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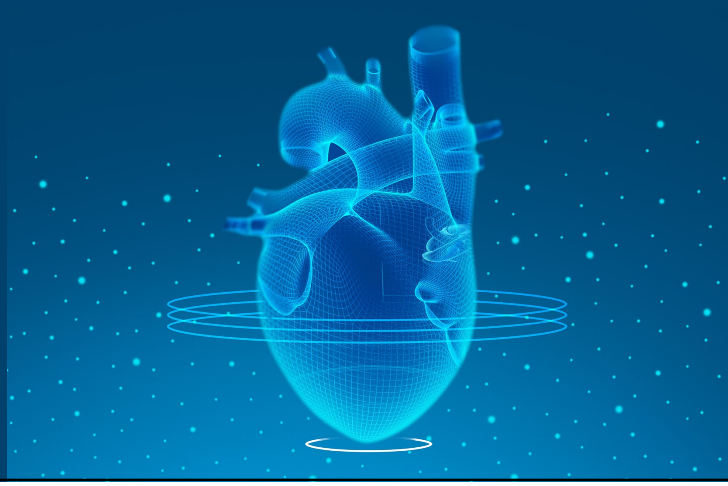

1

Revascularization Strategy for STEMI with Multivessel Coronary Artery Disease

Mohsin Salih, MD, MS, FACP
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Minneapolis Heart Institute

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Disclosure

- None

3

Objective

- Background for MV CAD and STEMI.
- Strategies for treatment of STEMI with MV CAD.
- Overview of the available data and the guidelines.

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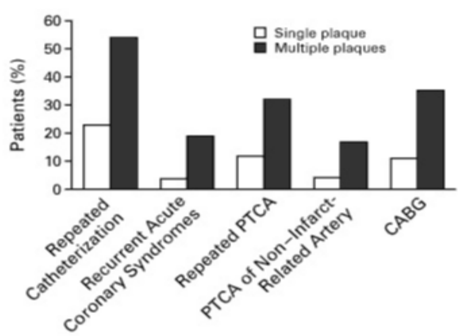
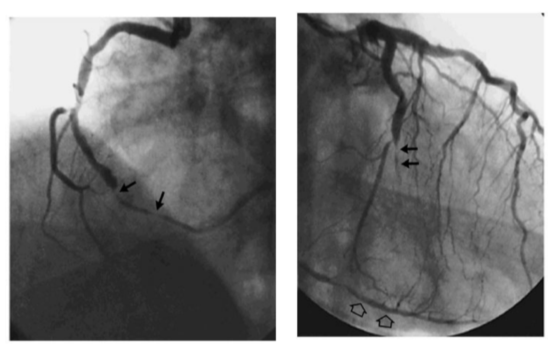
Background

- 40-50% of patients with STEMI have significant lesions in non-IRA.
- MV CAD associated with higher mortality and rate of reinfarction.
- This could be related to multiple vulnerable plaques in non-IRA.

Multivessel plaque associated with worse prognosis



253 Patients with STEMI, 40 % had MV CAD



Goldstein JA et al, N Engl J Med 2000

Treatment Strategies for STEMI with MV CAD

- Culprit vessel Intervention only (CVI).
- Only if the patient has ischemic symptoms or high-risk non-invasive testing.

- CVI with staged PCI of non-culprit vessel.
- During the index hospitalization or after few weeks from discharge.

- Complete revascularization during index procedure.

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Supportive evidence

- Conflicting data:
- Depend only on observational studies, and meta-analysis
- Different inclusion criteria
- End points
- Small sample size
- Time of intervention
- Selection bias

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2013 STEMI Guideline

- Long procedure time
- More contrast
- Stent thrombosis
- Procedure complications

O'Gara PT *et al. J Am Coll Cardiol* 2013

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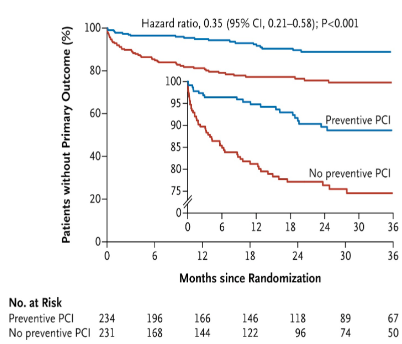
PRAMI Trial

Preventive: PCI to non-culprit artery (N 234)

Non-Preventive: PCI to culprit artery only (N 231)

Primary end point: CV death, MI, & refractory angina

Result: 9 % in preventive group, 23 % in non-preventive. Relative RR 65 % & absolute RR 14 %



Wald D, et al. PRAMI Trial, NEJM, September 19, 2013

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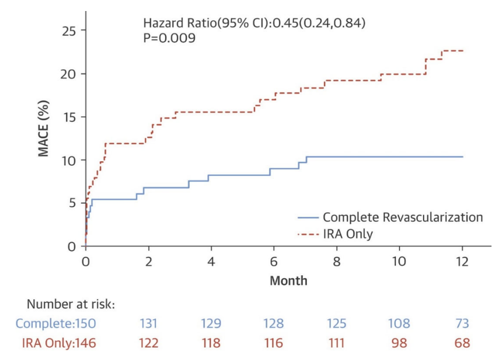
CvLPRIT Trial

Complete revascularization group at index hospitalization (N 150)

Infarct related artery only revascularization group (N 146)

Primary endpoint: All cause mortality, recurrent MI, HF, and ischemia driven revascularization

Results: 53% reduction in composite endpoint (10 vs 21.2%). No safety differences seen between treatment groups



Gershilick A, et al: JACC March 2015

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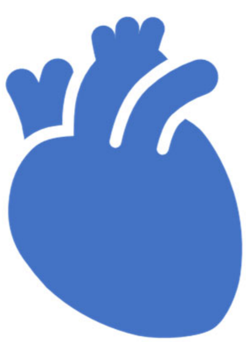
Which non-IRA we should treat?



- Angiographic severity.
- Vulnerability of the lesion.
- Complexity of the lesion.
- Safety and feasibility of the intervention.
- Coronary physiology.

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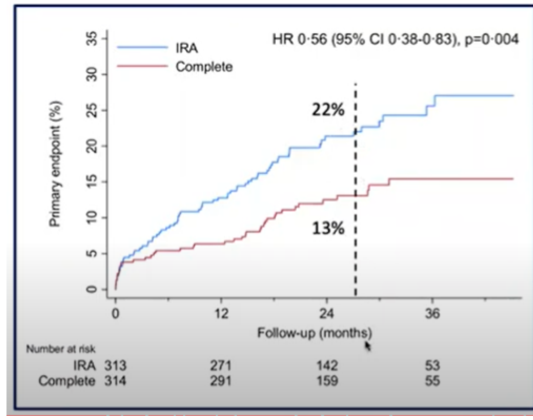
DANAMI-3-PRIMULTI Trial

- Complete FFR guided PCI to non-culprit artery (N 314)
- PCI to culprit artery only (N 313)

- **Primary endpoint:** All cause mortality, recurrent MI, ischemia driven revascularization
- **Results:** 44% reduction in primary composite endpoints (13 % vs 22 %)
- MV PCI guided by FFR significantly reduced number of revascularization



Engsterm T, et al. Lancet. August 2015

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Updated STEMI Guideline 2015

2013 Recommendation	2015 Focused Update Recommendation	Comment
Class III: Harm PCI should not be performed in a noninfarct artery at the time of primary PCI in patients with STEMI who are hemodynamically stable (11-13). (*Level of Evidence: B*)	*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 (11-24). (*Level of Evidence: B-R*)	Modified recommendation (changed class from "III: Harm" to "IIb" and expanded time frame in which multivessel PCI could be performed).

PCI indicates percutaneous coronary intervention; and STEMI, ST-elevation myocardial infarction.

- III → IIb
- Ok to treat non-IRA
- Hemodynamic stable
- Either at the index procedure or staged.

