Clinical Advancements in Cardiovascular Care
Pomona Valley Hospital Medical Center

Mechanical Circulatory Support in Advanced Heart Failure and Cardiogenic Shock

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Disclosures:

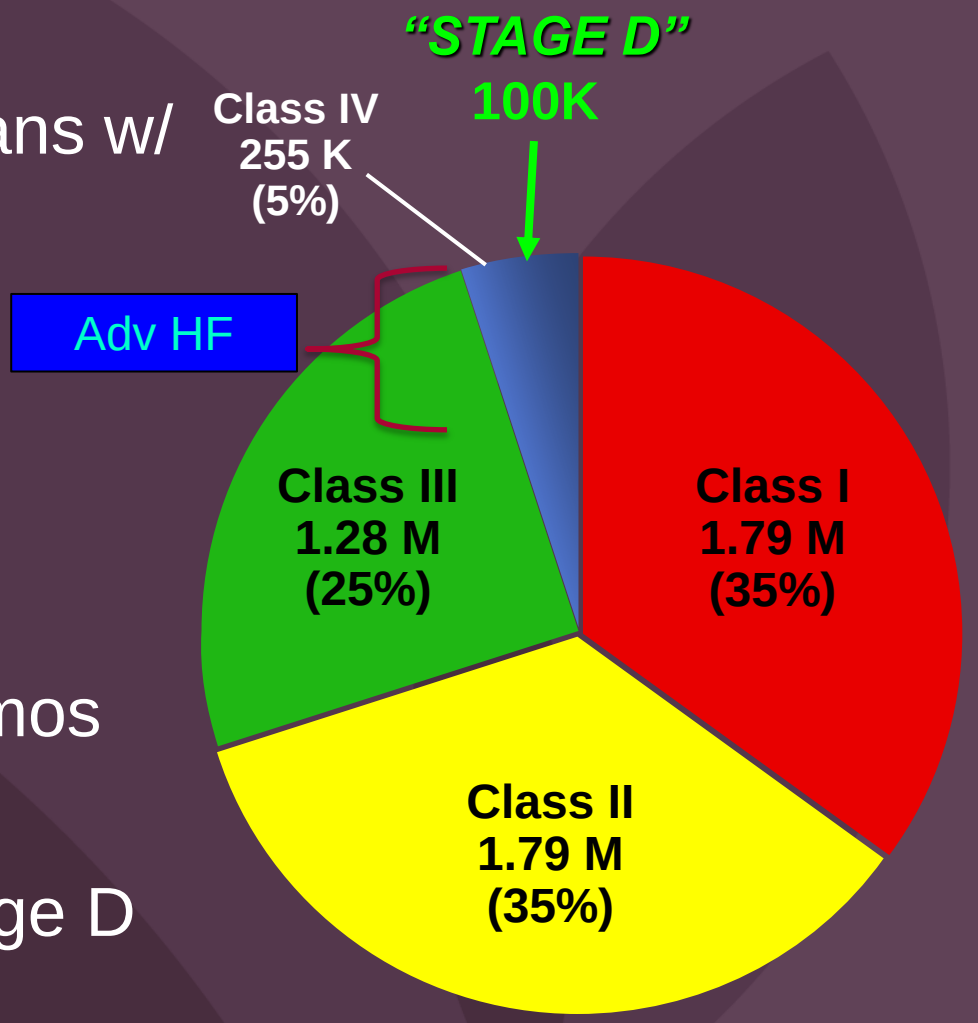
Research grant (Medtronic)

HF Advisory Board (Abiomed)

Research Grant (Actelion)

The Burden of Congestive Heart Failure

- Nearly 6.5 million Americans w/ HF ~ 8 million by 2030
- > 960,000 new cases/yr
- $32 billion expenditures
- ~ $70 billion 2030
- #1 DRG > 1 million hosp
- 50% readmitted within 6 mos
- 50% dead within 5 years
- 90% 1 yr mortality for Stage D



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AHA Heart and Stroke Statistical Update 2017.

