Mechanical Cardiac Support in Acute Heart Failure

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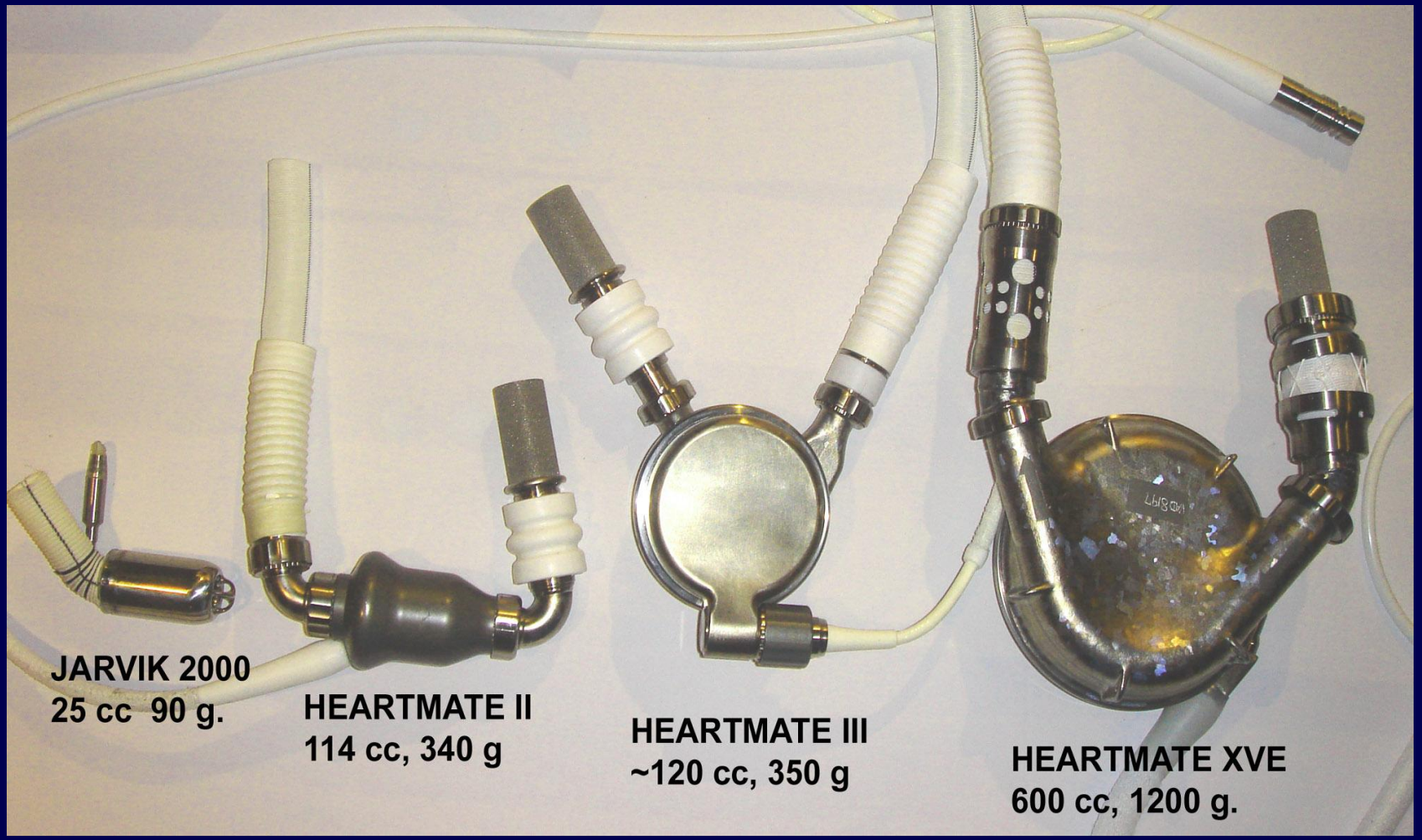
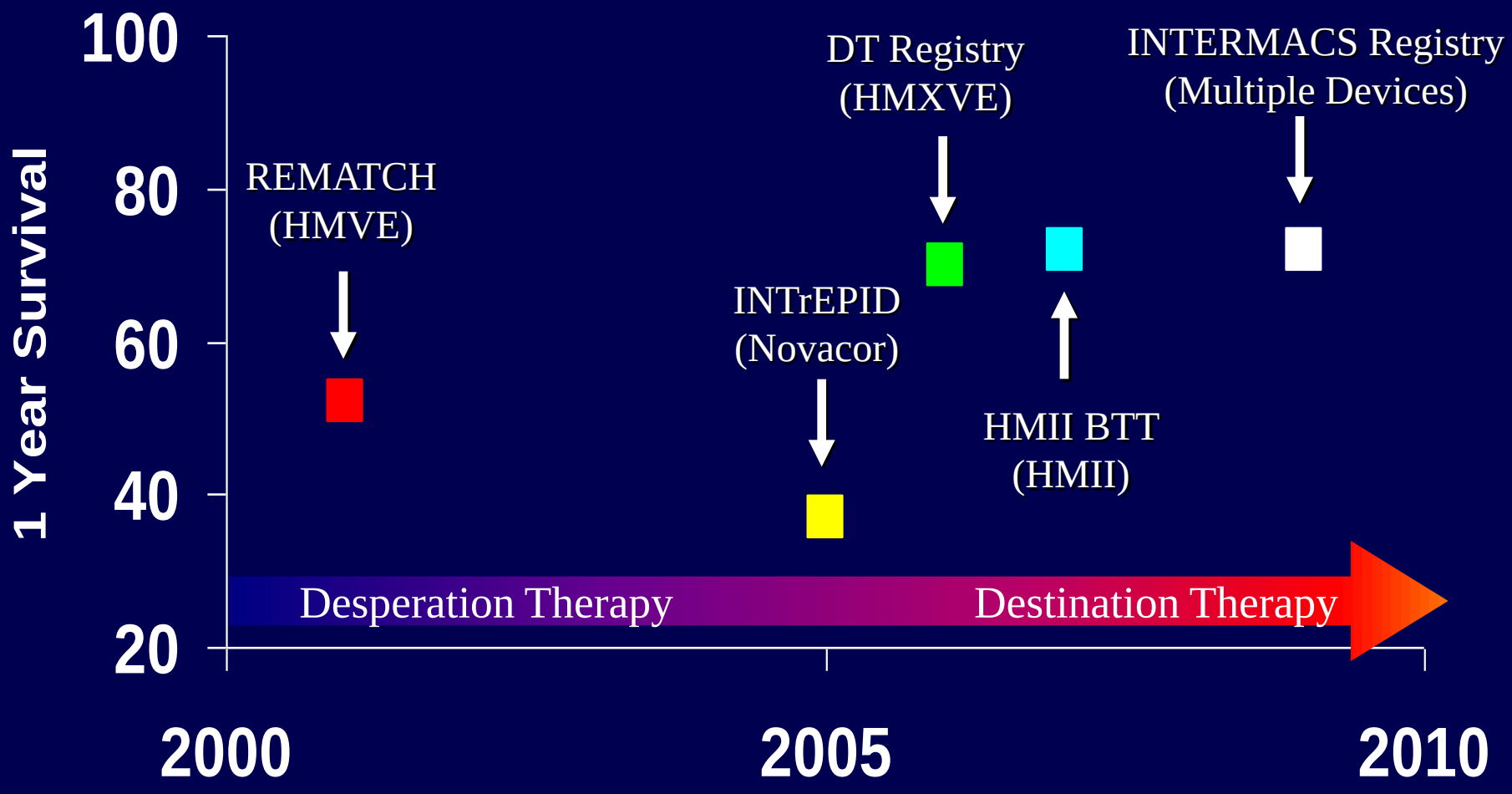
Disclosures

- Research Support and/or Consulting
  - NHLBI
  - Amgen
  - Cytokinetics
  - Roche Diagnostics
  - Otsuka
  - BG Medicine

