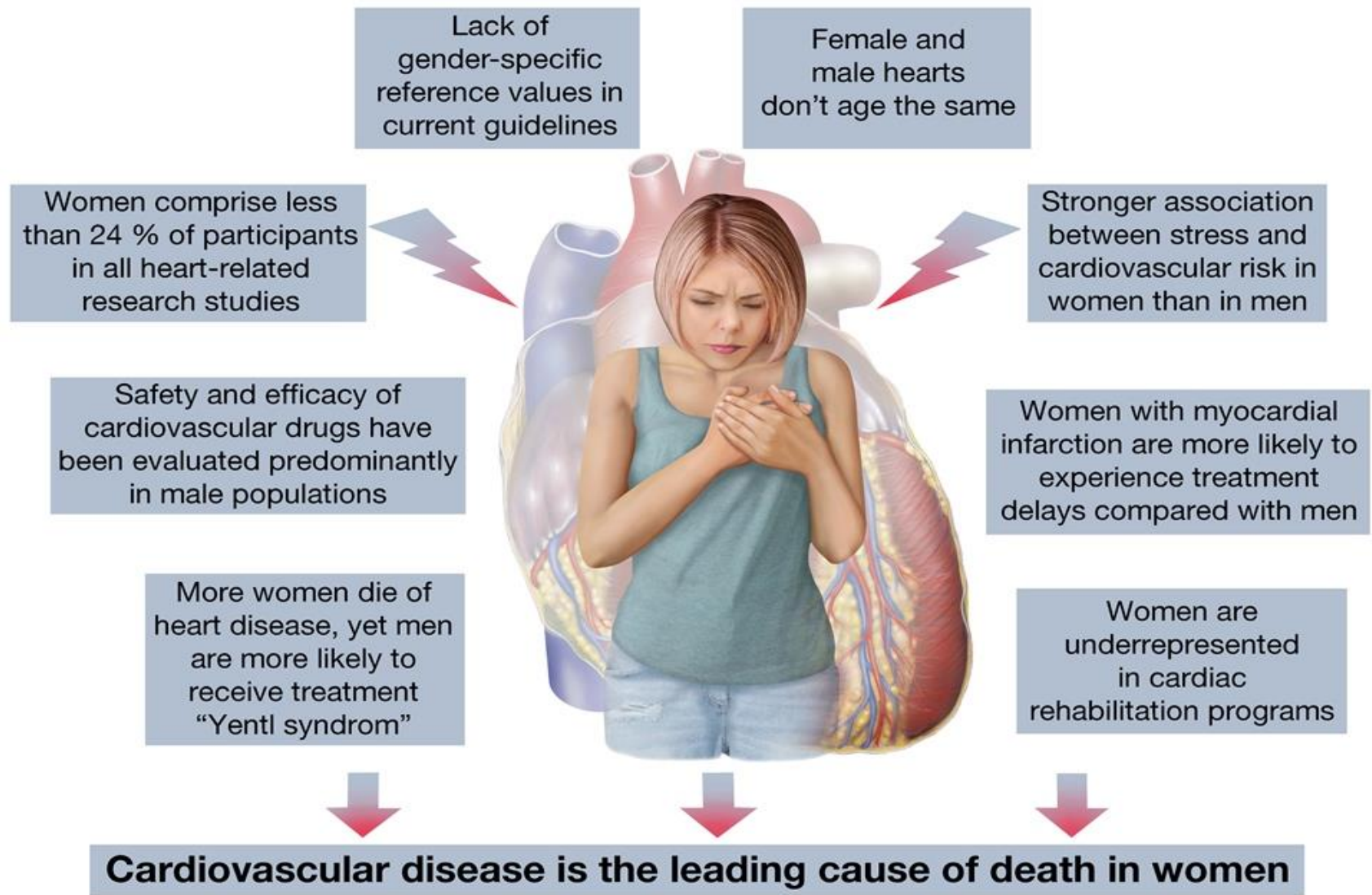
To compare, **1 in 30** women die from breast cancer each year.



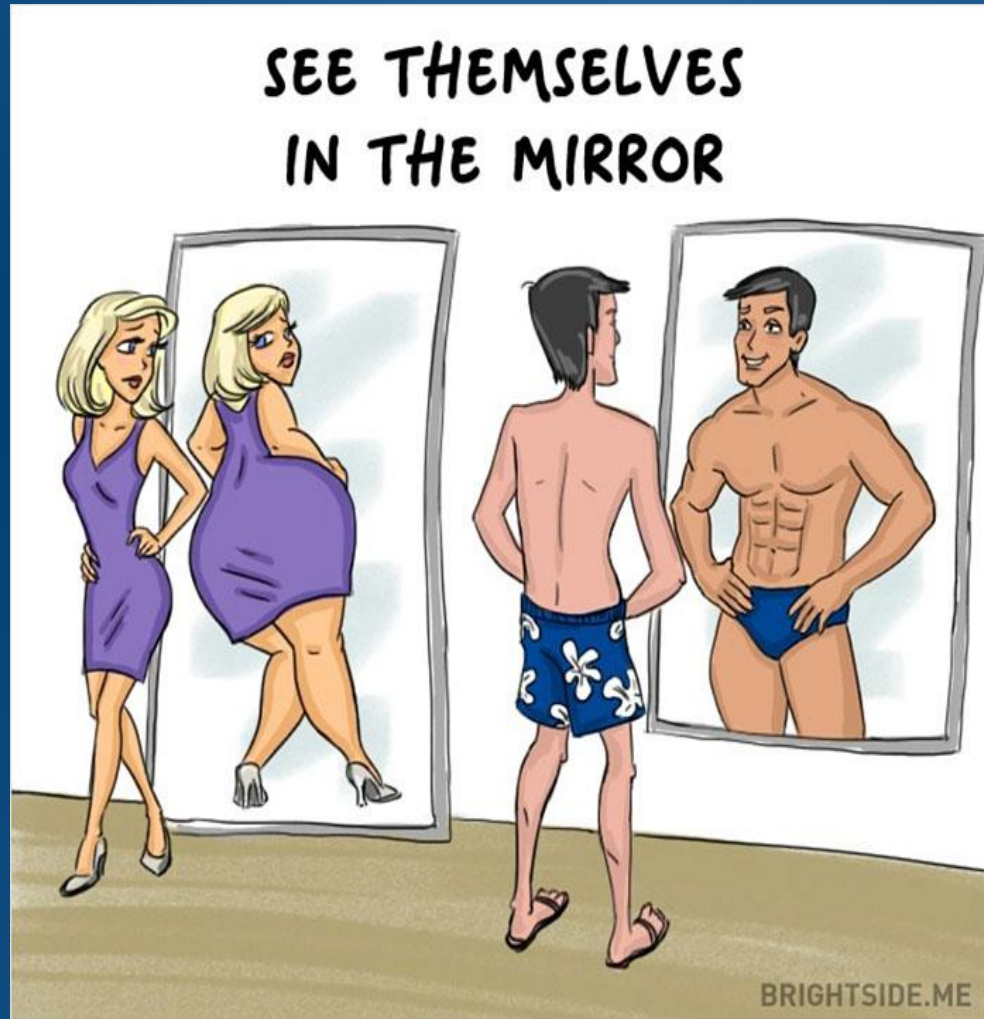
# Cardiovascular Disease Mortality Trends