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FFR in acute MI

- **FFR may be inaccurate after acute MI**

- Microvascular spasm.
- Microvascular flow limitation secondary of edema.

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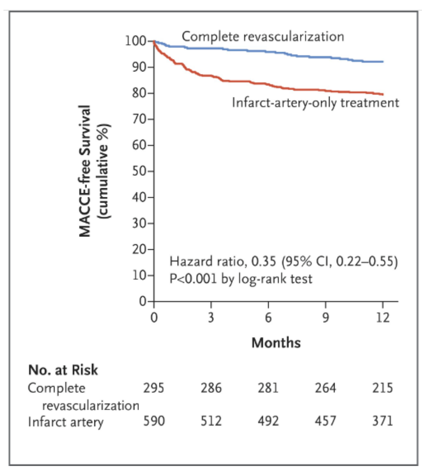
COMPARE-ACUTE

- Complete FFR guided PCI to non-culprit artery (N 295)
- PCI to culprit artery only and FFR to non-culprit artery (N 590)

- **Primary endpoint: MACE (**Death, MI, CVS, revascularization)
- **Results:** Reduction in primary composite endpoints (7.8 % vs 20.5 %)
- Safe to defer FFR negative lesion.
- **FLOWER-MI trial** showed opposite result?



Smith P, et al. COMPARE-ACUTE Trial, NEJM, March 2017

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COMPLET Trial

- ❑ NNT to prevent cardiovascular death or myocardial infarction is 37 patients.
- ❑ NNT to prevent cardiovascular death, myocardial infarction, or ischemia-driven revascularization is 13 patients.

Shamir M , et al. COMLET, NEJM, October 2019

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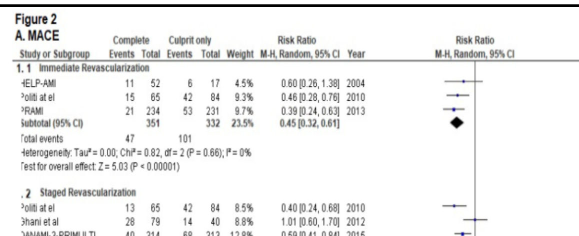
Complete Versus Culprit-Only Revascularization in Patients Presenting With ST-Segment Elevation Myocardial



- 10 RCT
- 7114 patients (3426 complete revascularization, and 3688 culprit only revascularization).
- Complete revascularization significantly reduced the risk of MACE compared with culprit only (10.7% vs 20.1%), reinfarction (5.0 % vs 6.9 %), and revascularization (4.2 % vs 12.7 %).

Mohsin S , et al. CRM, December 2020

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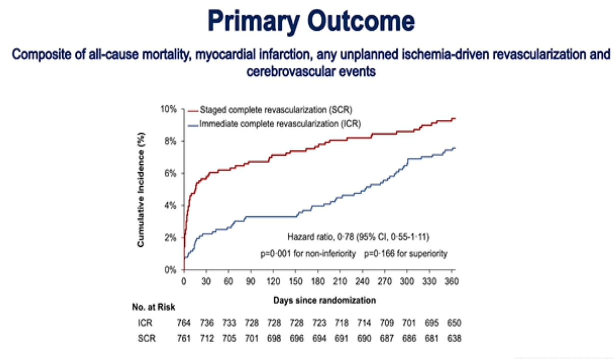
BIOVASC Trial

Immediate complete revascularization (N 764)

Staged complete revascularization(N 761)

Primary endpoint: Death, MI, ischemia-driven revascularization, CVA

Results: Immediate complete revascularization was non-inferior to staged complete revascularization.



Diletti, R, et al. Lancet. March 2023

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Recommendations for Revascularization of the Non-Infarct Artery in Patients With STEMI Referenced studies that support the recommendations are summarized in Online Data Supplement 8.		
COR	**LOE**	**Recommendations**
1	**A**	1. In selected hemodynamically stable patients with STEMI and multivessel disease, after successful primary PCI, staged PCI of a significant non-infarct artery stenosis is recommended to reduce the risk of death or MI.[1-4]
2a	**C-EO**	2. In selected patients with STEMI with complex multivessel non-infarct artery disease, after successful primary PCI, elective CABG is reasonable to reduce the risk of cardiac events.
2b	**B-R**	3. In selected hemodynamically stable patients with STEMI and low-complexity multivessel disease, PCI of a non-infarct artery stenosis may be considered at the time of primary PCI to reduce cardiac event rates.[1,2,5-7]
3: Harm	**B-R**	4. In patients with STEMI complicated by cardiogenic shock, routine PCI of a non-infarct artery at the time of primary PCI should not be performed because of the higher risk of death or renal failure.[8-10]

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Conclusion

- MV CAD elevates mortality risk in STEMI
- Evolving in the supportive data, leading to change in the non-IRA strategy (Previous III and now Ia in staging & IIb in index procedure)
- We need more data (Imaging/Physiology, what lesion, and when)

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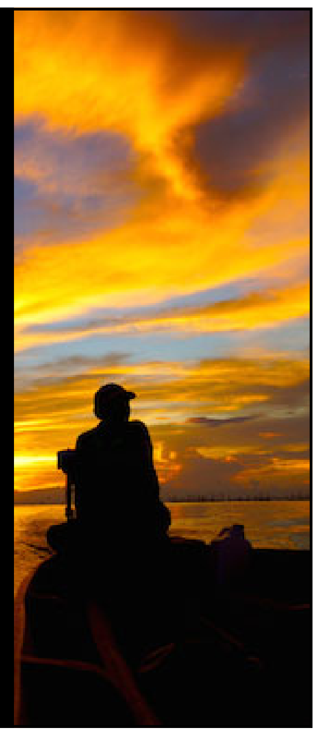
Thank you



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Revascularization in ST-Elevation MI and Cardiogenic Shock

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PGY7
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Cardiogenic shock

- Clinical syndrome manifested by either a sudden or acute-on-chronic reduction in cardiac output, leading to systemic hypotension and end-organ hypoperfusion.
  - (1) frank or relative hypotension, defined by a systolic BP below 80 or 90 mm Hg or a reduction in mean arterial pressure (MAP) of 30 mm Hg;
  - (2) inadequate cardiac index, defined as less than 1.8 liters/min/m^2 without mechanical or pharmacologic support, or less than 2.2 liters/min/m^2 with support;
  - (3) elevated end-diastolic pressures on the right (>10 to 15 mm Hg) and/or left (>18 mm Hg) side of the heart;
  - and (4) evidence of end-organ hypoperfusion.

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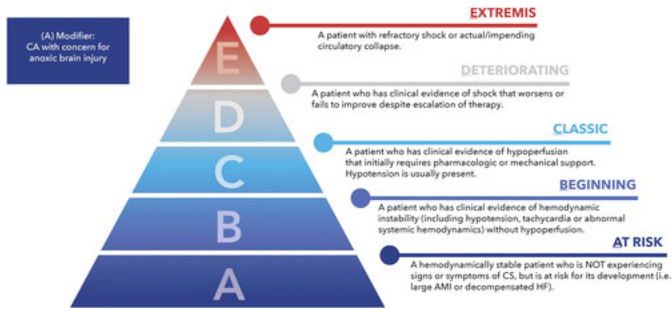

Srihari S. Naidu et al. *J Am Coll Cardiol* 2022; 79:933-946.