The Evolution of Left Ventricular Assist Devices



Improving Survival with LVAD Therapy



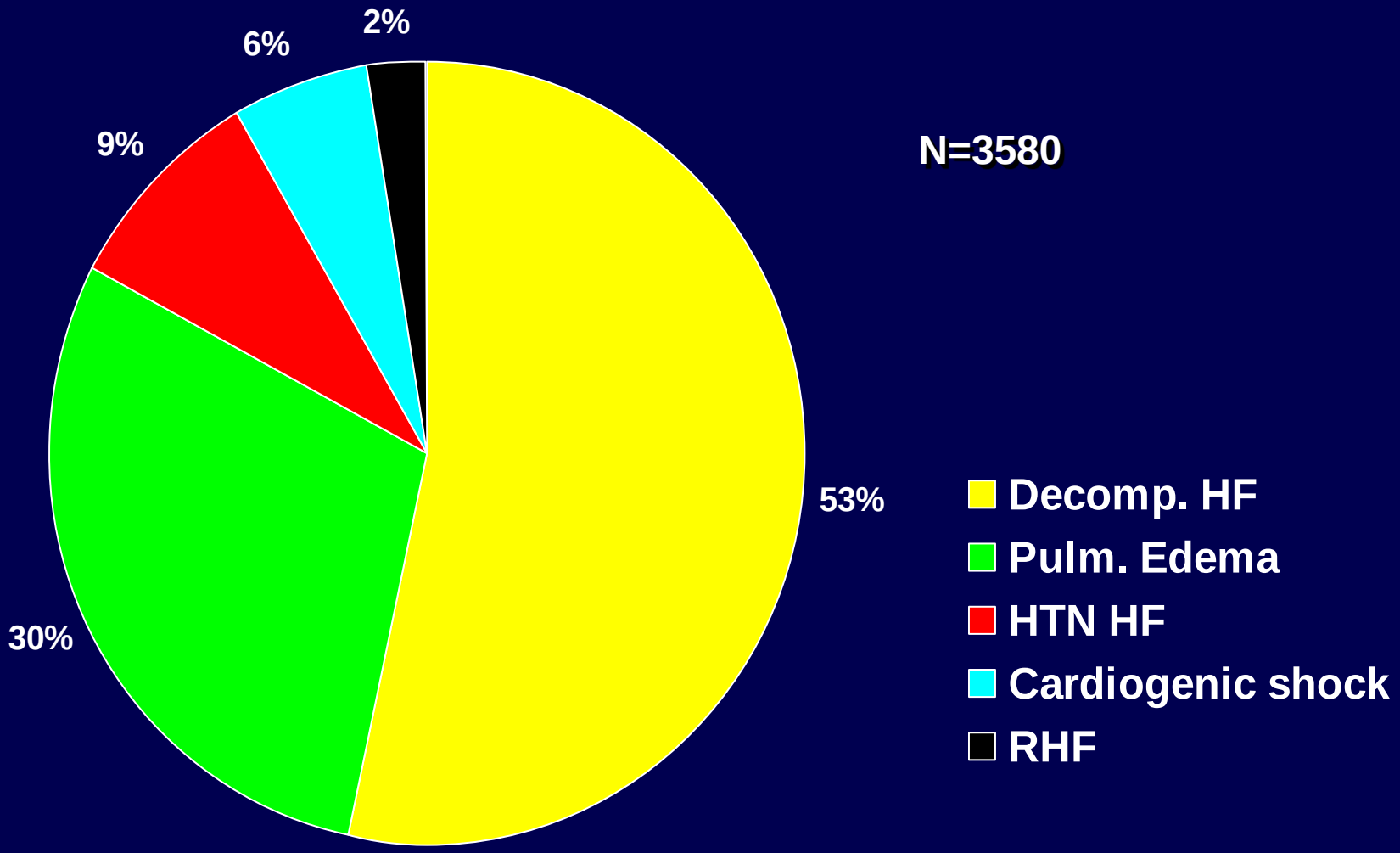
Indications for VAD Therapy

Bridge to Recovery/ Explantation	Device intended for short term support for a condition that is anticipated to reversible
Bridge to Bridge	Device intended for short term support (typically inserted in an emergent situation) until a more permanent device can be implanted
Bridge to Transplant*	Device typically intended for short- to intermediate-term support in patients actively listed for transplantation
Bridge to Decision	Device inserted to support a patient in whom the ultimate therapy is not able to be determined at the time of implantation. Device may be used for short or long-term support.
Destination Therapy*	Device inserted with the intention of long-term support in patients who are not candidates for transplantation

Outline

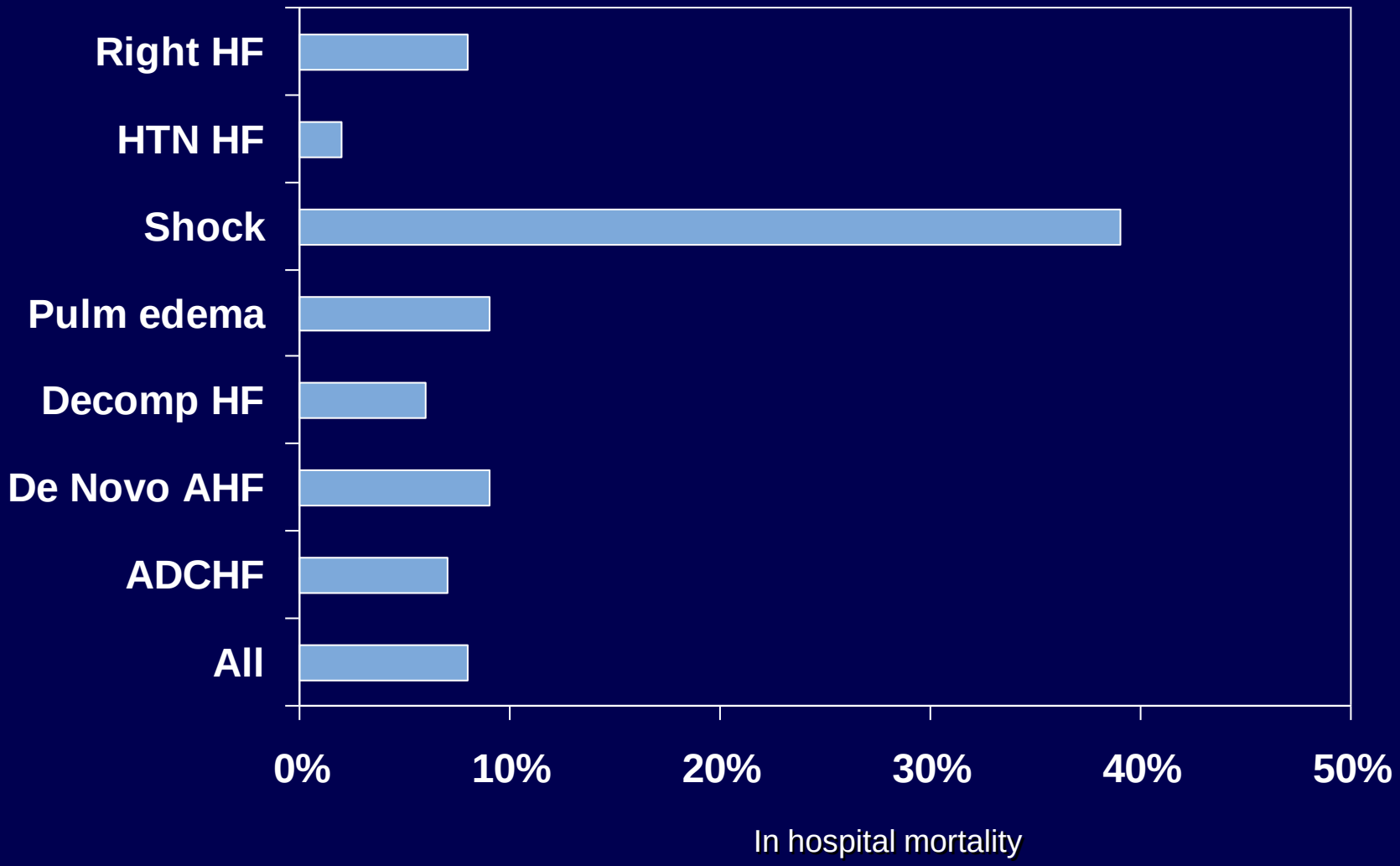
- Which Patients?
- Which Device?
- What Next?