*Women's rates are not declining in line with men's*





# A FEW WAYS HEART DISEASE IN WOMEN DIFFERS...



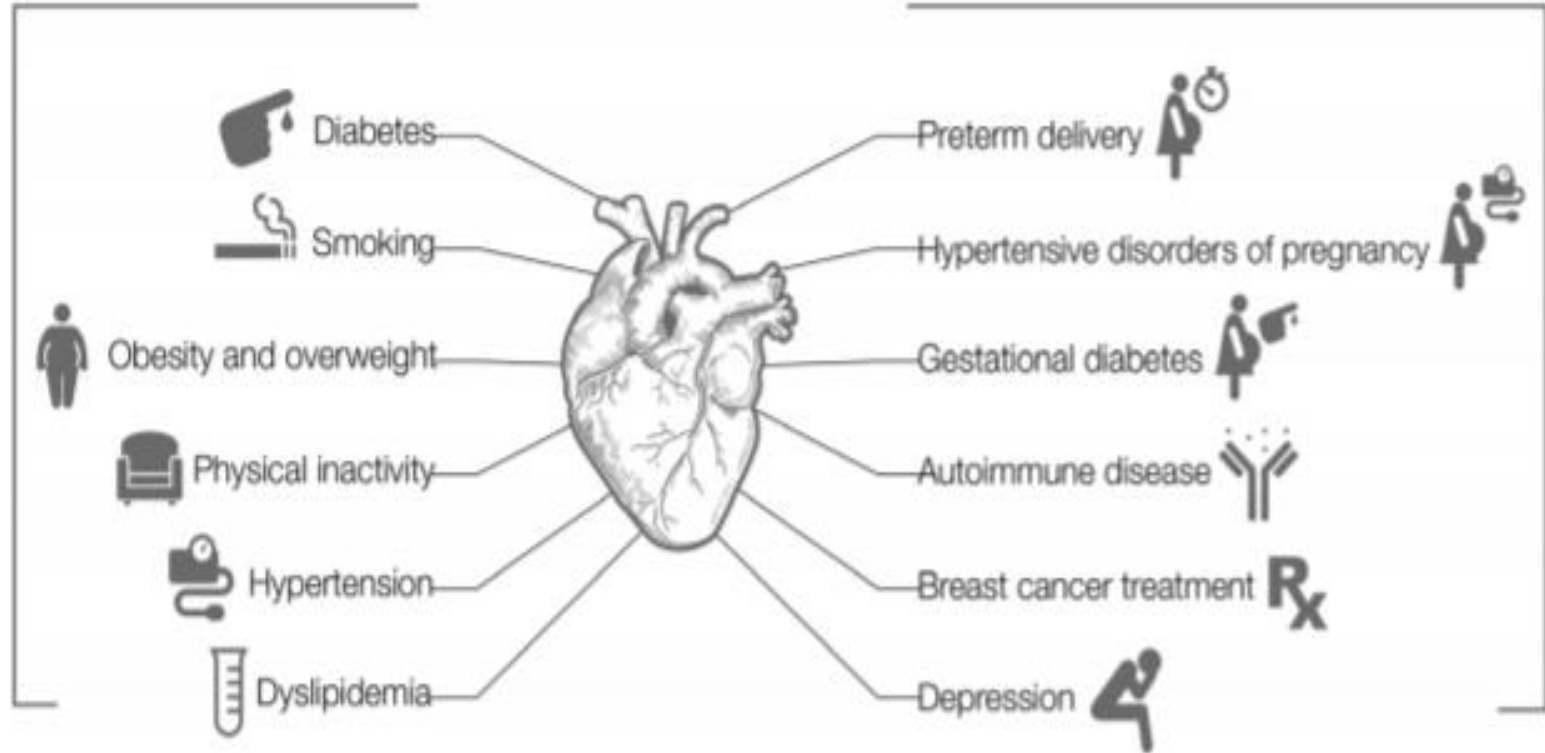
- Risk Factors
- Symptoms
- Pathophysiology
- Treatment
- Outcomes