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JACC

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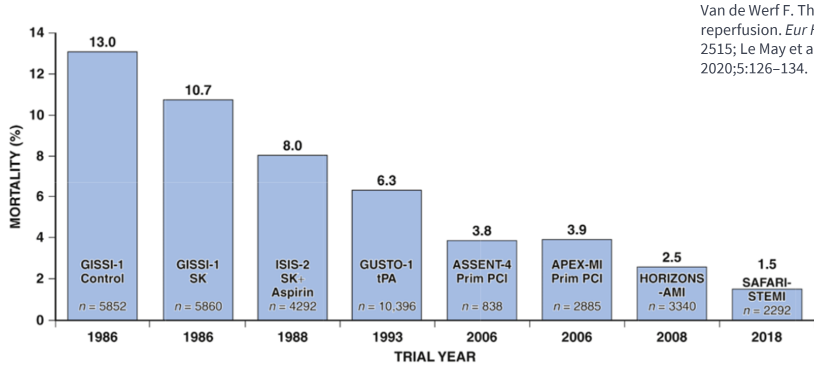
Early mortality rates have declined in major randomized trials of STEMI patients from 1986 to 2018 with the introduction and improvement in pharmacologic and/or mechanical reperfusion therapy

Van de Werf F. The history of coronary reperfusion. *Eur Heart J*. 2014;35;2510–2515; Le May et al. *JAMA Cardiol*. 2020;5:126–134.



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STEMI and Cardiogenic Shock Mortality

- Mortality remains high, i.e., more than 50%
- CS remains one of the most common causes of hospital mortality after AMI

Helgestad OKL et al. Temporal trends in incidence and patient characteristics in cardiogenic shock following acute myocardial infarction from 2010 to 2017: a Danish cohort study. *Eur J Heart Fail* 21 (11):1370–1378, 2019

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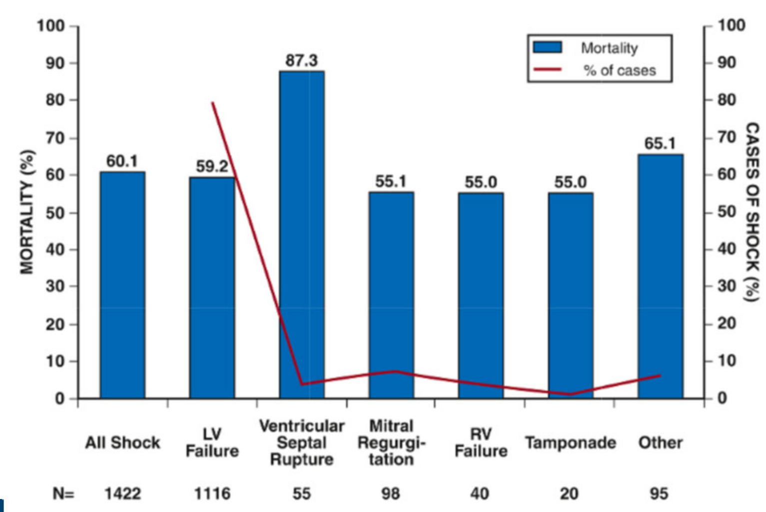
Mortality by etiology of cardiogenic shock following acute myocardial infarction (AMI).



Hochman JS, Buller CE, Sleeper LA, et al. Cardiogenic shock complicating acute myocardial infarction—etiologies, management, and outcome: a report from the SHOCK Trial Registry. Should We Emergently Revascularize Occluded Coronaries for Cardiogenic Shock? *J Am Coll Cardiol*. 2000;36[3 Suppl A]:1063–1070.

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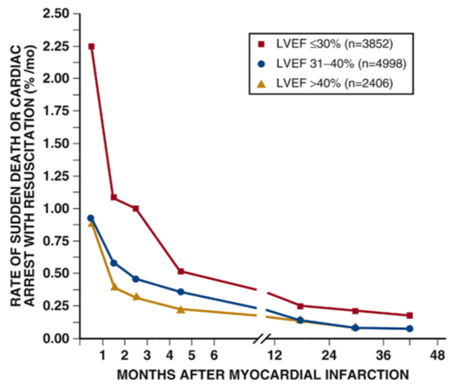
The high rate of sudden death or cardiac arrest occurs within the first month after MI



Zaman S, Kovoor P. Sudden cardiac death early after myocardial infarction: pathogenesis, risk stratification, and primary prevention. *Circulation*. 2014;129[23]:2426–2435.

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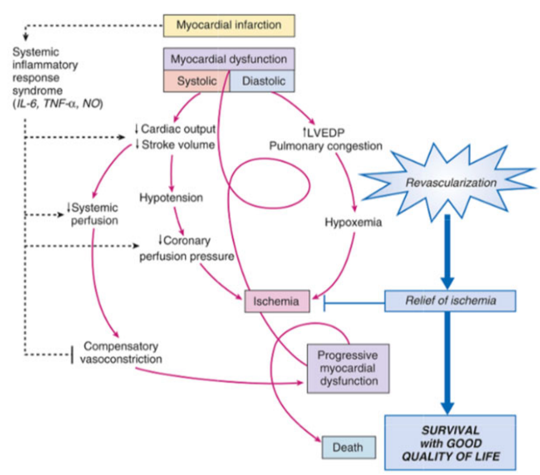
Pathophysiology of Cardiogenic Shock in STEMI



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Hemodynamic Patterns for Common Clinical Conditions

Cardiac Condition	Hemodynamic Parameter						
	RA	RV	PA	PAPi	PCW	CI	CPO
Normal	0–6	25/0–6	25/0–12	>1	6–12	≥2.5	>0.6
AMI without LVF	0–6	25/0–6	30/12–18	>1	≤18	≥2.5	>0.6
AMI with LVF	0–6	30–40/0–6	30–40/18–25	>1	>18	May be <2.0	<0.6
Biventricular failure	>6	50–60/>6	50–60/25	May be <1	18–25	May be <2.0	<0.6
RVMI	12–20	30/12–20	30/12	Often <1	≤12	May be <2.0	<0.6
Cardiac tamponade	12–16	25/12–16	25/12–16	Often <1	12–16	<2.0	<0.6
Acute Pulmonary embolism	12–20	30–50/12–20	30–50/12	Often <1	<12	<2.0	<0.6

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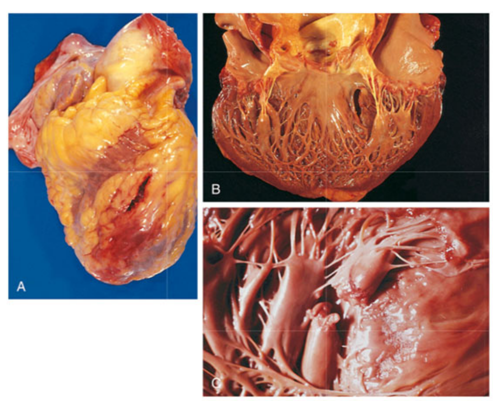
Exclude Mechanical Complications

- Their treatment usually requires prompt invasive management with intervening mechanical support of the circulation.
- May Require Urgent Surgical Treatment



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Survival

- Revascularization improves survival.
- Inotropes/vasopressors, MCS: useful temporizing maneuvers.

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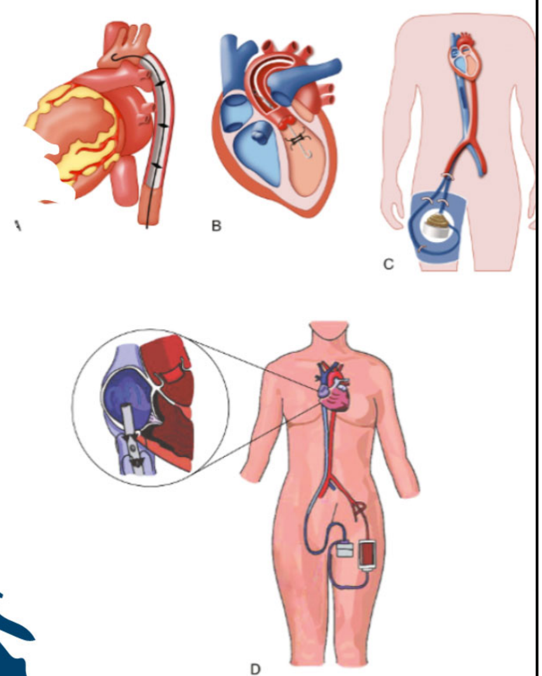
Major categories of nonsurgical mechanical circulatory support.