Mechanical Circulatory Support: Indications

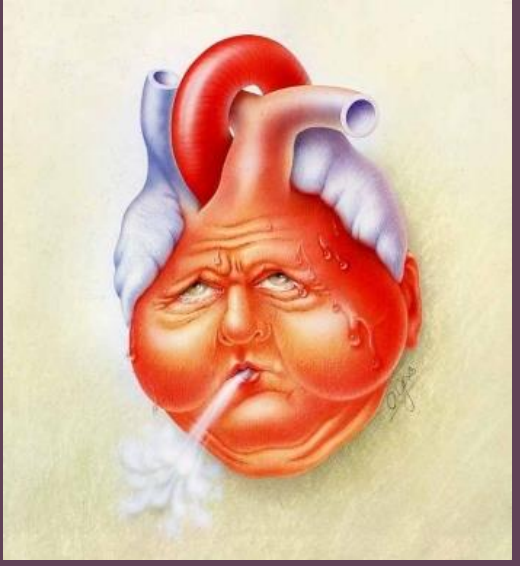
- Cardiogenic Shock (post-MI, dilated, valvular)
- Post-cardiotomy syndrome (failure to wean off CPB)
- Hemodynamic instability/deterioration despite OMM
- Long anticipated wait for suitable donor (big O)
- Inotrope / IABP / ECMO dependence
- Recurrent ventricular tachycardia / VT storm
- Viral myocarditis / PP CMY w/ CS (BTR vs BTT)
- Frequent admissions for ADHF
- Cardio-renal syndrome / intolerance to HF therapies
- S/P cardiac arrest; support until candidacy det. (BTD)

Contraindications to MCS

- Absolute contraindications
  - Irreversible hepatic disease (cirrhosis)
  - Irreversible renal dz/chronic HD (unless kid tx candidate)
  - Irreversible neurologic dz
  - Severe lung dz or systemic illness limiting survival
  - Severe psycho-social limitations (no caregiver) non-compl.
- Relative contraindications
  - Obesity (BMI > 35) cachexia (< 18)
  - Neuromuscular disorder impairing rehab / survival
  - Active sepsis / recent CVA/ICH or vent dependence
  - Untreated malignancy / active GIB / coagulopathy / +HIT
  - Severe PVD / Diabetes w/ mod end organ involvement
  - Active substance abuse / psychiatric disorder / cognitive impair.

MCS:
General Considerations

- Importance of selecting critically ill patients to justify risk of surgical intervention (risk stratification)
- Need to avoid patients who are too ill for any reasonable chance for successful outcome (IM 0/MSOF/adv age)
- Selecting the correct MCS device
  - Temporary vs durable device
  - Left, right or biventricular support
  - Need for short term MCS/RHC to optimize
  - Estimated waiting period for donor
- Expeditious intervention once decision made to proceed
- Cost and insurance considerations