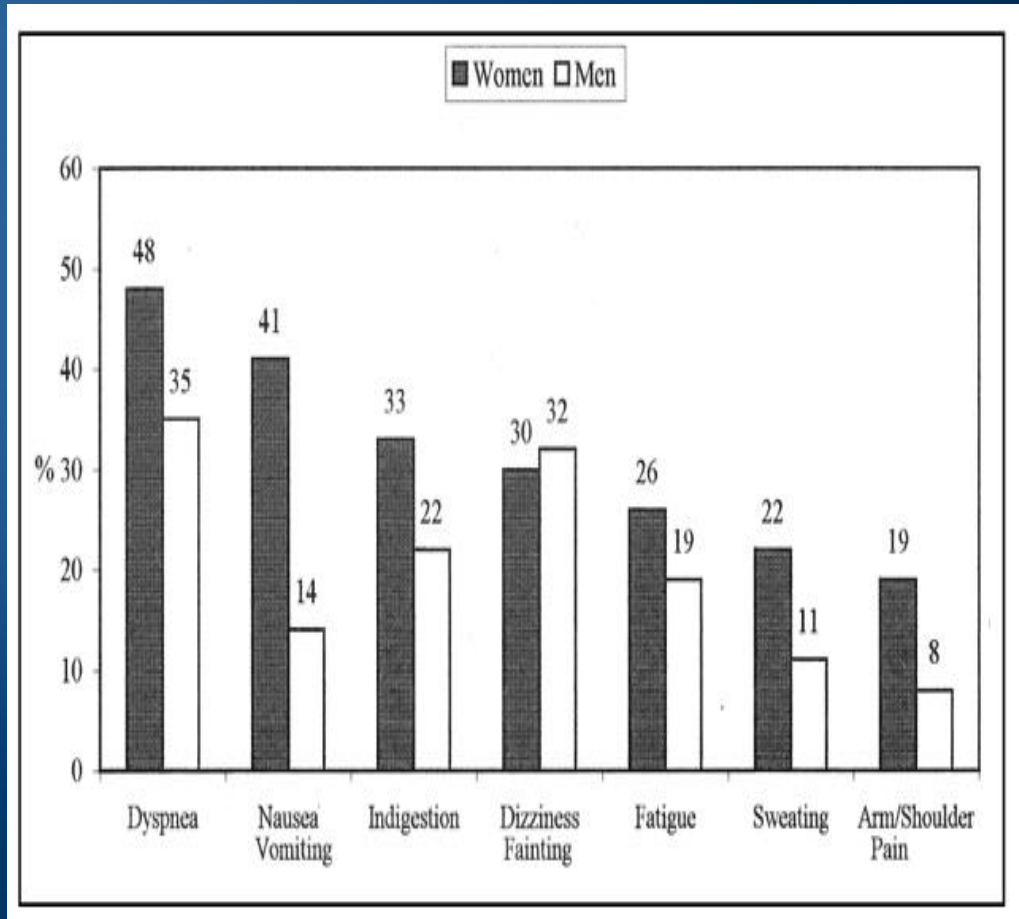
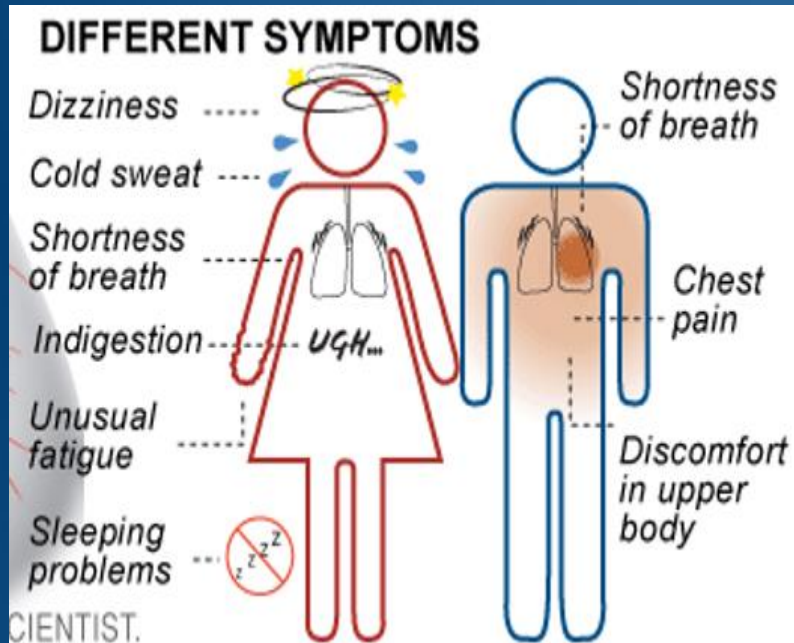
# CV Risk Factors in Women