- IABP
- Impella
- VA- ECMO
- Tandem Heart



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Mechanical Circulatory Support

- (1) maintain end-organ perfusion and prevent progressive shock,
- (2) reduce intracardiac filling pressures and congestion,
- (3) reduce LV volumes, wall stress, and myocardial oxygen consumption,
- (4) augment coronary perfusion,
- (5) allow time for recovery of stunned or hibernating myocardium, and
- (6) limit infarct size

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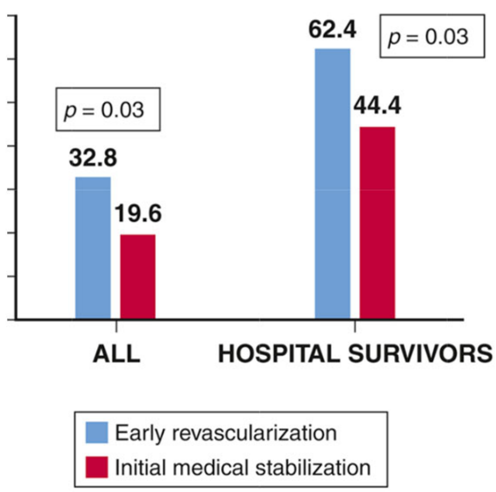
SHOCK (Should We Emergently Revascularize Occluded Coronaries for Cardiogenic Shock?)

- shock caused by LV failure complicating STEMI were randomly assigned to emergency revascularization (*n* = 152), accomplished by either CABG or angioplasty, or to initial medical stabilization (*n* = 150).
- Hochman JS, et al. JAMA 2006;295:2511.



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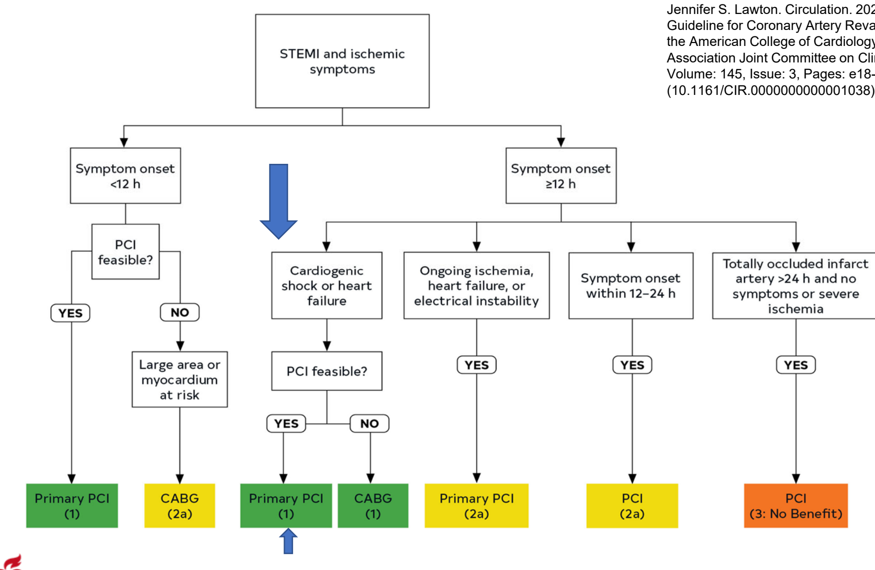

Jennifer S. Lawton. Circulation. 2021 ACC/AHA/SCAI Guideline for Coronary Artery Revascularization: A Report of the American College of Cardiology/American Heart Association Joint Committee on Clinical Practice Guidelines, Volume: 145, Issue: 3, Pages: e18-e114, DOI: (10.1161/CIR.0000000000001038)

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How Urgently Should Revascularization be Pursued in Cardiogenic Shock and STEMI?

FITT-STEMI trial

- *n* = 12 675 STEMI patients who used emergency medical service transportation and were treated with primary percutaneous coronary intervention (PCI)
- In CS patients with no OHCA, every 10-min treatment delay resulted in 3.31 additional deaths in 100 PCI-treated patients.

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PCI after 12 hours

- There are no RCTs examining the benefit of PCI in patients with STEMI presenting >12 hours after symptom onset who have clinical evidence of ongoing ischemia, acute severe heart failure, or life-threatening arrhythmias.
- Expert Consensus: a strategy of delayed reperfusion in these unstable patient subsets expected to improve symptoms and outcomes, and for this reason PCI should be considered.

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Fibrinolysis

Immediate transfer to a PCI-capable hospital is recommended in patients with shock or acute severe HF regardless of the time delay.

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Non-Infarct artery in Cardiogenic Shock

- Multivessel disease affects 70% to 90% of patients with cardiogenic shock and acute MI
- The optimal extent of initial revascularization has undergone intense clinical investigation

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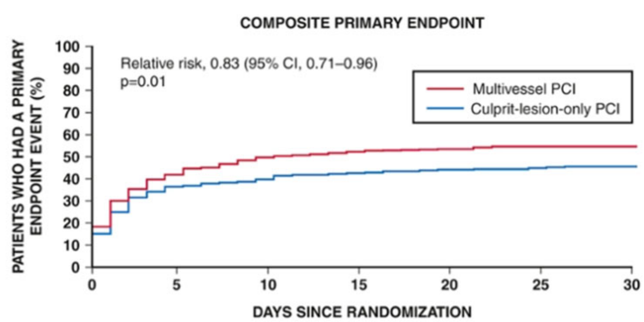
CULPRIT SHOCK

- 706 patients with cardiogenic shock onset within 12 hours in the setting of acute MI



No. at Risk	0	5	10	15	20	25	30
Multivessel PCI	341	199	172	162	156	153	152
Culprit-lesion-only PCI	344	219	207	198	192	189	184

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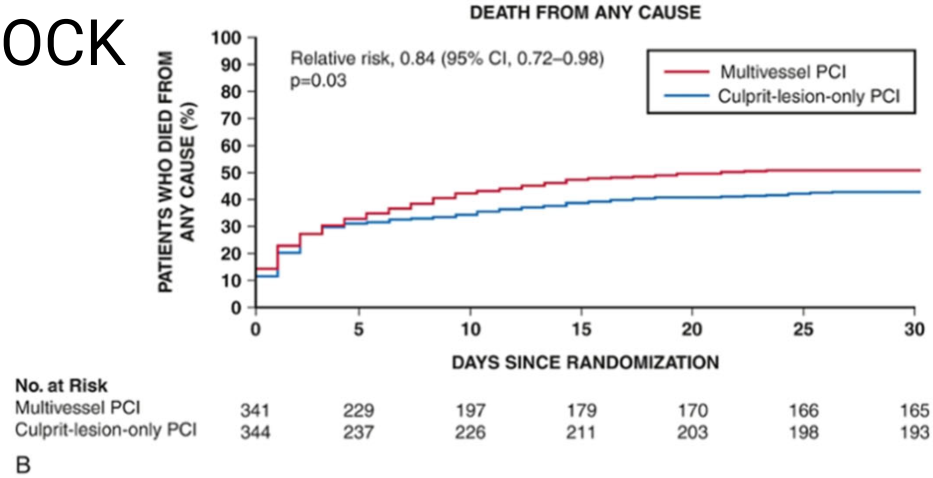
CULPRIT SHOCK