Clinical Profiles in AHF:
Data from Euro Heart Failure Survey II



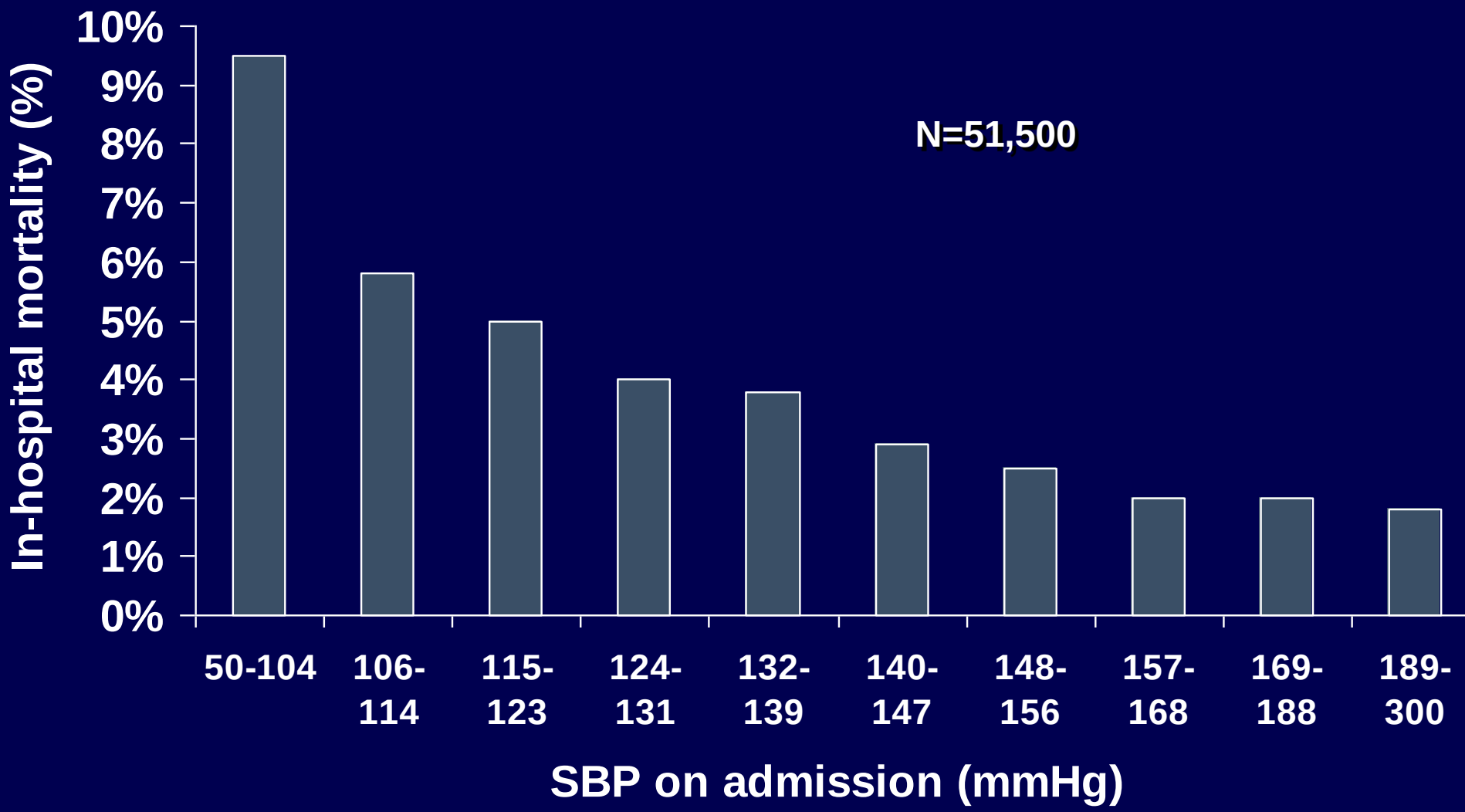
Nieminen, M et al Eur Heart J 2006

Mortality in AHF by Clinical Classification



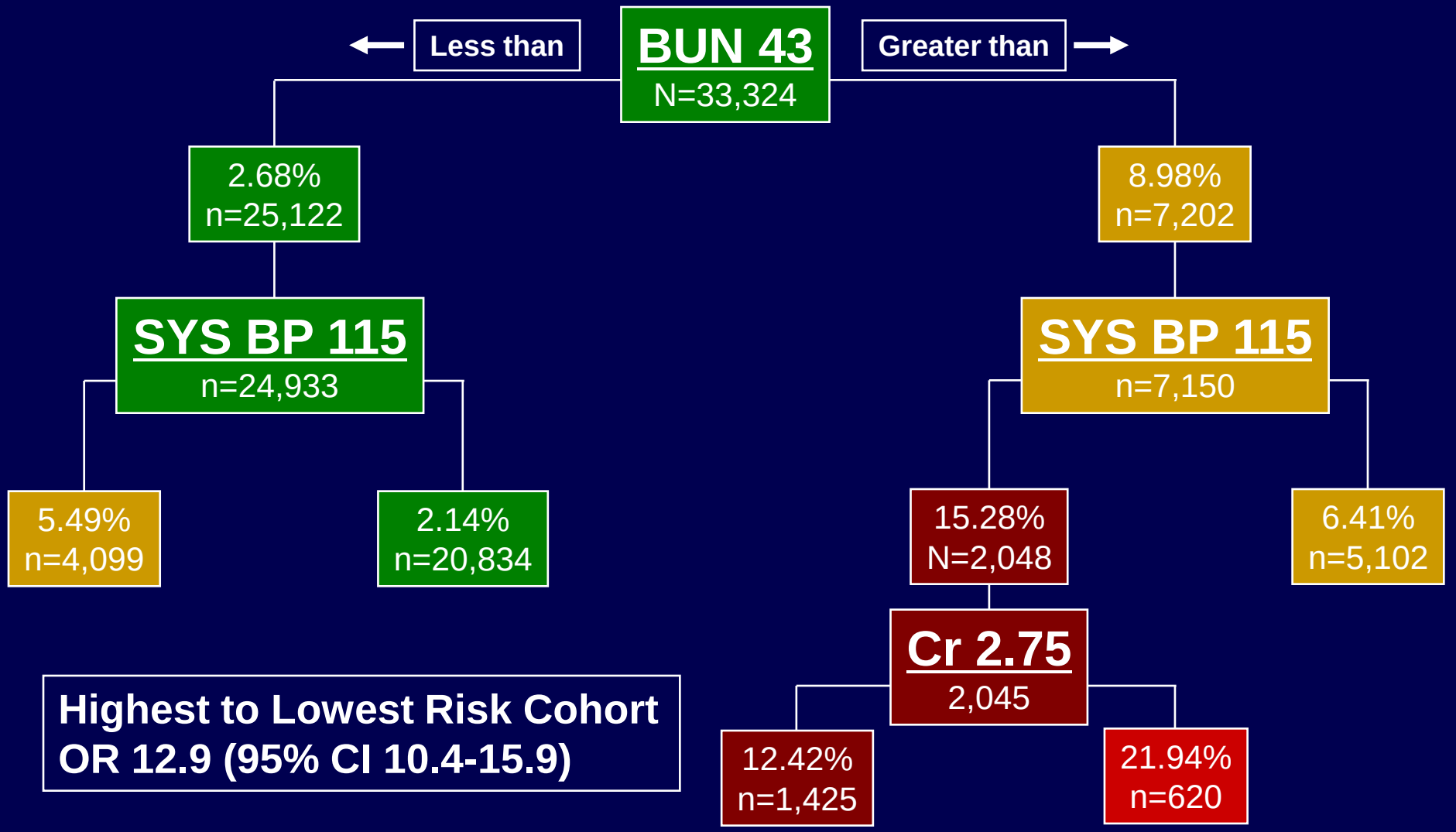
Nieinen MS et al. Euro Heart J 2006

SBP in AHF: Higher is Better?



Gheorghiade M et al JAMA 2007

ADHERE CART: Predictors of Mortality



Highest to Lowest Risk Cohort
OR 12.9 (95% CI 10.4-15.9)

Fonarow et al., JAMA 2005

Outline

- Which Patients?
- Which Device?
- What Next?