## Traditional ASCVD Risk Factors

## Emerging, Nontraditional ASCVD Risk Factors



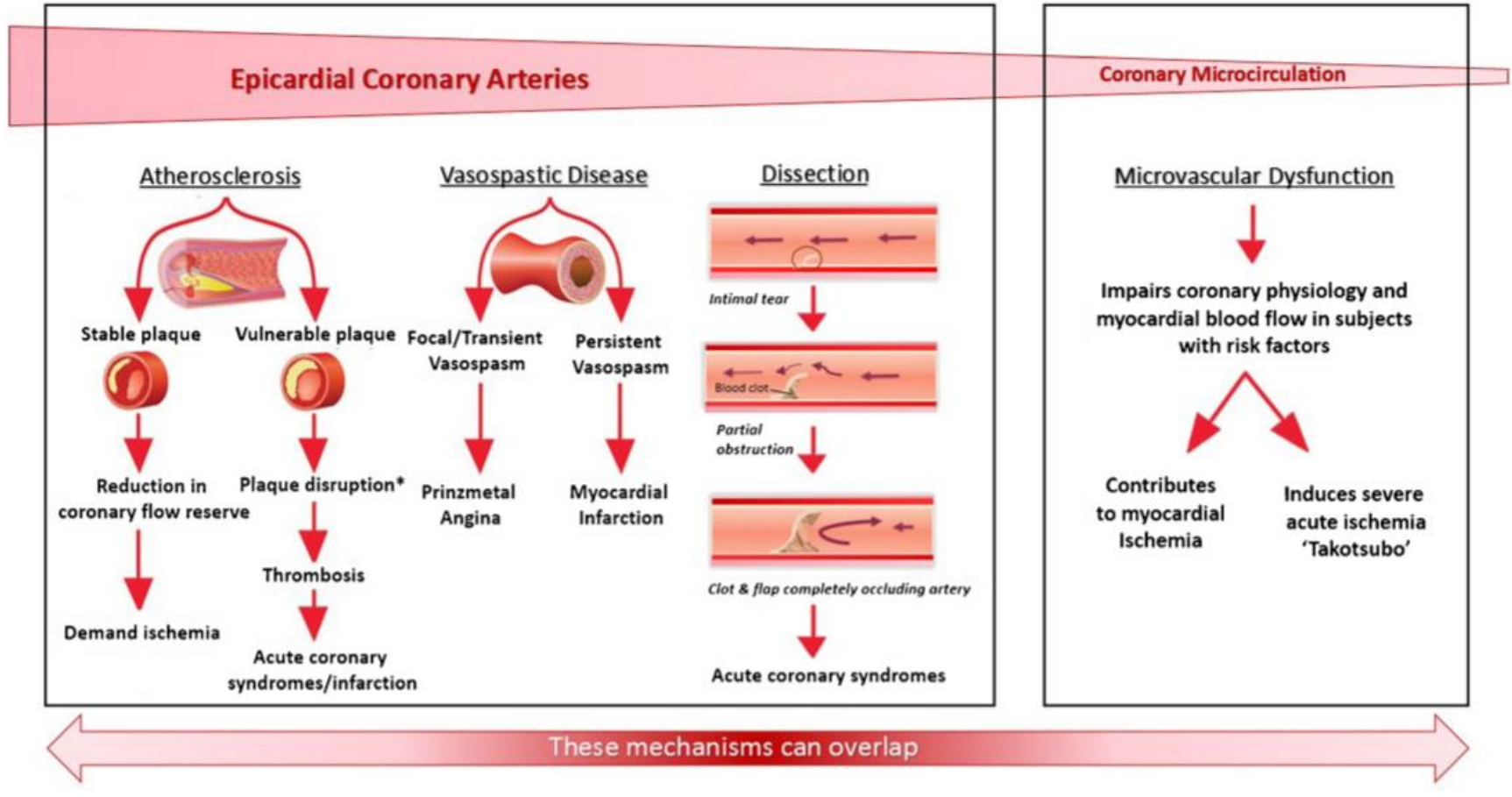
# SYMPTOM VARIATION IN WOMEN





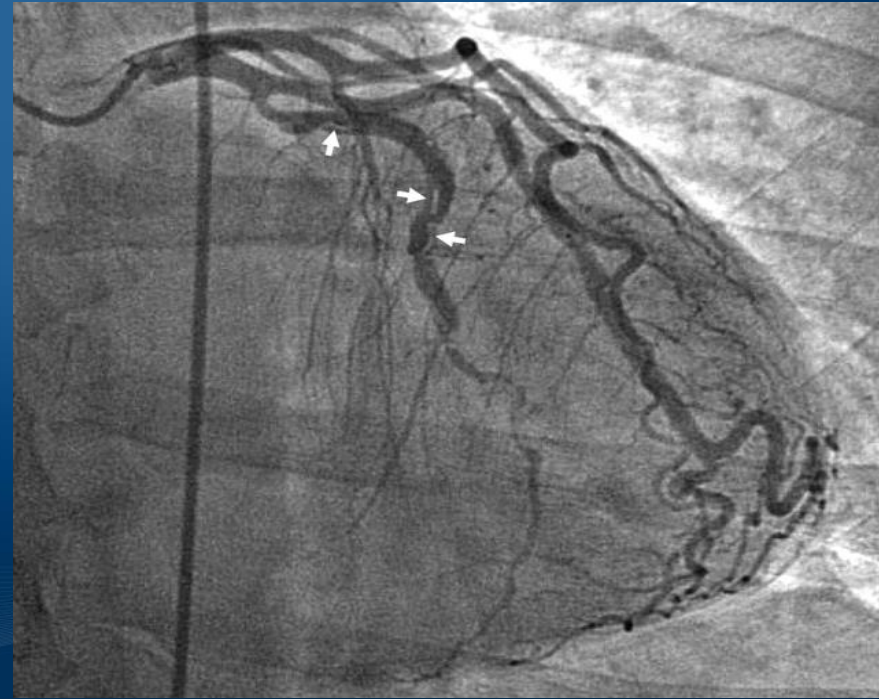
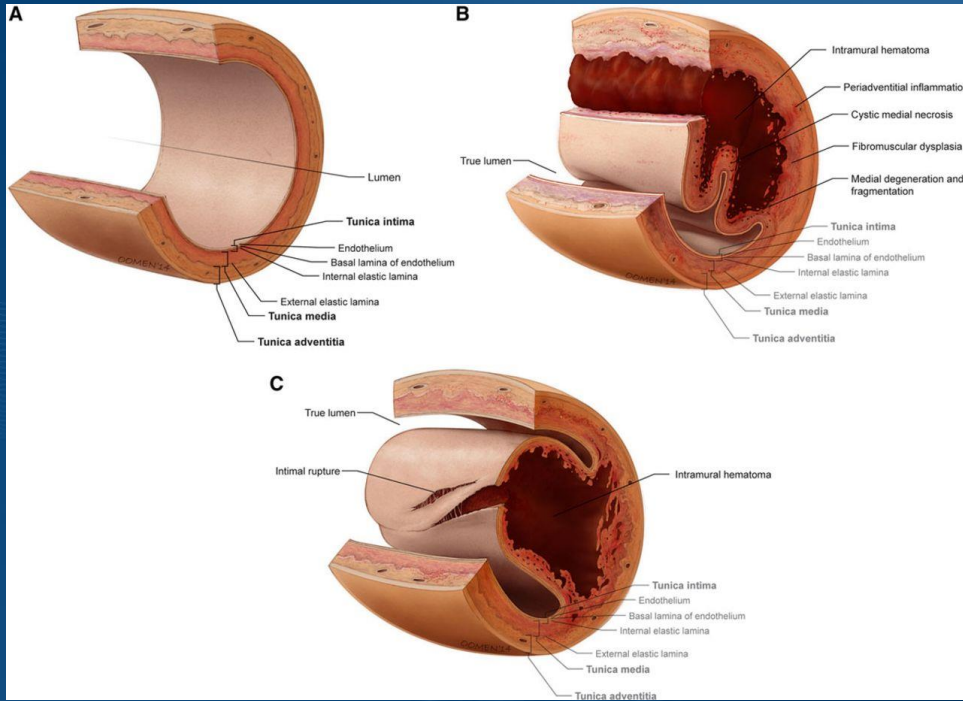
# FEMALE SPECIFIC PATHOPHYSIOLOGY