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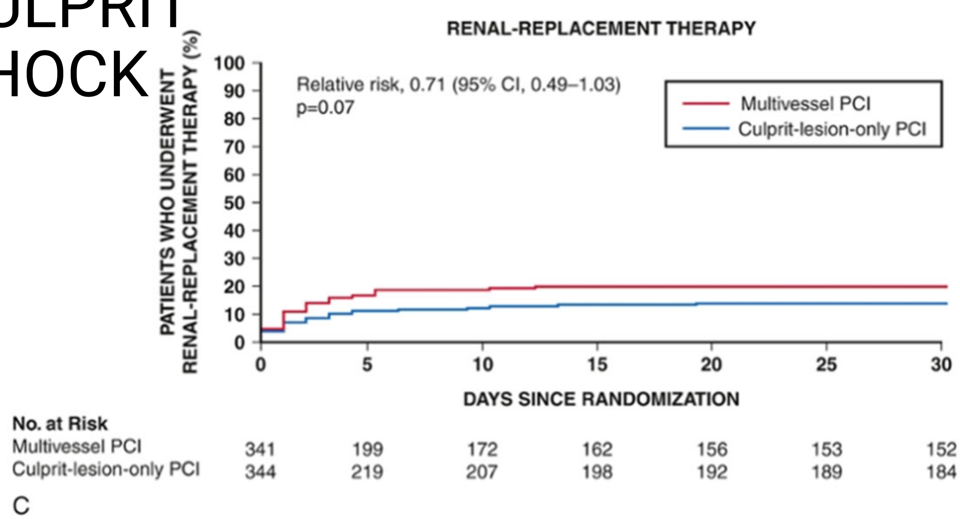
CULPRIT SHOCK



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Recommendations for Revascularization of the Non-Infarct Artery in Patients With STEMI
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FUTURE

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National Cardiogenic Shock Initiative

- Single arm, 80 Centers recruiting
- Historical Cohort for comparison
- Non-Randomized Data

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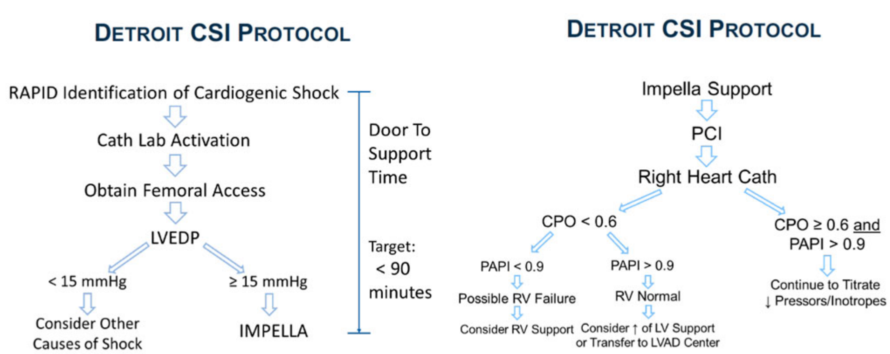
Upfront Use of Impella Prior to PCI



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RESULTS

- A survival rate of 71% to hospital discharge in 406 patients who presented with acute myocardial infarction (AMI) complicated by cardiogenic shock

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Door-To-Unload in STEMI Pilot Trial

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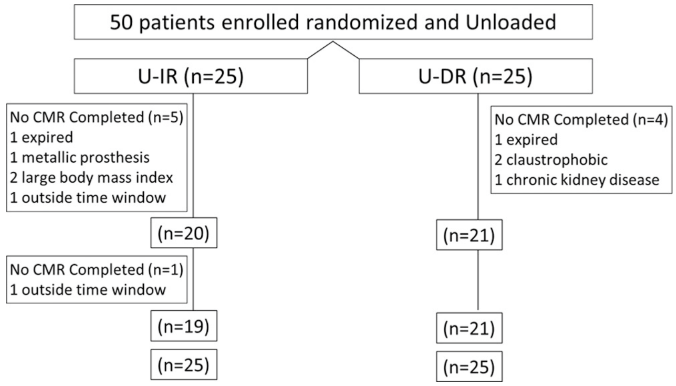

Navin K. Kapur. Circulation. Unloading the Left Ventricle Before Reperfusion in Patients With Anterior ST-Segment–Elevation Myocardial Infarction, Volume: 139, Issue: 3, Pages: 337-346, DOI: (10.1161/CIRCULATIONAHA.118.038269)

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No difference in Delayed vs. Immediate Reperfusion

- Major adverse cardiovascular and cerebrovascular event rates were not statistically different between the U-IR versus U-DR groups (8% versus 12%, respectively, *P*=0.99).
- In comparison with the U-IR group, delaying reperfusion in the U-DR group did not affect 30-day mean infarct size measured as a percentage of LV mass (15±12% versus 13±11%, U-IR versus U-DR, *P*=0.53).

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THANK YOU!

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Cerebral Embolic Protection during Transcatheter Aortic Valve Replacement

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Advanced Adult Structural and Congenital Heart Disease Interventions Fellow
Abbott Northwestern – Minneapolis Heart Institute

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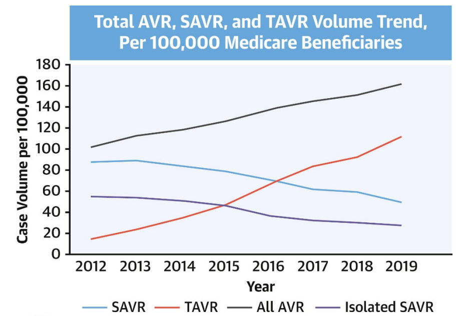
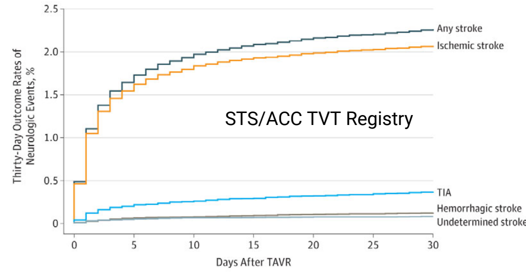
Stroke and TAVR

- TAVR use has significantly increased over the past 10 years
- Clinical stroke occurs in about 2.5% of cases and is usually peri-procedural





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Mori et al. J Am Coll Cardiol. 2021 Nov, 78 (22) 2161–72
Huded et al. JAMA. 2019;321(23):2306-2315

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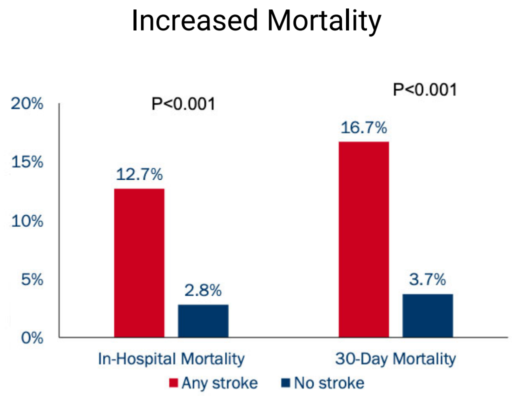
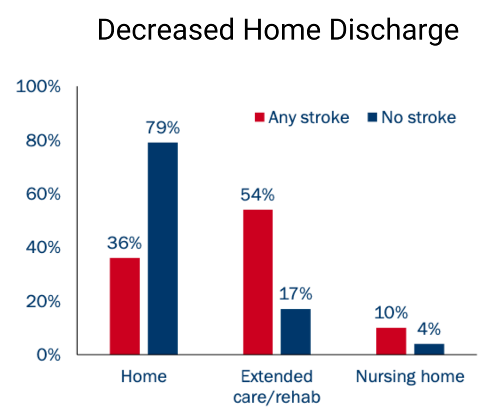
Stroke after TAVR





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Huded et al. JAMA. 2019;321(23):2306-2315

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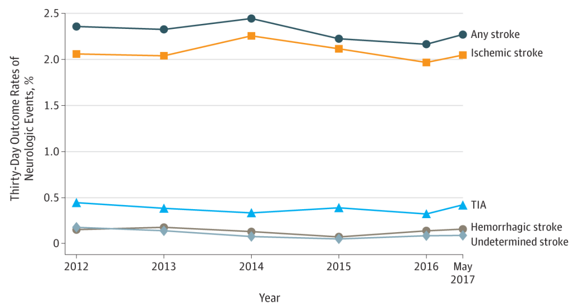
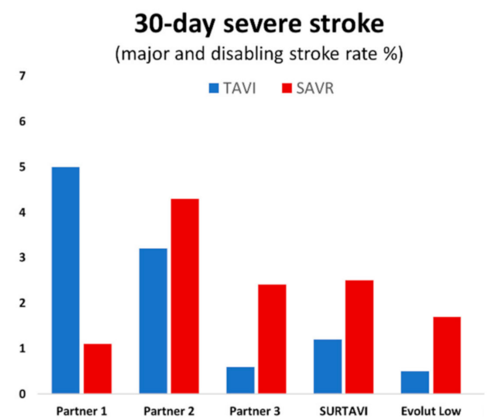
Stroke and TAVR: Incidence