Patient Selection for MCS: Risk Assessment

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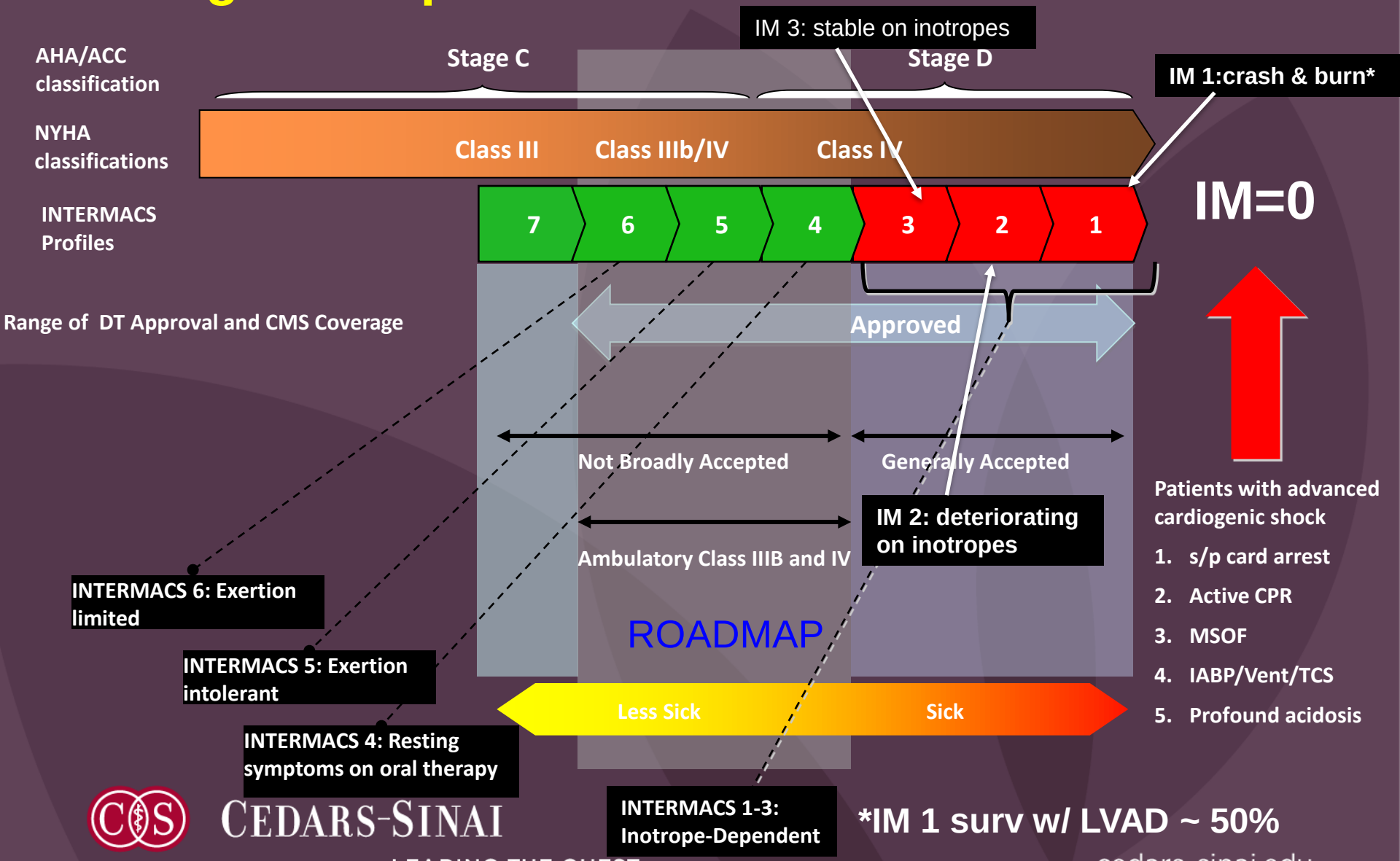
Defining the Population with Advanced Heart Failure