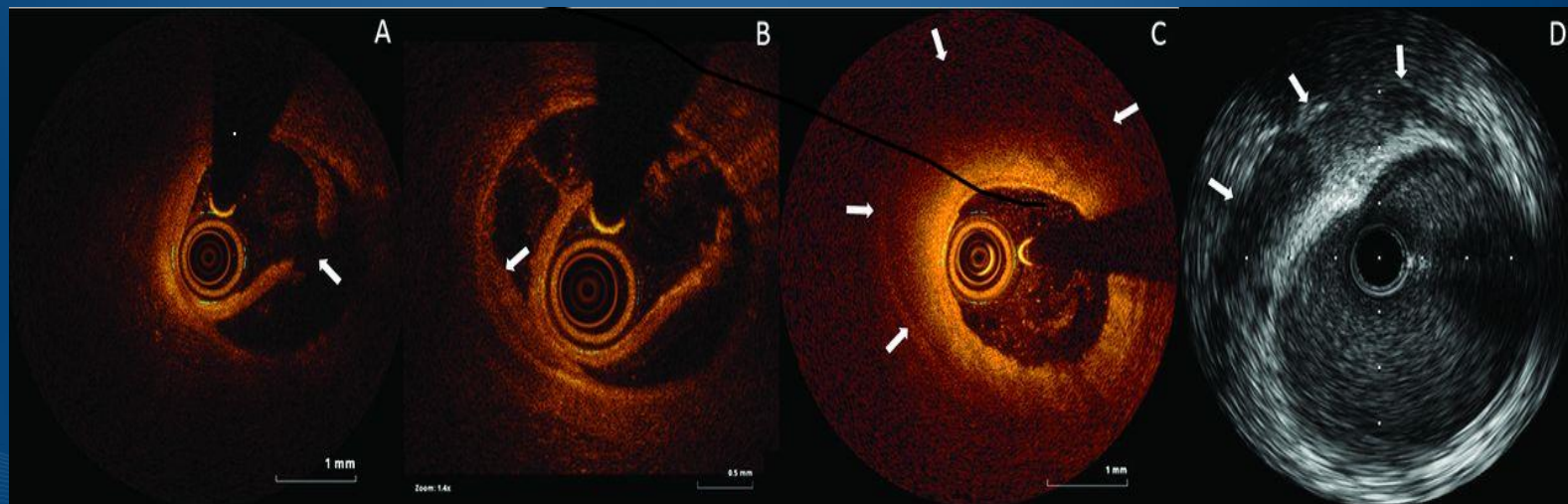
## Mechanisms of Myocardial Ischemia

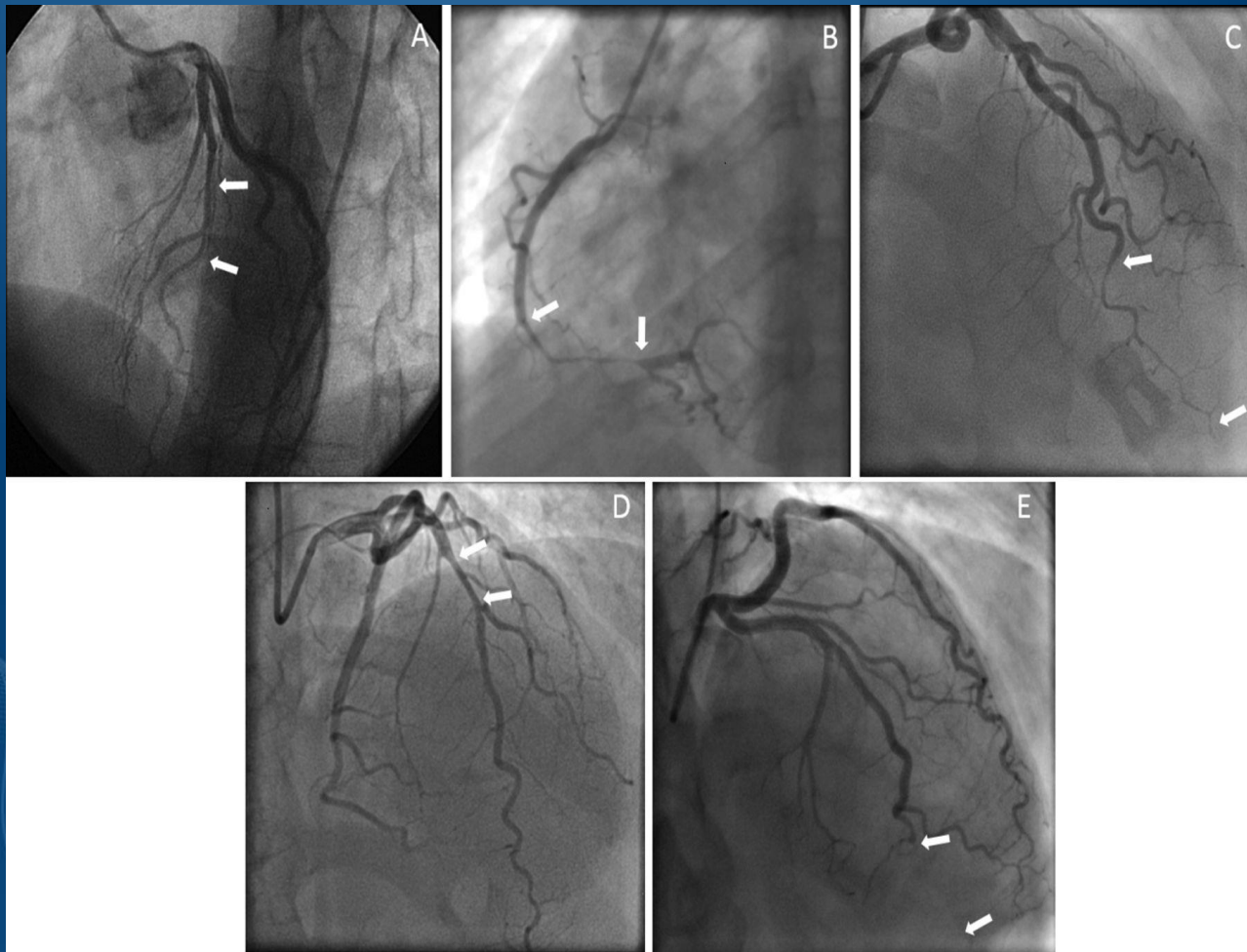


# SCAD: WHAT IS IT?

- “Spontaneous Coronary Artery Dissection”
  - Spontaneous tear or separation of the coronary arterial wall leading to narrowing or blockage of the artery
  - Spectrum of clinical presentations from chest pain to heart attack, lethal heart rhythms, cardiogenic shock and death









# SCAD: HOW OFTEN DOES IT OCCUR?

- True incidence unknown
- 80% female with mean age 42 (Mayo Clinic Study)
- Retrospective registries report SCAD in 0.07%-1.1% of all coronary angiograms performed
- Single center with world renowned SCAD expert reported 24% prevalence in women <50yo who had a heart attack