STS/ACC TVT Registry



No. of patients	4030	8042	14895	23019	33958	17486
No. of events						
Any stroke	95	187	364	512	735	397
Ischemic stroke	83	164	336	487	668	358
TIA	18	31	50	90	110	74
Hemorrhagic stroke	6	14	19	16	46	27
Undetermined stroke	7	11	11	11	28	15



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Huded et al. JAMA. 2019;321(23):2306-2315

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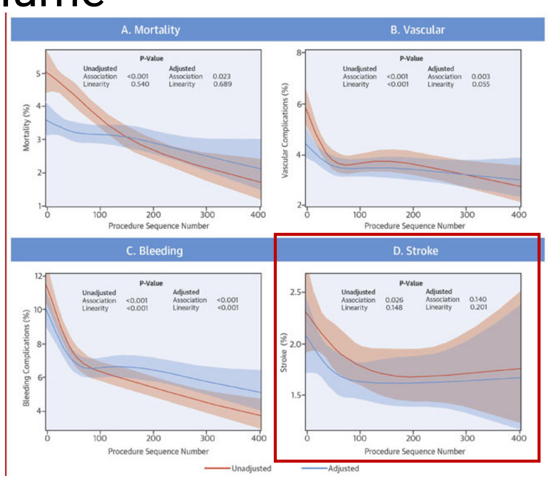
Stroke and TAVR Volume

High volume does not reduce stroke rate



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Carroll, J.D. et al. J Am Coll Cardiol. 2017:70(1):29-41.

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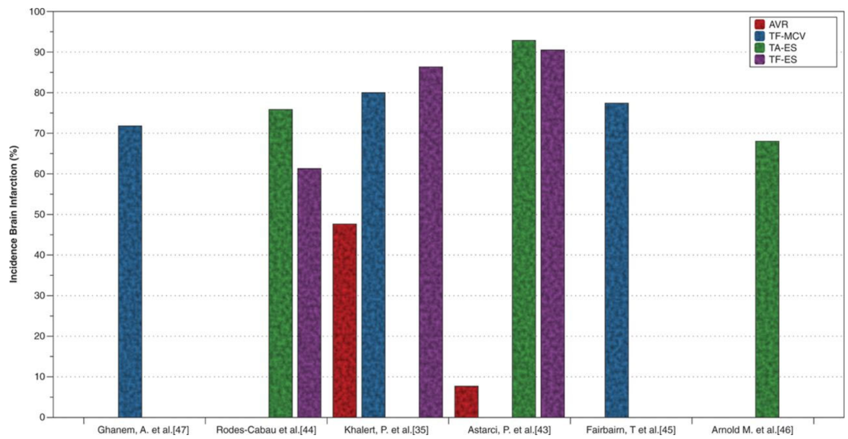
Embolic CNS Injury – MRI

- Extremely frequent (70-93%)
- More frequent than SAVR
- Size of lesion significantly smaller
- Majority silent



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Fanning et al. Circulation. 2014;129:504–515

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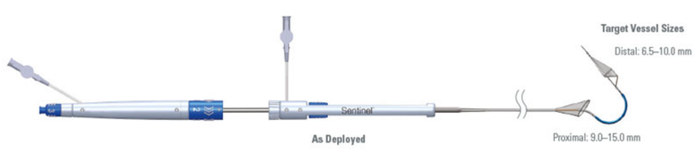
Cerebral Embolic Protection - Sentinel

- 6-Fr radial access, deflectable catheter
- 2 independent filter baskets (140um pores)
- Protects 3 of 4 great vessels (90% circulation)
- Debris capture in >99% of TAVR cases



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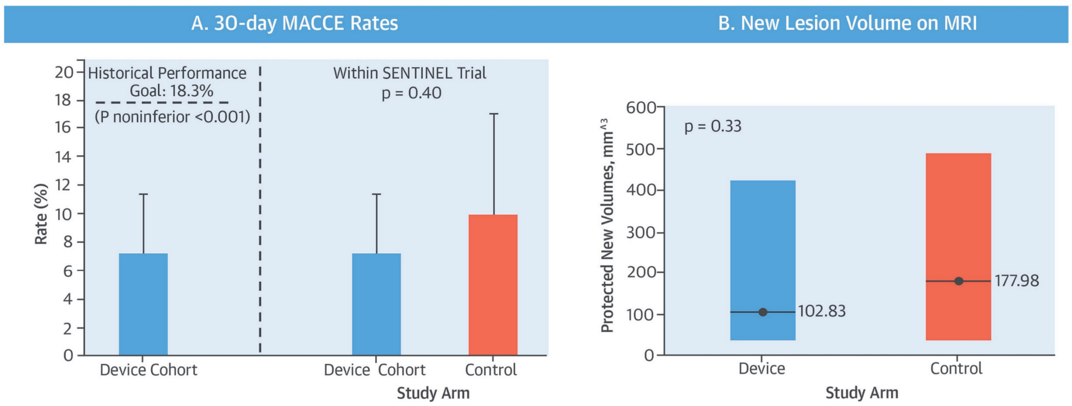
Sentinel IDE Trial



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Kapadia et el. J Am Coll Cardiol. 2017 Jan, 69 (4) 367–377

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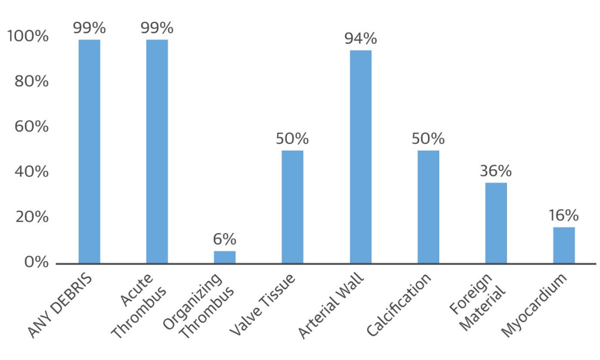
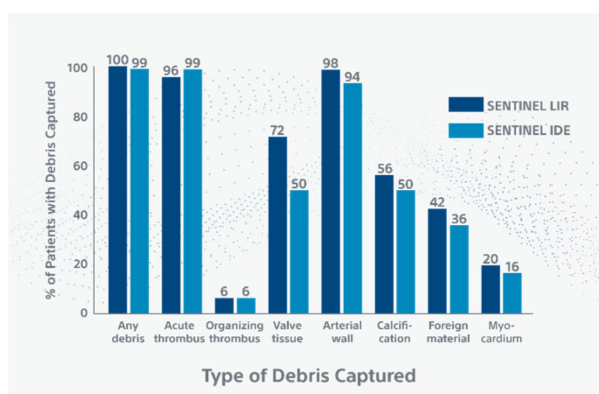
Sentinel IDE Trial



Debris Capture



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Kapadia et el. J Am Coll Cardiol. 2017 Jan, 69 (4) 367–377
Finn. CRT 2021