*IM 1 surv w/ LVAD ~ 50%

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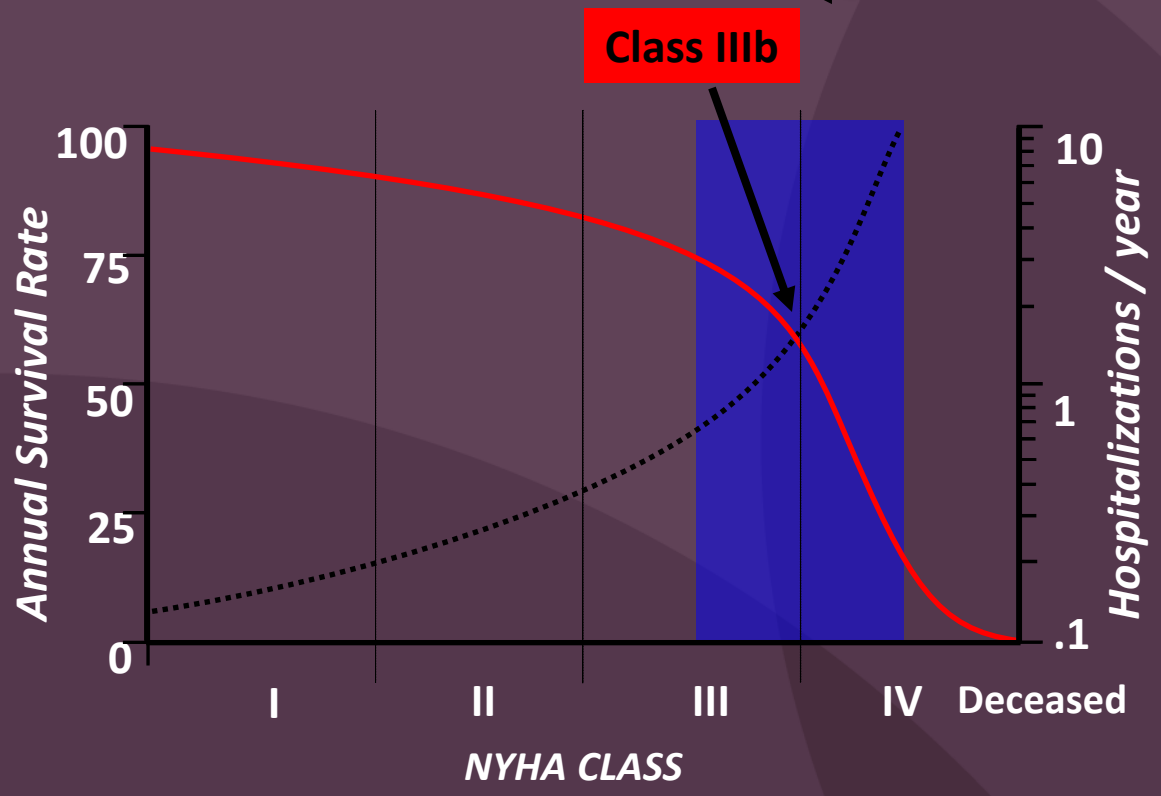
Slide Concept: David Farrar, PhD

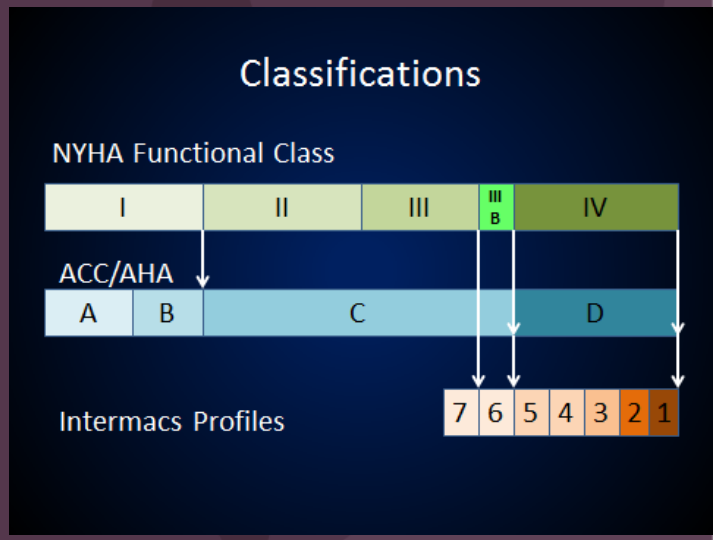
Natural History of Heart Failure and Timing of MCS

- 25% of HF Patients
- Frequent hospitalizations
- Worsening symptoms despite drug therapy
- Significant opportunity for new therapies



Survival Rate

Hospitalizations



Adapted from Bristow, MR Management of Heart Failure, Heart Disease: A Textbook of Cardiovascular Medicine, 6th edition, ed. Braunwald et al.