# SCAD: RISK FACTORS AND TRIGGERS

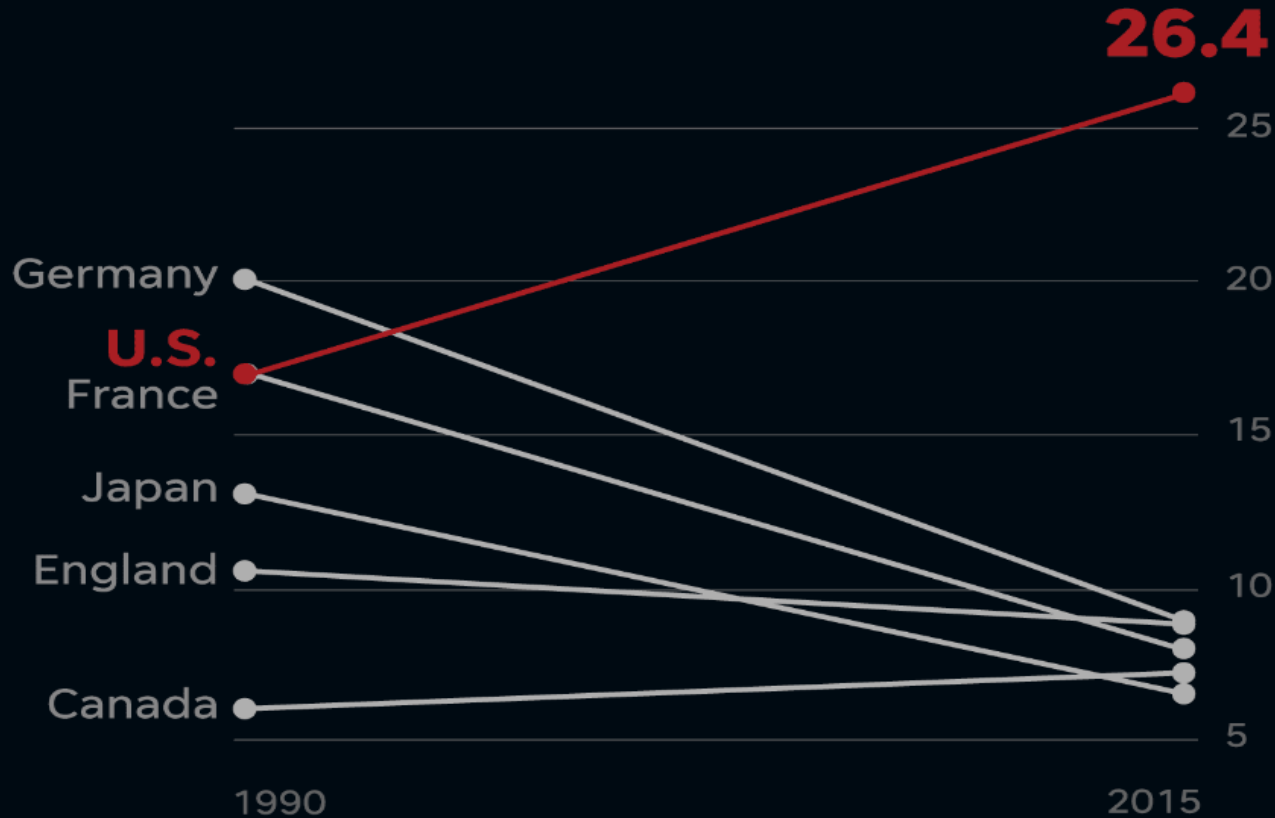
- Risk Factors
  - Underlying arteriopathy (fibromuscular dysplasia, connective tissue disorders)
  - Pregnancy (multiple, peri-partum)
  - Hormone therapy
  - Coronary artery spasm
  - Systemic inflammation (lupus, sarcoid, crohn's disease)
- Triggers
  - Intense exercise (aerobic or isometric)
  - Intense emotional stress
  - Labor and delivery
  - Intense Valsalva (severe repetitive coughing, retching/vomiting, BM)
  - Cocaine, amphetamines, metamphetamines

# SCAD: TREATMENT AND PROGNOSIS

- Optimal treatment in this patient population is still unknown
  - It is unclear if standard medical therapy for ACS is beneficial in SCAD
  - Conservative treatment preferred for stable patients as the natural history is that the majority heal spontaneously
  - Success rate of PCI and long term durability in SCAD are poor, 65% and 30% respectively
  - Long term durability with CABG poor with >70% grafts occluded at FU
- In hospital and 1 year mortality similar at 1%-5%
  - Recurrent dissection rate 13-17%
  - Strongest predictors of death:
    - Female Sex
    - Absence of Early Treatment
  - Postpartum SCAD have worst prognosis with larger infarcts and lower LVEFs