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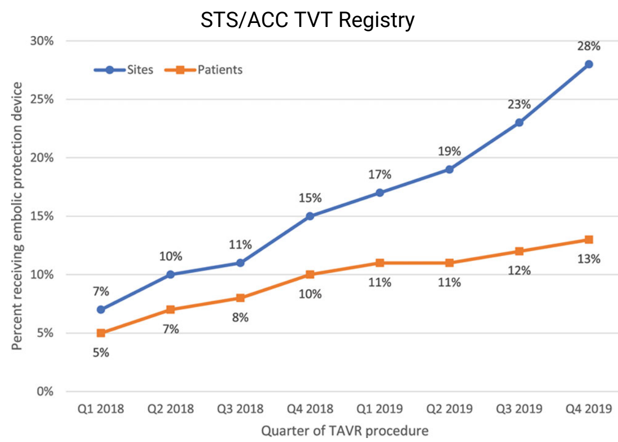
Cerebral Embolic Protection - Use



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Butala et al. Circulation. 2021;143:2229–2240

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PROTECTED TAVR trial – Study Design

- 3,000 patients across North America, Europe, and Australia undergoing TF-TAVR
- Randomized 1:1
- 1,501 were assigned to the cerebral embolic protection device group and 1,499 to the control group
- Primary end point - stroke within 72 hours after TAVR or before discharge (whichever comes first)
- Secondary end points - Disabling stroke, death, transient ischemic attack, delirium, major or minor vascular complications at the CEP access site, and acute kidney injury
- Neurologist examined all patients at baseline and after TAVR

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Kapadia et el. N Engl J Med 2022; 387:1253-1263

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PROTECTED TAVR trial – Baseline Characteristics

	Control (N=1499)	CEP (N=1501)
Age (years)	78.9±7.8	78.9±8.0
Female Sex	37.8%	42.0%
Society of Thoracic Surgeons score, %	3.4±2.8	3.3±2.7
STS score <3%	58.2%	55.6%
Surgical Risk (per Heart Team)		
Extreme/High Risk	30.4%	30.4%
Intermediate Risk	34.2%	33.2%
Low risk	35.4%	36.3%
Native Valve Calcification Severity (site-reported)		
None/Mild	15.2%	16.2%
Moderate	29.5%	29.4%
Severe/Extreme	55.3%	54.4%
CHA_2DS_2-VASC score	4.2±1.3	4.2±1.3

Operative risk was well-balanced

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Kapadia et el. N Engl J Med 2022; 387:1253-1263

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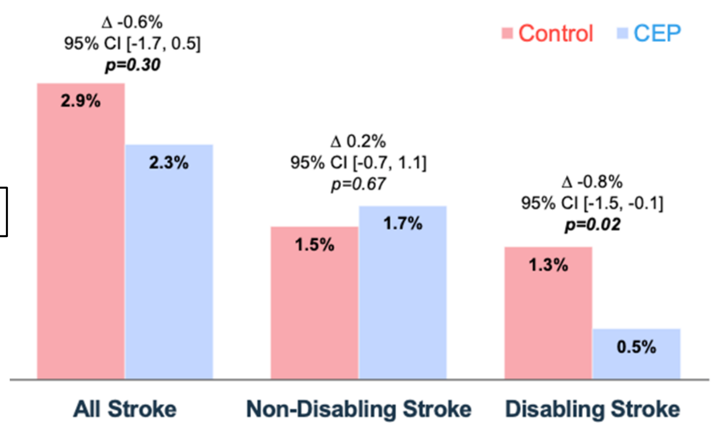
PROTECTED TAVR trial – Results

Negative trial



Primary Endpoint

Secondary Endpoint

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PROTECTED TAVR trial – Safety

Event at ≤72h / Discharge ITT population	Control (N=1499)	CEP (N=1501)
All-cause Mortality	0.3% (4)	0.5% (8)
Cardiovascular Mortality	0.3% (4)	0.5% (8)
Safety composite (all-cause mortality and stroke)	3.0% (45)	2.7% (41)
CEP Access Site-related Vascular Complication (Major or Minor)	N/A	0.1% (1)
Acute Kidney Injury (stage 2 or 3)	0.5% (7)	0.5% (8)

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Kapadia et el. N Engl J Med 2022; 387:1253-1263

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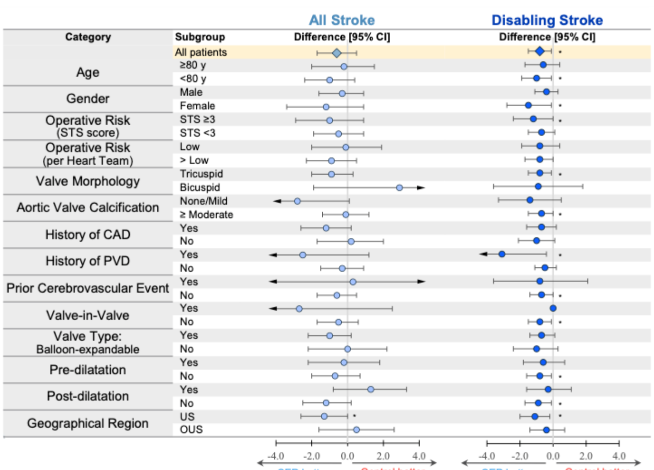
PROTECTED TAVR trial – Subgroup analysis



Limited ability to predict who will benefit

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Kapadia et el. N Engl J Med 2022; 387:1253-1263

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BHF PROTECT-TAVI

British Heart Foundation Randomised Clinical Trial of Cerebral Embolic Protection in Transcatheter Aortic Valve Implantation (BHF PROTECT-TAVI)

Patients undergoing transfemoral TAVI (n=7730)*

1:1 Randomisation

TAVI with CEP (n=3865)

TAVI without CEP (n=3865)

(Standardised questionnaire to assess stroke free status with mandated stroke physician review)

Primary outcome: Discharge or Stroke at 72hrs

Planned interim analysis for efficacy/futility at 50% and 70%

* Powered for control event rate of 3% and effect size of 33%

University of Oxford

British Heart Foundation

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Upcoming Devices

Competitive Landscape (Feb 2022	Sentinel BSC	TriGuard Venus	CAPTIS Filterlex	Emblok ICS	Emboliner Emboline	PointGuard Transverse	ProtEmbo Protembis	Embrace AorticLab
								
Cerebral embolic protection	Partial	√	√	√	√	√	√	√
Mesh pore size	140	115-145	115-145	125	150	105	60	70
Full-body embolic protection	X	X	√	√	√	X	X	√
Capture and removal	Partial	X	√	√	√	X	X	√
Protects aortic surface	X	X	√	X	X	X	X	X
Stable anchoring	X	X	√	X	X	X	X	X
Access	6Fr Rt Radial	8Fr Contralateral Femoral	Ipsilateral Same as TAVR	12Fr Contralatera l Femoral	10Fr Contralateral Femoral	10Fr Contralateral Femoral	6Fr Lt Radial	12Fr Contralateral Femoral
Clinical experience	Commercial	Commercial (EU only)	FIH	FIH	FIH	FIH	FIH	FIH
Regulatory status	FDA + CE	CE	X	X	X	X	X	X

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Weisz G TVT 2022

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Conclusion

- Clinical stroke occurs in about 2.5% of TAVR cases and is usually peri-procedural
- Associated with significant morbidity and mortality
- DW-MRI lesions frequent after TAVR (70-93%) – Majority silent
- Cerebral Embolic Protection with Sentinel
  - Safe
  - Does not reduce all strokes
  - ? Disabling strokes – more data needed (BHF PROTECT – TAVI)
- Multiple different devices coming

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Thank you!