Adapted from Mark Slaughter, MD

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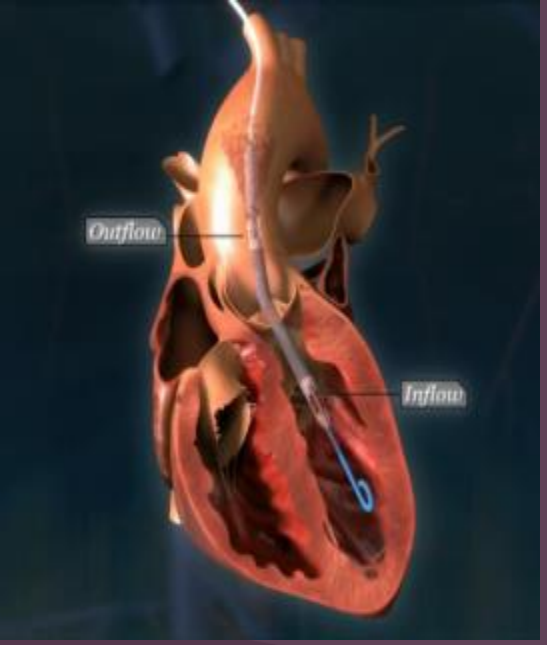
Keys to Successful MCS Outcome

- Appropriate Patient Selection
- Timing of implantation
  - INTERMACS profile 3-4 ideal
  - IM profile 1-2 higher risk (may need TAH, ECMO as short term bridge to decision or BTB
  - IM 5-6 if long anticipated wait
- Device selection
- Early referral to tertiary center!



Device Selection

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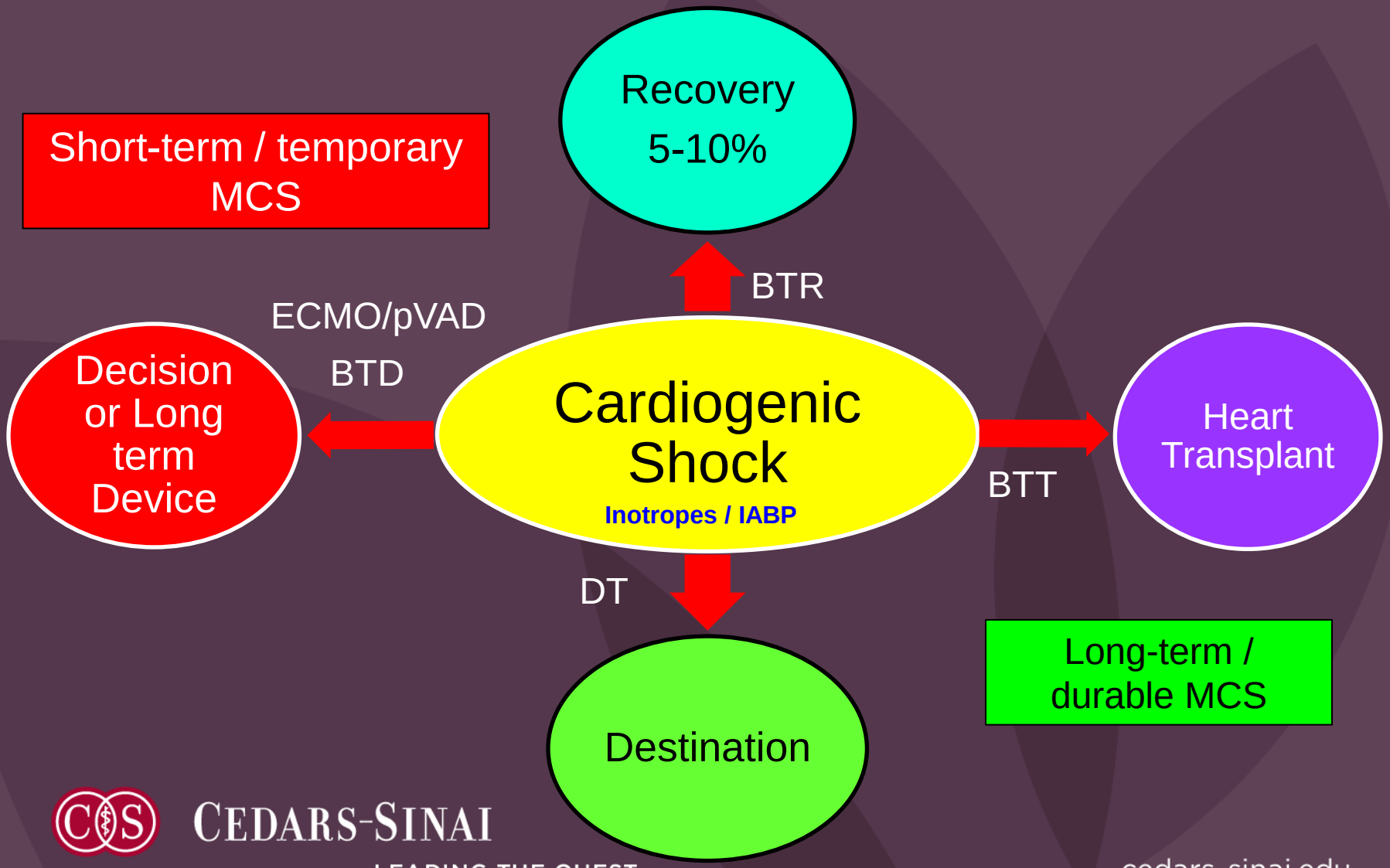
Strategies for MCS