# MATERNAL MORTALITY IS INCREASING IN THE US

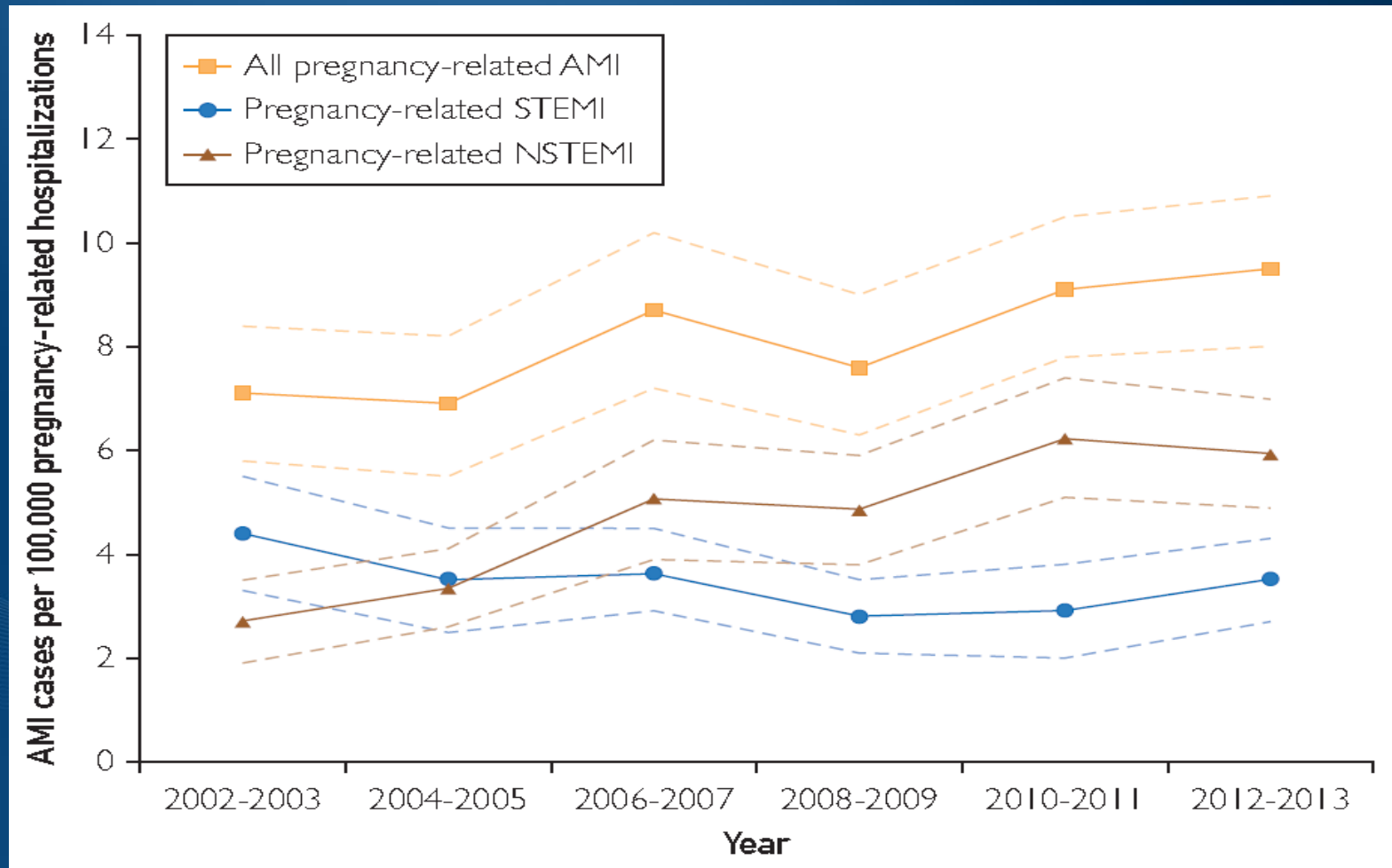
From 1990 to 2015, the number of maternal deaths per 100,000 births in most developed nations has been flat or dropping. In the U.S., the rate has risen sharply.



SOURCE The Global Burden of Disease 2015 Maternal Mortality study as published in The Lancet medical journal.



# PREGNANCY RELATED AMIs INCREASING OVER TIME

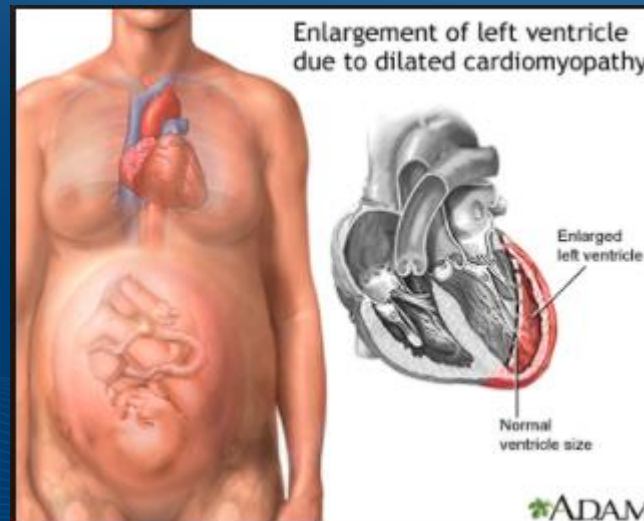


# PERIPARTUM CARDIOMYOPATHY: WHAT IS IT?

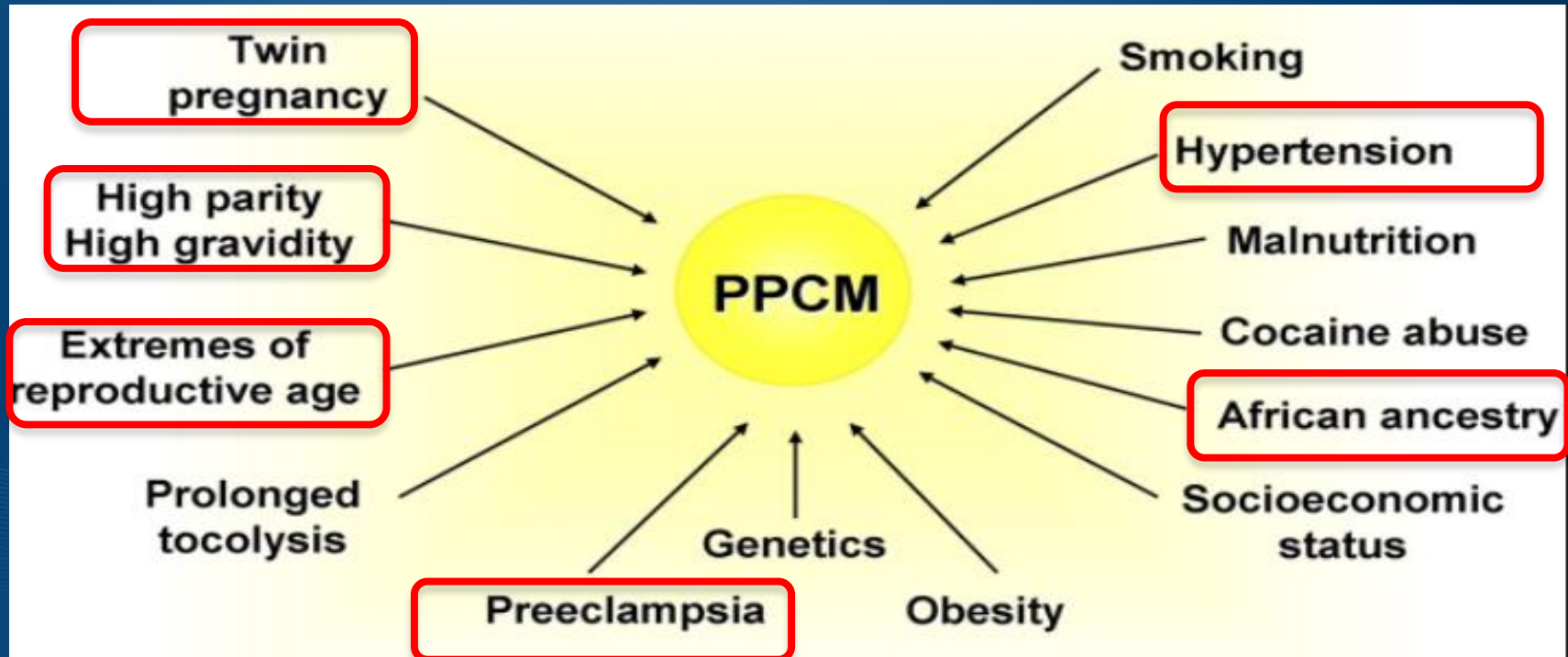
- Heart Failure within:
  - last month and up to 5 months after pregnancy
- Absence of prior heart disease
- No identifiable cause of heart failure
- LVEF<45%