Choices of Device

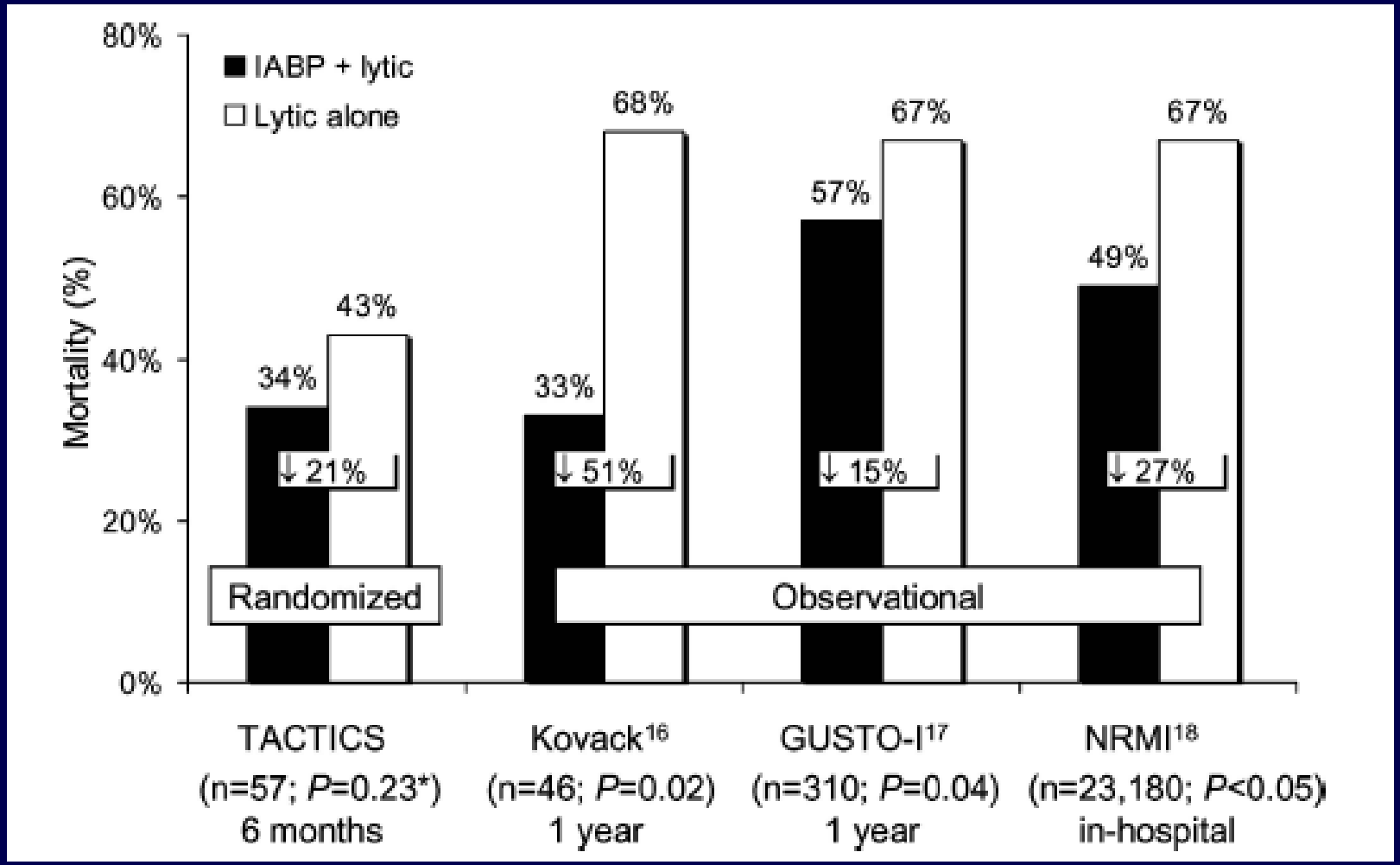
- Choices continue to evolve with changing technology
- Percutaneous
  - Intra-aortic balloon pump
  - Impella
  - Tandem-heart
  - Cancion (no longer in development)
  - ECMO
- Surgically implanted
  - Centrimag
  - Abiomed AB5000
  - Thoratec pVAD
  - Long term VADS (e.g., HeartMate II)

The Physiology of Counterpulsation

Enhanced coronary blood flow	▪ Diastolic balloon inflation increases intra-aortic pressure and coronary perfusion ▪ MAP increases from greater increase in diastolic pressure than reduction of systolic pressure ▪ Absolute change in coronary perfusion dependent upon vasoregulation
Left ventricular unloading	▪ Displacement of blood into the periphery ▪ Reduction of SBP ▪ Reduction of LVEDP ▪ Reduced LV wall stress ▪ Reduced LV O2 consumption
Improved cardiac output	▪ Preserved or increased stroke volume ▪ Increased cardiac output as a result of afterload reduction

Rogers, J. Mechanical Devices in Cardiogenic Shock, AHA 2009

IABP as an Adjunct to Thrombolytic Therapy

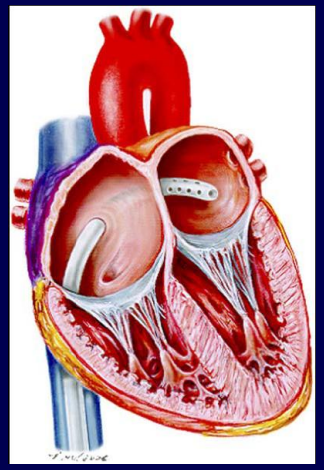


J Thromb Thrombolysis 2005; 19:33-9

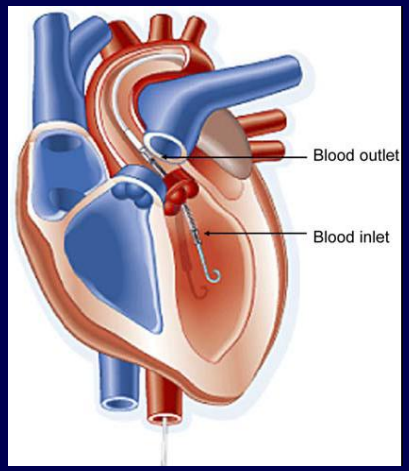
Clinical Pearls about IABP in AHF

- Use “too early” rather than “too late”
- Often effective even in non-ischemic patients
- May be less effective in very young patients due to greater aortic distensibility

Percutaneous MCS Devices



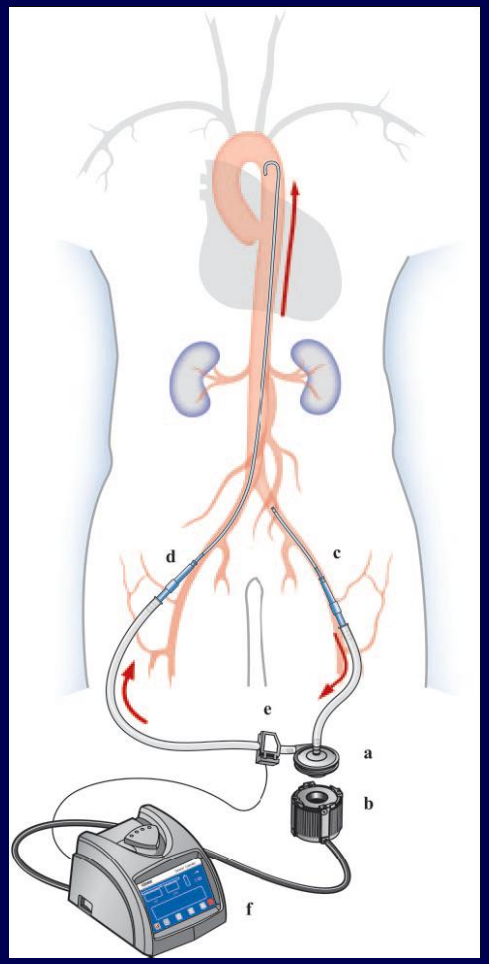
TandemHeart



Impella

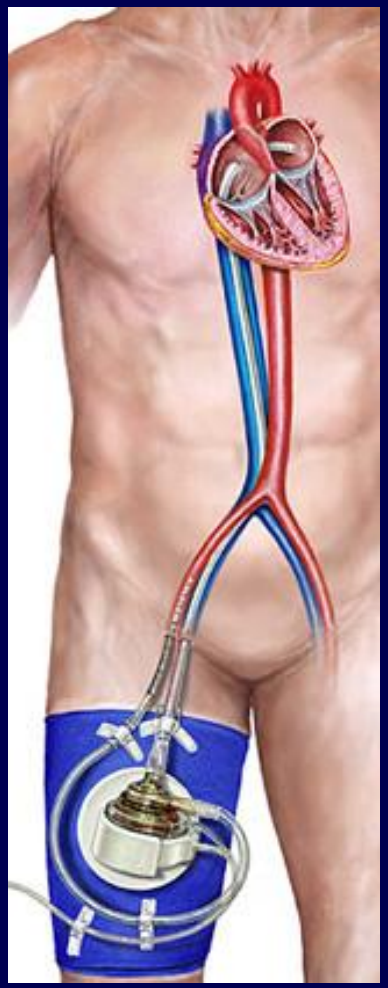
Potential Clinical Utility of Percutaneous VADS