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Penetrating Aortic Ulcers

Sarah Langdon, MD, Christopher Pedersen, MD

4/10/23

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- No financial disclosures

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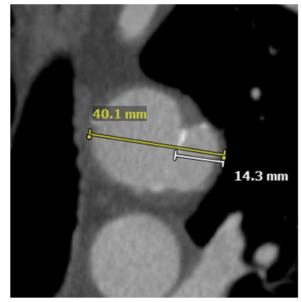
Case

- 84M with PAU found during AVR/CABG



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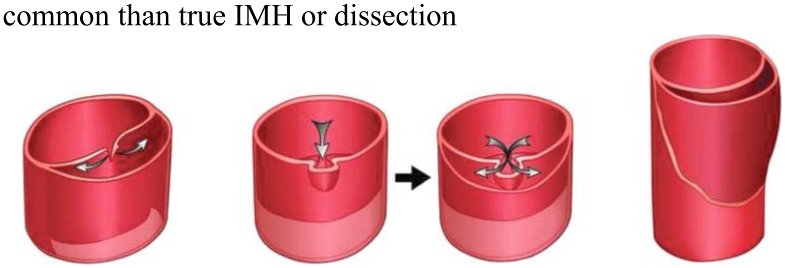
Background

- Atherosclerotic lesion with disruption of internal elastic lamina
- Can progress into intramural hematoma (IMH), dissection, pseudoaneurysm, rupture, or degenerate into aneurysms
- More common in the descending thoracic aorta
- Often seen with severe atherosclerotic disease
- Much less common than true IMH or dissection



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Presentation and Diagnosis

- Asymptomatic or incidentally found on imaging
- Chest pain, back pain, abdominal pain – similar to aortic dissection
- Hypertension common

- CTA gold standard imaging modality
  - Outpouching of the aortic wall

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Management

- Anti-impulse control with goal SBP <120, HR 60-80
  - Beta-blockade first line

- Symptomatic PAU or those associated with IMH should be repaired
- Asymptomatic PAUs with high-risk features should be considered for repair

- Historically treated with open aortic repair, but there is growing evidence for endovascular repair
  - Open treatment remains important for ascending aorta and aortic arch
  - Endovascular therapies for descending thoracic aorta
  - New technologies for disease near the arch

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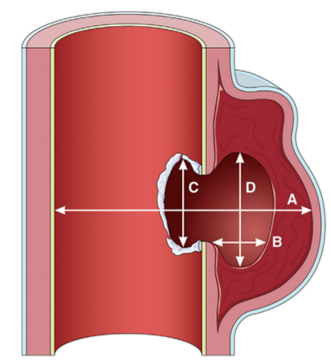
High Risk Imaging Features

- Maximum diameter >13-20mm
- Maximum depth >10mm
- Significant growth
- PAU associated with a saccular aneurysm
- PAU with increasing pleural effusion

FIGURE 22 **Dimensions of Penetrating Atherosclerotic Ulcers**



(A) Maximal aortic diameter at ulcer site diameter (from ulcer across to opposite aortic wall). **(B)** Depth of intramural blood pool. **(C)** Length of intimal defect at ulcer site. **(D)** Width of intramural blood pool. Adapted from Gifford et al,[11] Copyright 2016, with permission from Elsevier, Inc., and from Cho et al[9] Copyright 2004 with permission from the Society for Vascular Surgery.

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Outcomes

- Asymptomatic
  - 6.5% developed symptoms, radiographic progression, or rupture over 10 years
- Open Repair
  - 9-19% perioperative mortality
- Meta-analysis of 310 TEVARs performed for PAU
  - 98.3% success rate, 30d mortality 4.8%, aortic related mortality of 4.1 at 18 months

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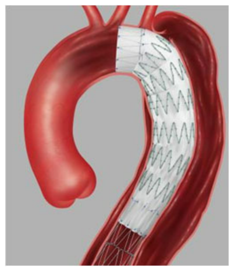
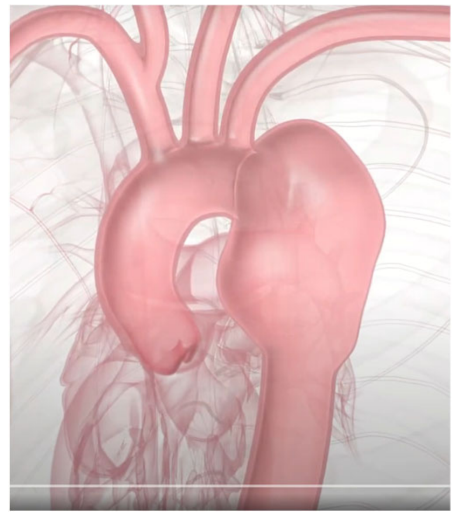
Endovascular Repair

- Thoracic endovascular aortic repair (TEVAR)
- GORE® TAG® Thoracic Branch Endoprosthesis (TBE)



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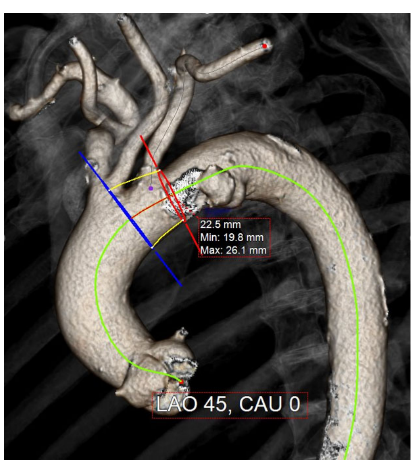
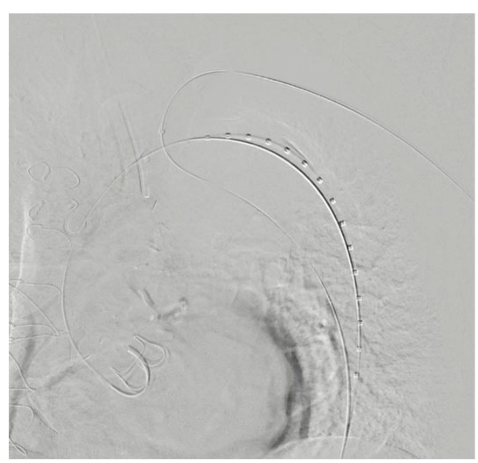
Back to Case

- Decided to perform TBE





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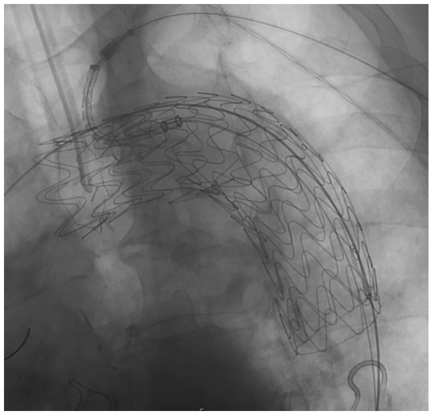
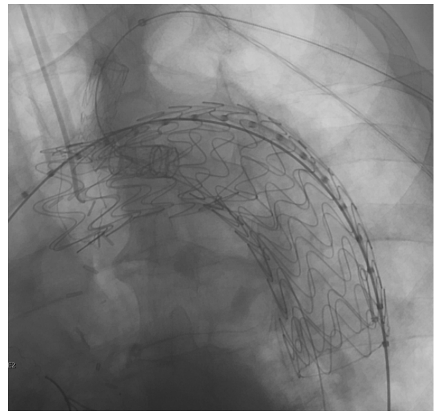
- Intra-operative graft deployment





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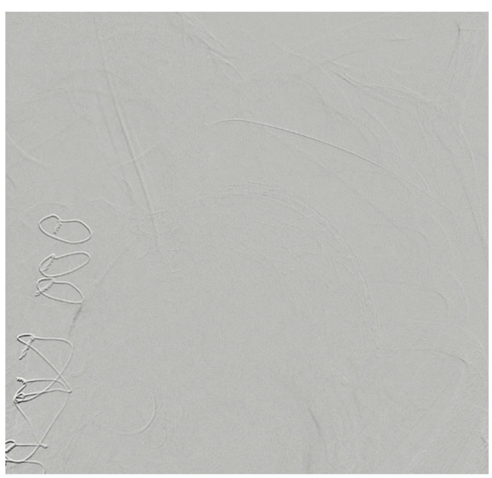
- Completion angiogram



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Follow-up Imaging

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Summary

- Uncommon aortic pathology
- Medical management is sufficient for a majority of asymptomatic patients however patients with symptoms or high risks features should be considered for repair
- TEVAR and Branched TEVAR devices provide less invasive options

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