# PERIPARTUM CARDIOMYOPATHY: HOW OFTEN DOES IT OCCUR?

- In US, incidence ranges from 1000-4000 live births
  - Wide range bc underreporting, different population demographics, rigor of definition
- >50% in southern US
- Relatively uncommon but incidence is rising



# PERIPARTUM CARDIOMYOPATHY: WHAT ARE THE RISK FACTORS?



# PERIPARTUM CARDIOMYOPATHY: PROGNOSIS

- In-hospital mortality 1.3%, overall long term mortality 10%
- Recovery often occurs within 2-6 months after diagnosis but may be delayed up to 5 years
- 20-25% progress to end-stage HF
- 4-11% receive LVADs or heart transplant
  - INTERMACS Study 2014:
    - 8% women received LVADs had PPCM and had better survival vs non PPCM
    - 48% of these received heart transplants
    - Only 6% had native heart recovery leading to LVAD explant
  - 5% heart transplants in US women for PPCM
    - vs women without PPCM, graft and age-adjusted survival is lower
- Complete LV recovery is frequent, even in women with very severe LV dysfunction

# TREATMENT AND OUTCOMES: ACS AND HEART FAILURE

- Gender Paradox: While women with ACS have 50% less likelihood of obstructive CAD vs men, the mortality and event rates in non-obstructive CAD are higher in women<sup>1,2</sup>
- Women with STEMI are less likely to be treated than men and more likely to have delays, exceeding door to balloon times <sup>3</sup>
- Women are hospitalized more frequently, have higher readmission rates and die more often from heart failure than men <sup>4</sup>
- Female sex associated with lower use of guideline recommended therapies<sup>5</sup>

1. Maas et al. Eur Heart J 2011(32):1362-1368

2. Gulati et al. Clin Cardiol.2012 March; 35(3):141-148

3. D'Onofrio et al. Circulation. 2015;131:1324-1332

4. Lloyd-Jones D et al. Circ 2009; 119:480-6

5. Frankenstein et al Cardiovasc Ther 2012; 30(3):182-192

# TREATMENT AND OUTCOMES: ACUTE MCS DEVICES

- Women are less likely to receive acute MCS devices even when in Cardiogenic Shock despite
  - High prevalence of women presenting with AMI-CGS<sup>1</sup>
  - Higher risk profile (vs men) with advanced age and worse hemodynamics (lower CI, lower bp) <sup>1,2</sup>, higher STS mortality risk scores<sup>3</sup>, more likely to have sustained cardiac arrest <sup>3</sup>
  - Greater survival benefit (vs men) to hospital discharge with early LV unloading prior to PCI<sup>3</sup>

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



# TREATMENT AND OUTCOMES: VADs AND HEART Tx

- Women are less likely to receive VADs <sup>1,2</sup> or heart transplants <sup>3</sup> and appear to have higher complication rates:
  - With VADs, women have higher reported rates of major bleeding<sup>4</sup>, neurologic complications including hemorrhagic stroke<sup>1</sup>, perioperative RV failure<sup>4,5</sup> and mortality <sup>4, 7</sup>
  - With cardiac transplant, women are more likely to experience moderate or severe allograft rejection and to be hospitalized for acute rejection<sup>5,6</sup>
- Heart Recovery should be a goal, for all these patients, particularly in those who are young. Yet, this too remains a gap.

1. Bogaev et al J Heart Lung Transplant 2011; 30:515-22

2. Birks, et al. J Heart Lung Transplant 2015; 34:815-24

3. OPTN/SRTR 2011 annual data report: heart. US Depart Health and Human Services

4. Magnussen et al. J Heart Lung Transplant 2018;37:61-70

5. Ochiai et al Circ 2002;106:I-198-I-202

6. Morgan et al J Thorac Cardiovasc Surg 2004;127:1193-5

7. Hickey et al. The NEW HEART Study. Eur J Cardiovasc Nurs 2017 March; 16 (3): 222-229

8. Baum et al. J Heart Lung Transplant 2017; 36(4):Supplement S233



# CARDIOGENIC SHOCK EXPANDED FDA INDICATION:

## CARDIOMYOPATHY

The Impella 2.5®, Impella CP®, Impella 5.0®, and Impella LD® Catheters, in conjunction with the Automated Impella® Controller, are temporary ventricular support devices intended for short term use ( $\leq 4$  days for the Impella 2.5 and Impella CP, and  $\leq 14$  days for the Impella 5.0 and Impella LD) and indicated for the treatment of ongoing cardiogenic shock that occurs immediately ( $< 48$  hours) following acute myocardial infarction or open heart surgery, or in the setting of cardiomyopathy, including peripartum cardiomyopathy, or myocarditis as a result of isolated left ventricular failure that is not responsive to optimal medical management and conventional treatment measures.

The intent of the Impella Support Systems therapy is to reduce ventricular work and to provide the circulatory support necessary to allow heart recovery and early assessment of residual myocardial infarction.

*The Impella® platform is the only percutaneous temporary ventricular support devices that are FDA-approved as safe and effective for Cardiogenic Shock*

# CONCLUSIONS

- Cardiogenic Shock and High risk PCI is effectively treated with percutaneous mechanical circulatory devices
- Heart Disease remains the number 1 cause of death in women
- Women have been underrepresented in clinical trials and do less well than men in shock and ACS.
- SCAD and Peripartum CM are unique disease sets to women with high mortality
- Current initiatives are underway to increase awareness and research in this underrepresented higher risk population.
- In this younger population – heart recovery should be the goal

THANK YOU

A decorative graphic consisting of several thin, light blue wavy lines that flow from the left side towards the right, positioned in the lower third of the slide.