- Acute cardiogenic shock
- Chronic decompensated heart failure
- Post-cardiotomy
- Hemodynamically assisted high risk coronary interventions
- Supported percutaneous valve repair/replacement
- Supported ventricular arrhythmia ablation



Cancion

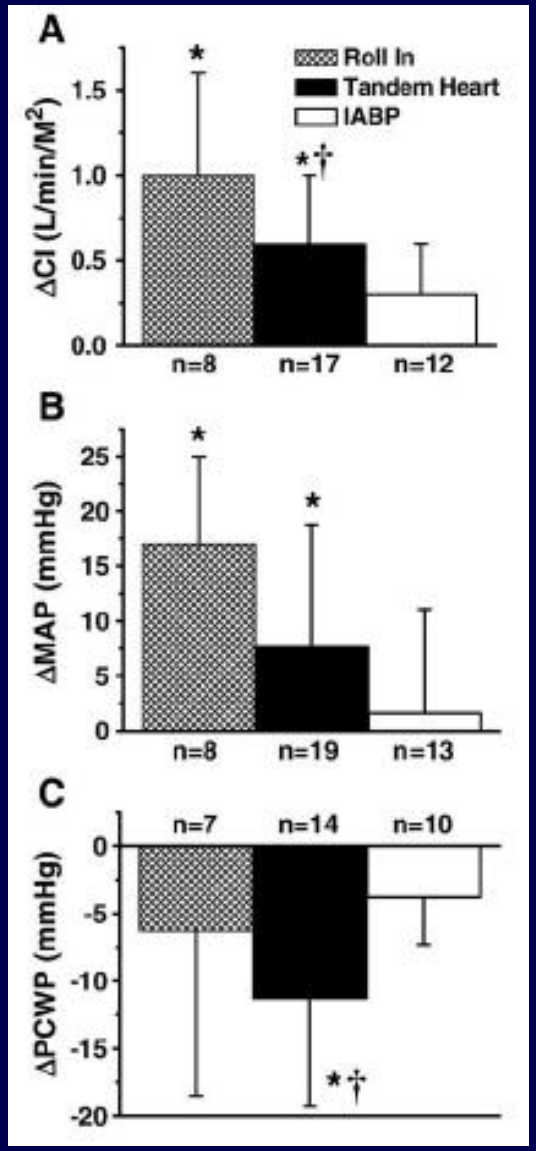
Percutaneous Mechanical Support



TandemHeart pVAD

- Percutaneous insertion
  - 21F venous cannula passes to left atrium via a transseptal puncture
  - 15-17 F arterial cannula
  - Centrifugal flow pump that can provide 3.5-4 l/min at 7500 RPM
- Systemic anticoagulation required
- Approved for short-term support

TandemHeart

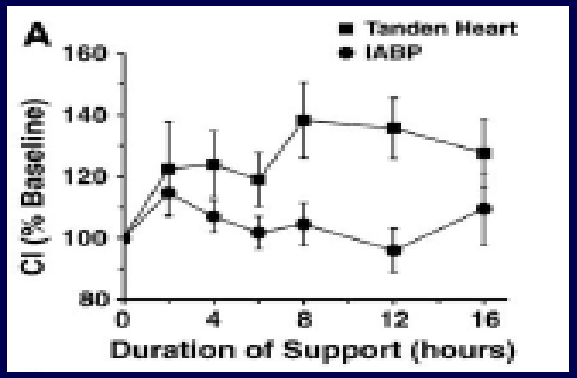


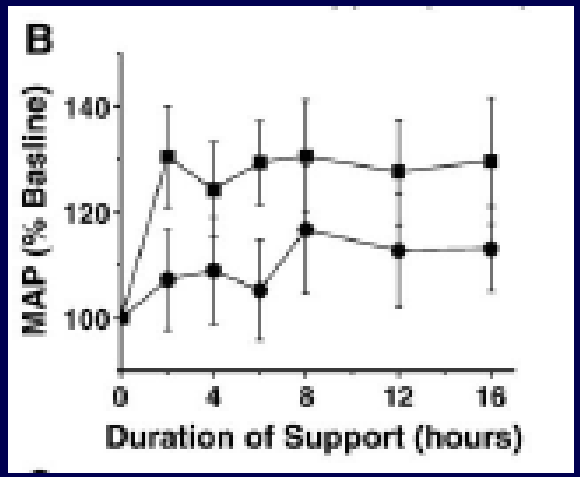
- Randomized trial of 42 patients with cardiogenic shock
  - 70% ACS
  - 30% Decompensated HF
- 71% with shock despite IABP
- Centers implanting first patient were allowed to implant the TandemHeart in the “Roll In” phase (non-randomized).
- Mean support duration=2.5 days