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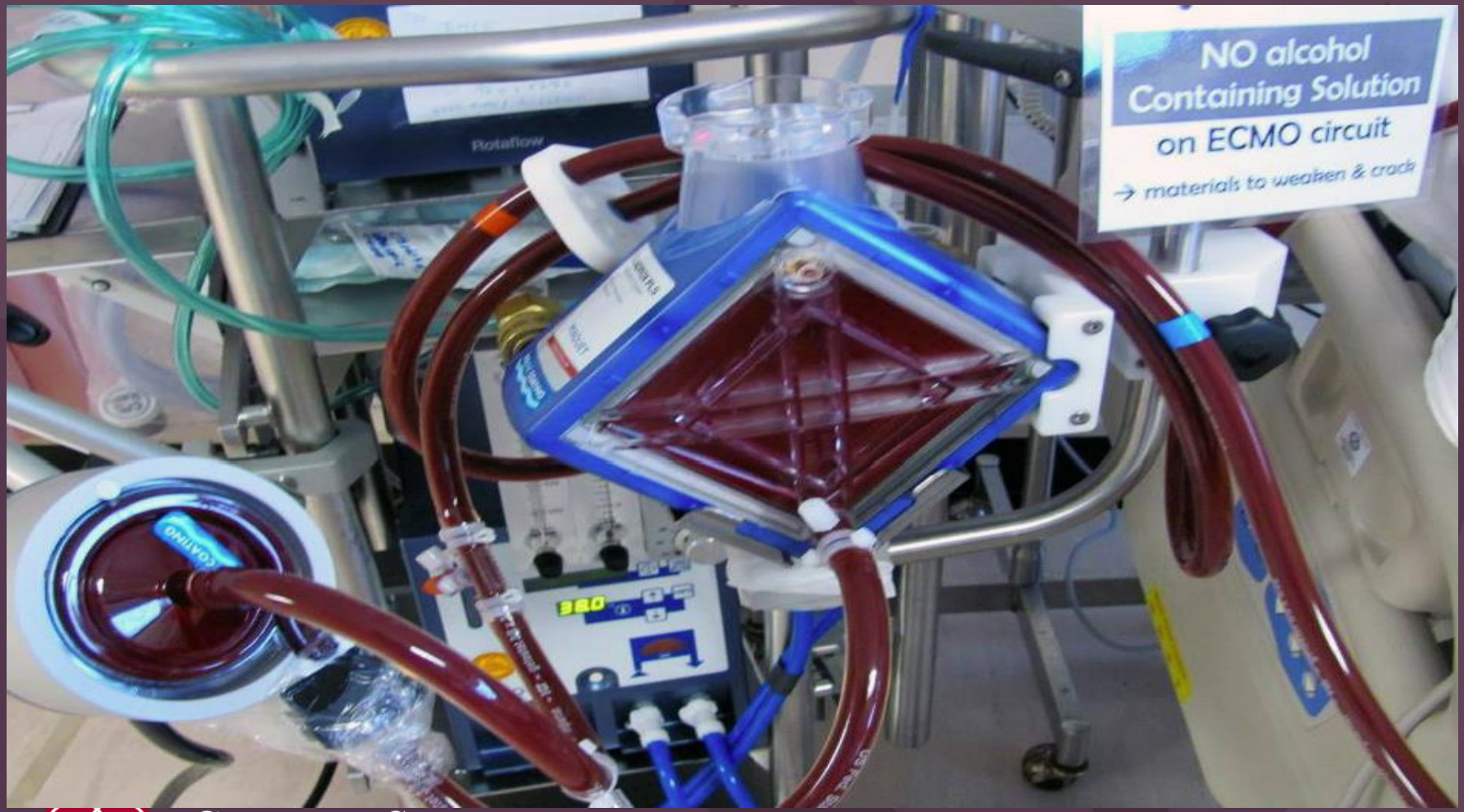
ECMO

Short-term bridge to decision(BTD) or (BTB)



VA ECMO
Indications*

- Cardiogenic shock refractory to medical management
- Witnessed cardiac arrest
- INTERMACS 0-1 profiles cardiogenic shock pts with potential for OHT/durable devices (BTD/BTB)
- Acute or fulminant myocarditis
- Post-partum cardiomyopathy with shock
- Acute massive MI with pulmonary edema
- Acute refractory transplant rejection
- Cardiotoxic poisoning / overdose
- Post-cardiotomy syndrome
- VA ECMO does not unload the LV

ECMO
Contraindications

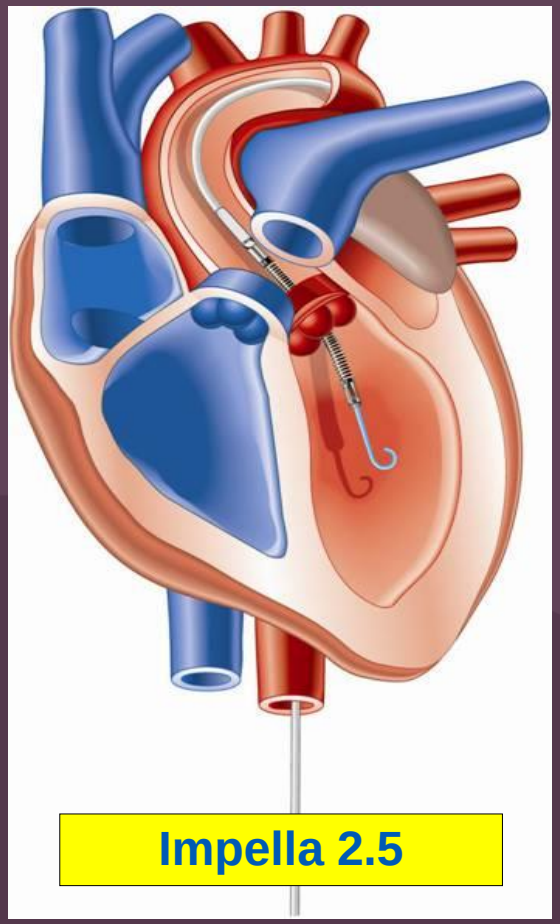
- Unrecoverable cardiac function in non-Tx/durable MCS pts
- MSOF
- Prolonged CPR w/o adequate tissue perfusion
- Unwitnessed cardiac arrest (neurologic)
- Terminal illness (end-stage COPD, malignancy, CVA etc)
- Massive septic shock*
- Non-medical contraindications
  - cognitive limitations
  - psychiatric limitations
  - social limitations
  - advanced age / size