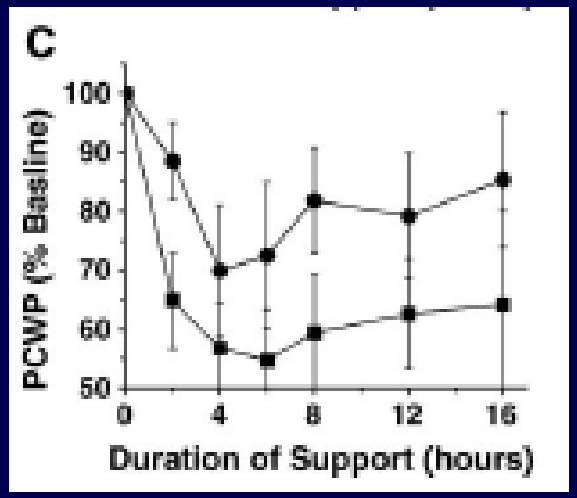
Burkhoff et al. Am Heart J 2006;152:469

TandemHeart Results

42 patients with cardiogenic shock randomized to IABP or TandemHeart



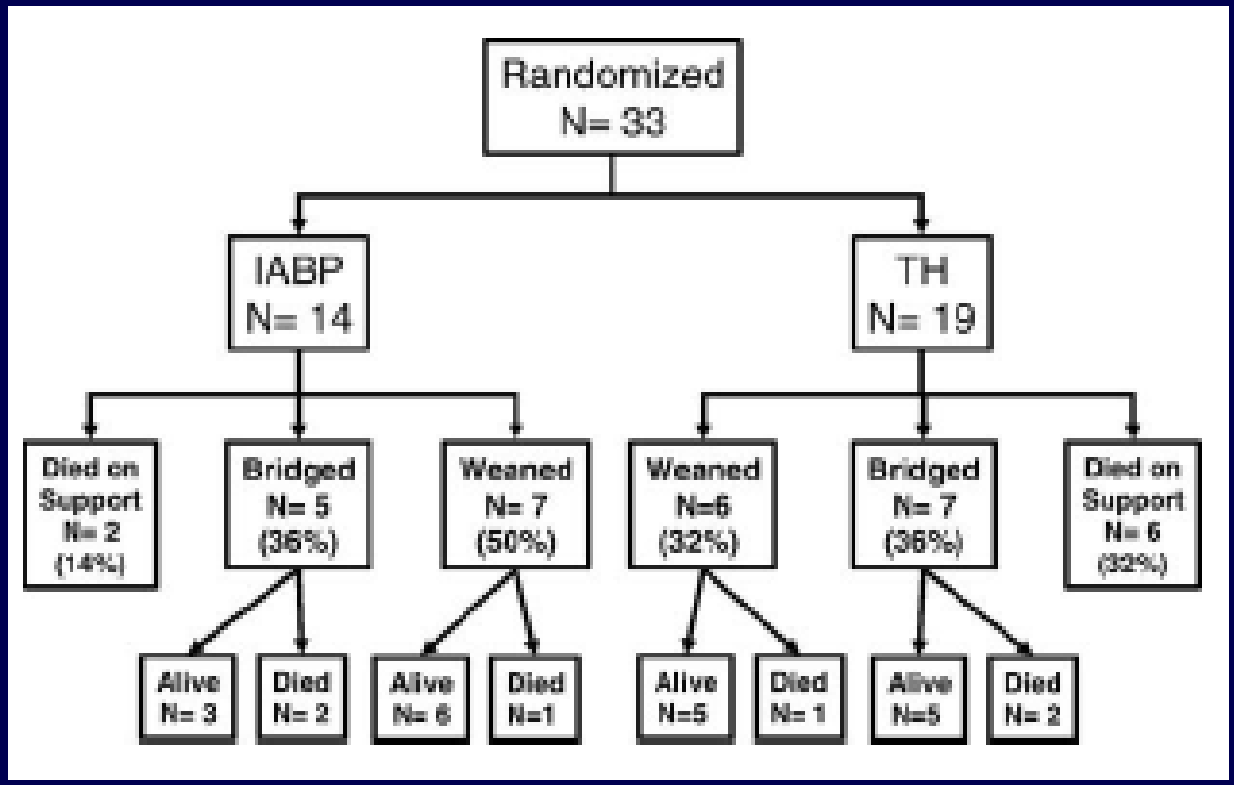




Am Heart J 2006;152:469

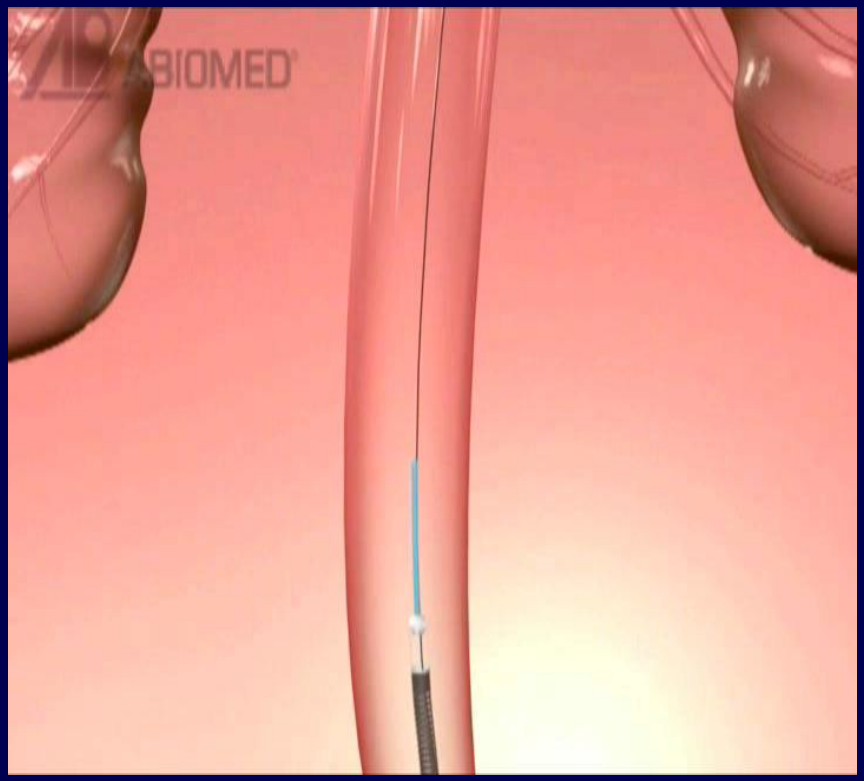
TandemHeart

- No difference in 30 day survival rates (IABP 64% vs. TandemHeart 53%)
- No difference in frequency of adverse events



Am Heart J 2006;152:469

Impella Recover



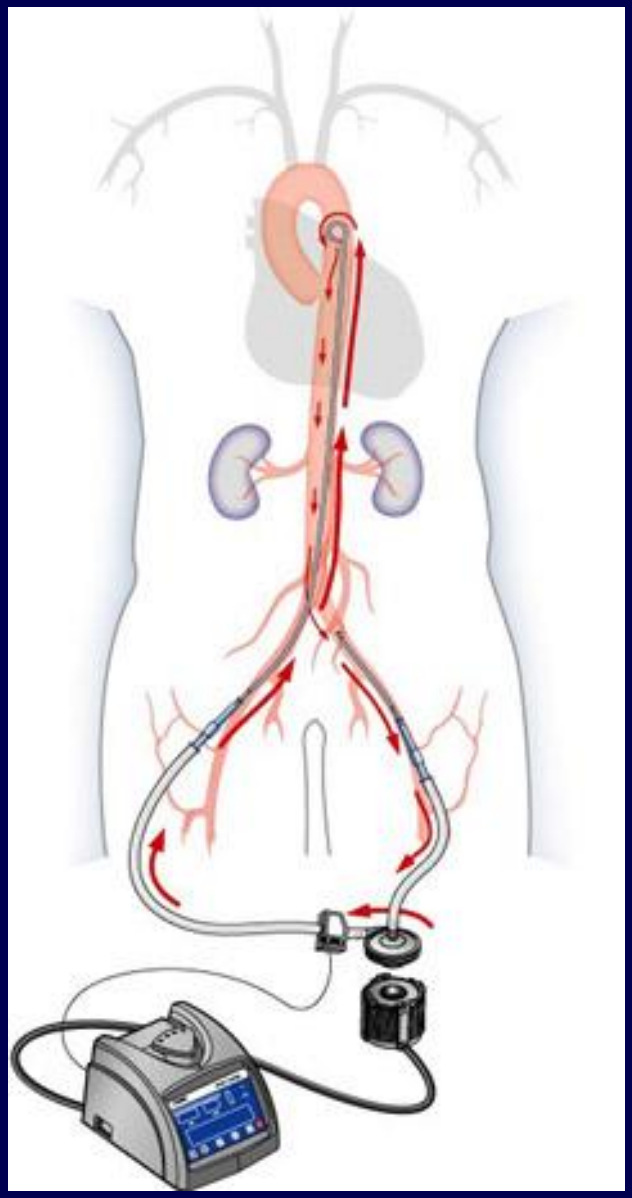
- Miniaturized rotary blood pump (axial flow)
- Provides up to 2.5 (percutaneous) or 5.0 (surgical) L/min at maximum speed of 50,000 rpm
- Inserted retrograde across the AoV to unload the LV
- No extracorporeal blood
- Requires heparin

Impella Trials

- *PROTECT II*: Prospective,randomized trial of Impella vs IABP in patients undergoing non-emergent high-risk PCI

- *RECOVER II*: Prospective, randomized trial of Impella vs. IABP in patients with post-MI hemodynamic instabilty

Cancion: Continuous Aortic Flow Augmentation

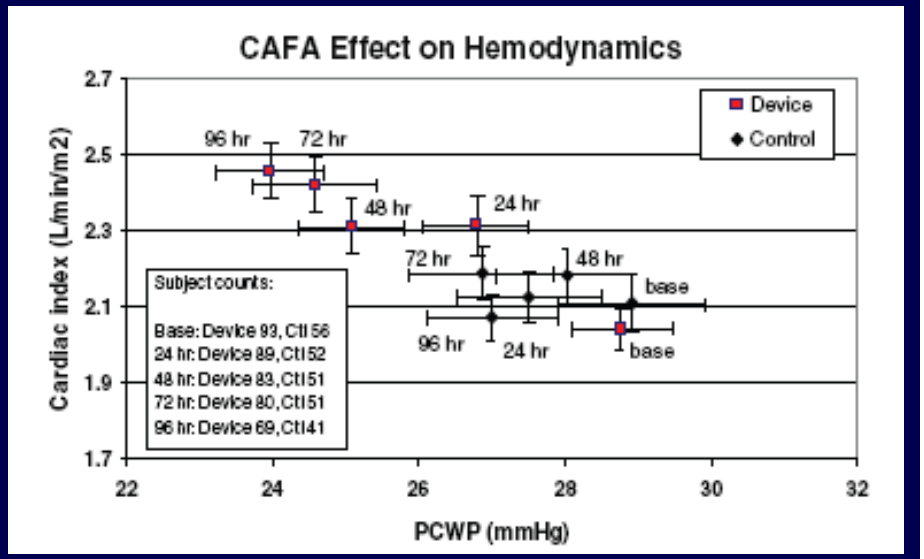


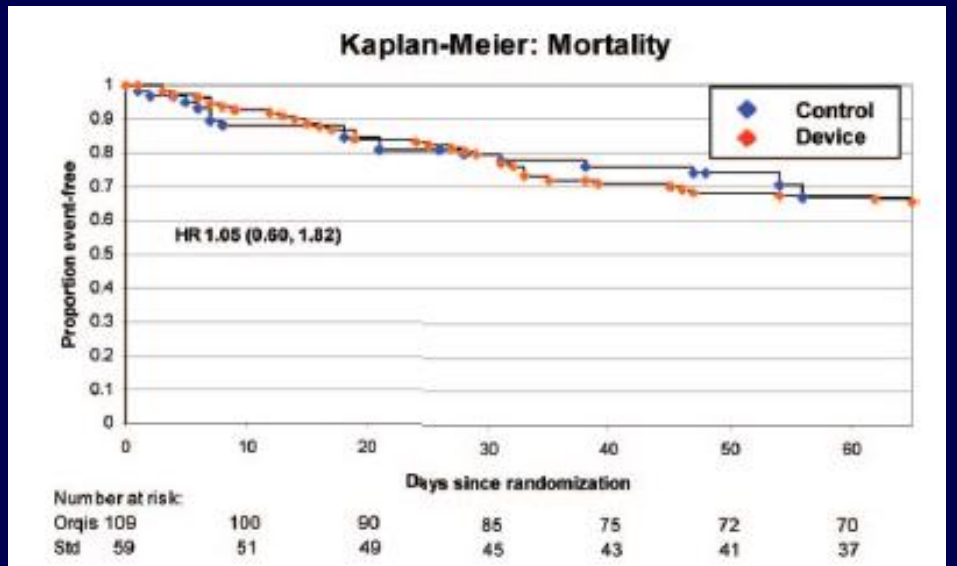
- Outflow from iliac artery and inflow to proximal descending aorta
- External pump drives the system. 2000-5400 rpm provides flows of 1.1-1.5 L/min
- Decreased afterload by reducing the inertia of a standing column of blood in the aorta at the onset of systole

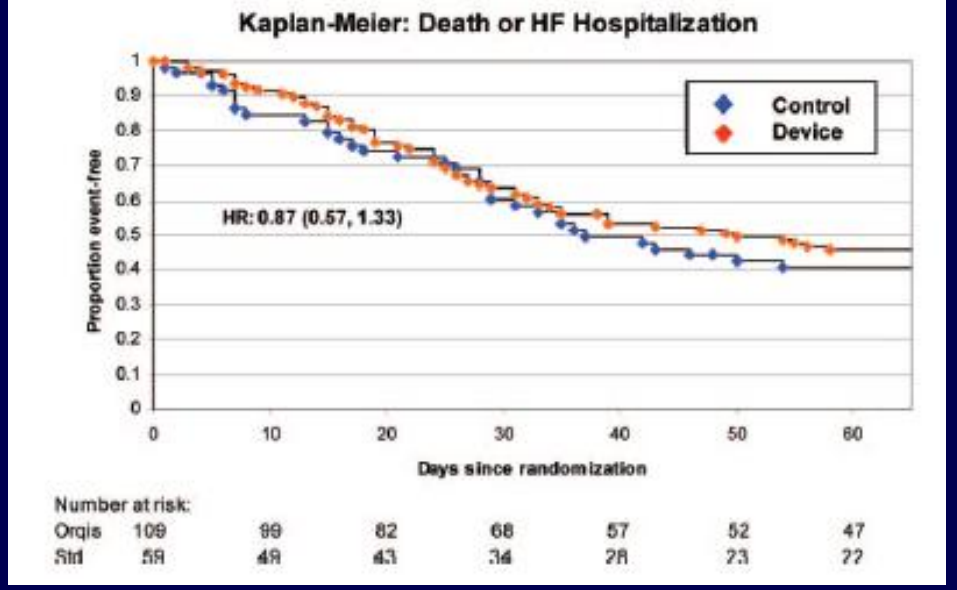
MOMENTUM

MOMENTUM Trial

- 169 patients (109 device; 59 control)
- Composite primary endpoint: PCWP and days alive and out of hospital at 35 days
- Stopped for futility and excess bleeding in the treatment arm

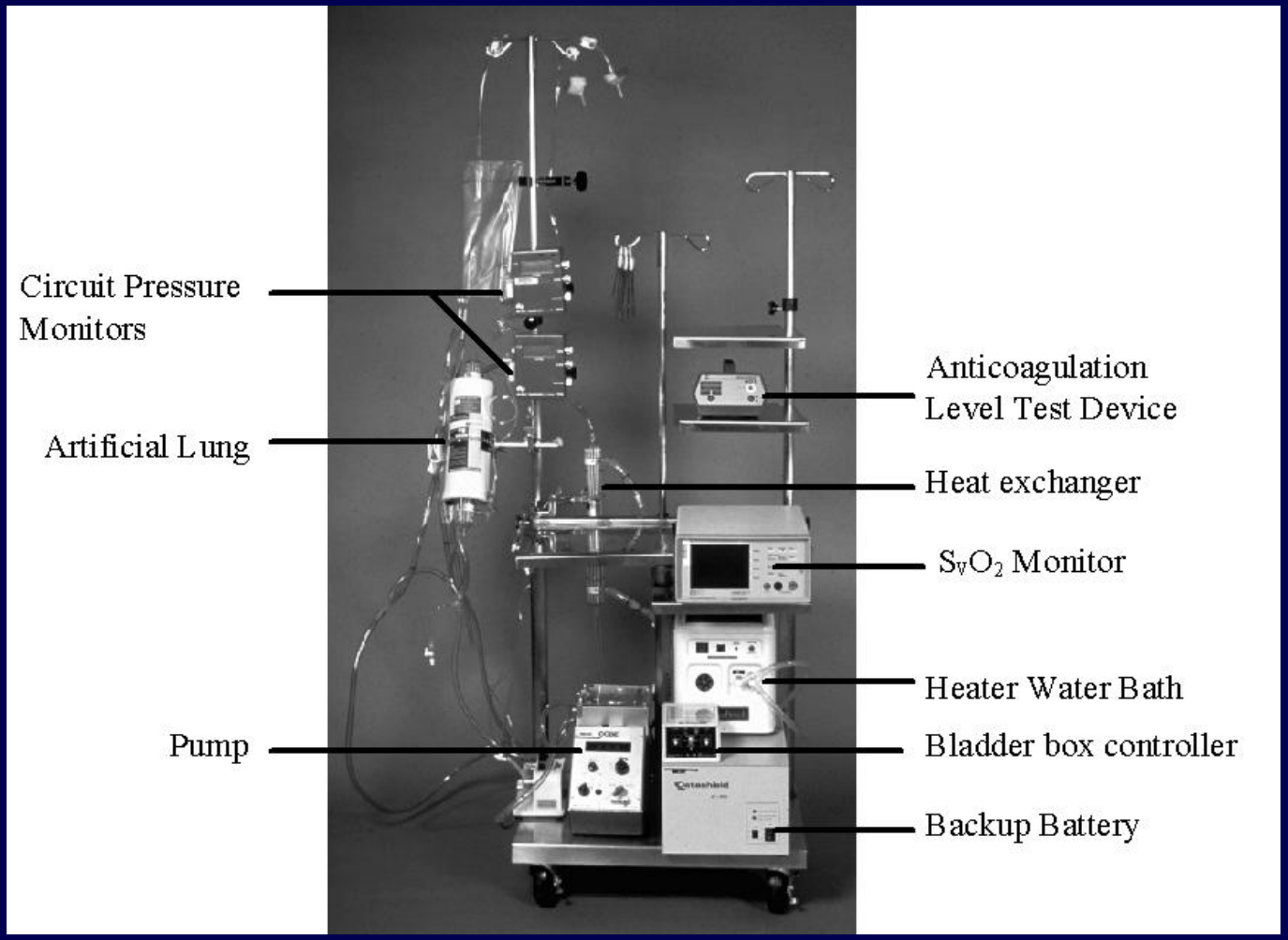






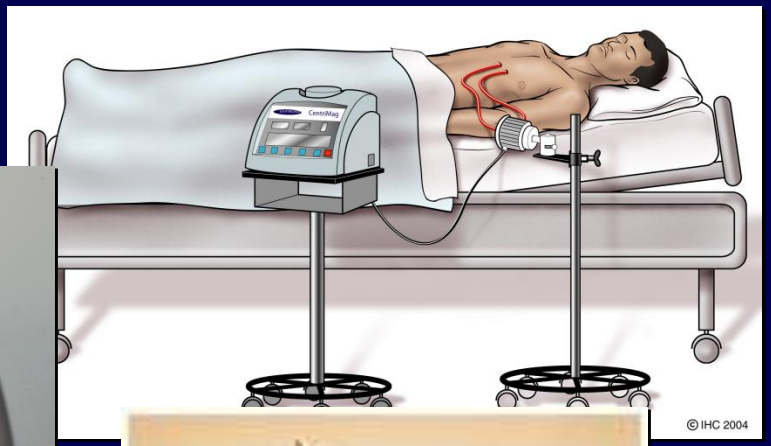
Circulation 2008;118:1241-9

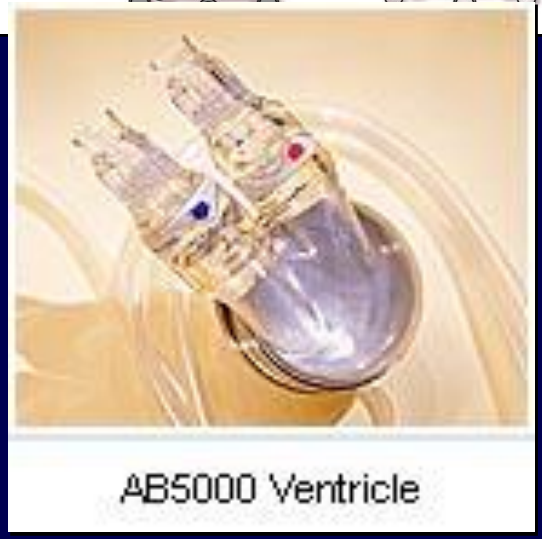
Extracorporeal Membrane Oxygenator



Surgically Implantable Temporary MCSD

Centrimag



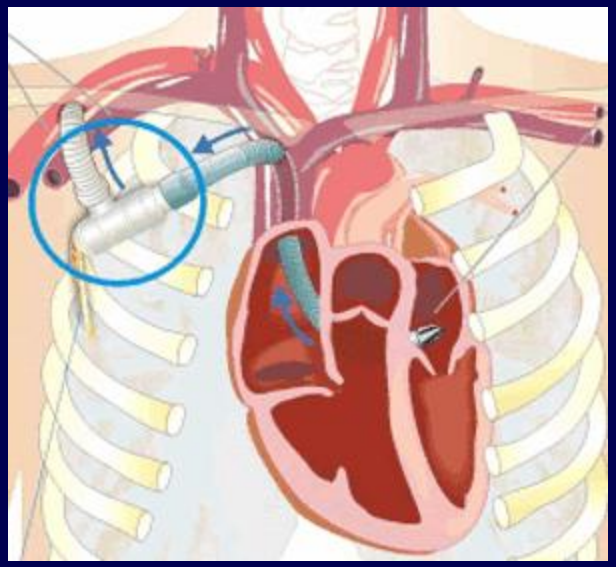


Abiomed

Thoratec pVad

Future of Percutaneously Placed MCS

Circulite Synergy



- Surgical or percutaneous implant
- Partial cardiac assist
- Flow 2-3 l/min
- Modeling suggests reduction of LVEDP 7-10 mm Hg
- 8-12 hours of untethered support

- 14 x 49 mm
- 25 gm

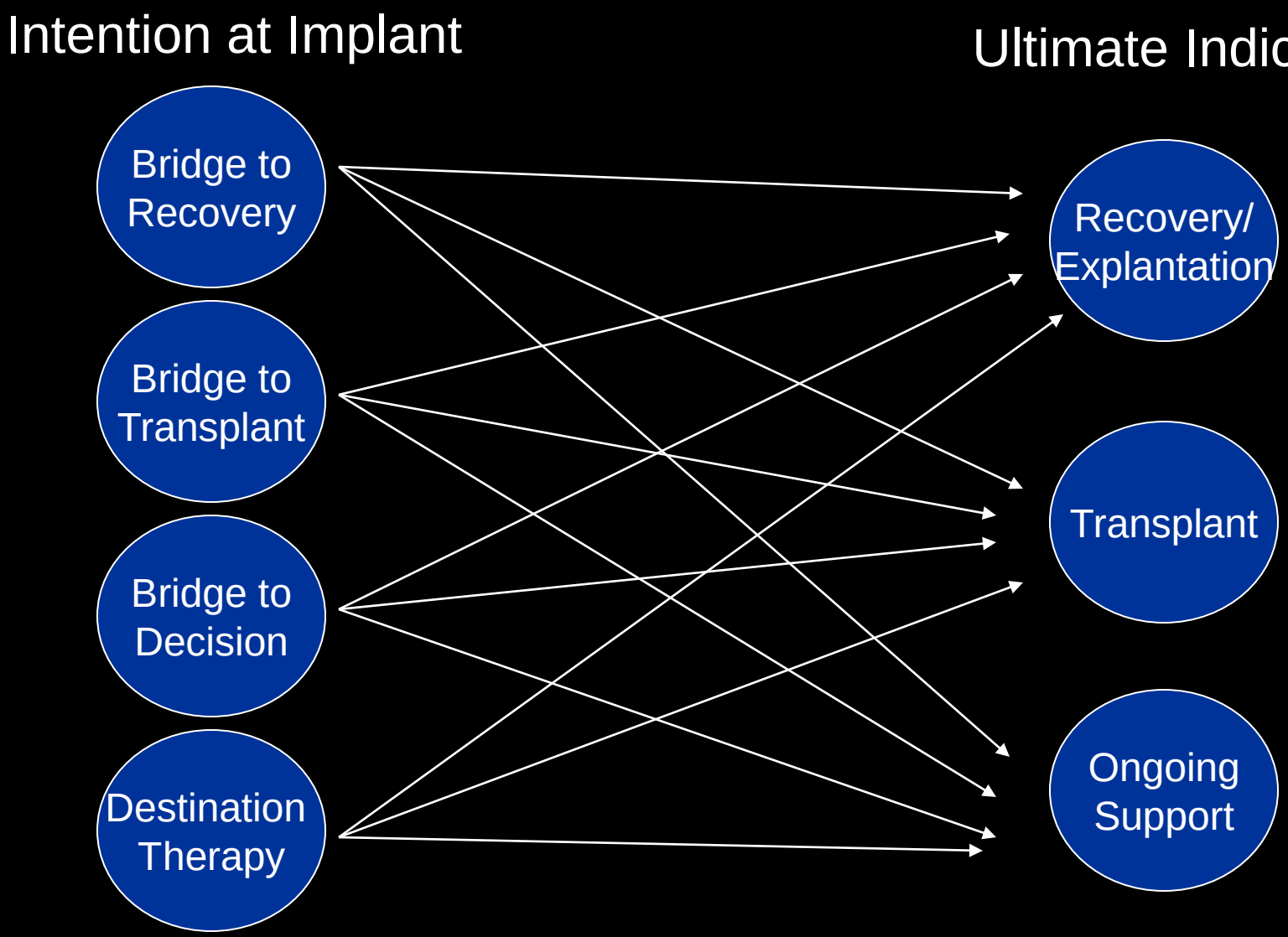
So, Which Device for my patient?

- Amount of Support Needed?
  - TandemHeart > Impella > IABP
- Duration of Support?
- Other issues (e.g., PVD, active bleeding)
- Local expertise?

Where to Next?

The eventual destination may not be immediately clear

Potential Outcomes of Device Implantation



Summary and Conclusions

- Percutaneous mechanical circulatory support devices are growing in capability and complexity
- Patient selection remains the most critical component of success with these devices
- Randomized data is sparse and complicated by the critical acute illness of many of these patients
- It is likely that centers invested in percutaneous circulatory support will require >1 device to satisfy the needs of the entire population
- Conceptually we are moving from total cardiac output replacement to partial hemodynamic support