Mortality inc exponentially > 7 days support

Temporary Mechanical Circulatory Support

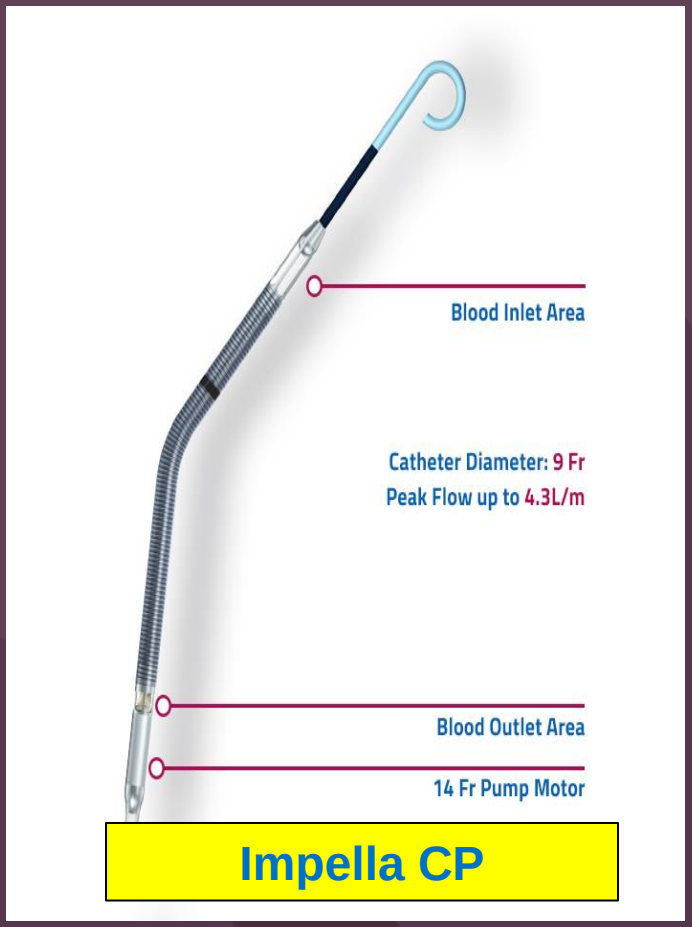
Role of Percutaneous
LVADs (or pVADs)

The Impella Catheters



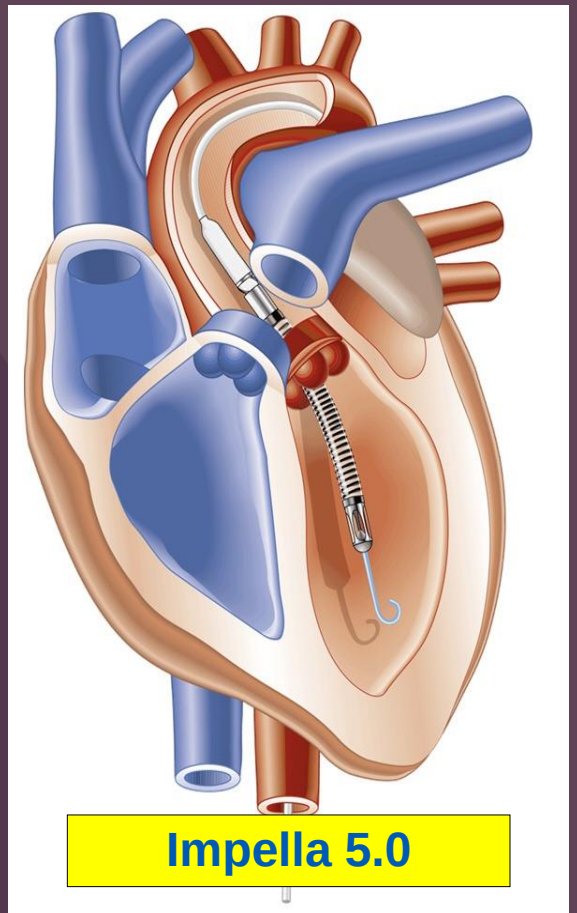
Impella 2.5

- Percutaneous access – 12F
- Actively unloads the LV
- Provides up to 2.5 liters/min of flow
- Rapid insertion in cath lab or CVOR



Impella CP

- Femoral / axillary artery percutaneous access
- Actively unloads the LV
- Provides up to 4.3 liters/min of flow
- Rapid insertion in cath lab or CVOR



Impella 5.0

- Femoral / Axillary cut-down using vascular graft (9 F catheter)
- Surgically placed (21 F pump)
- Provides up to 5.0 liters/min of flow
- Preferred pVAD for cardiogenic shock esp large BSA

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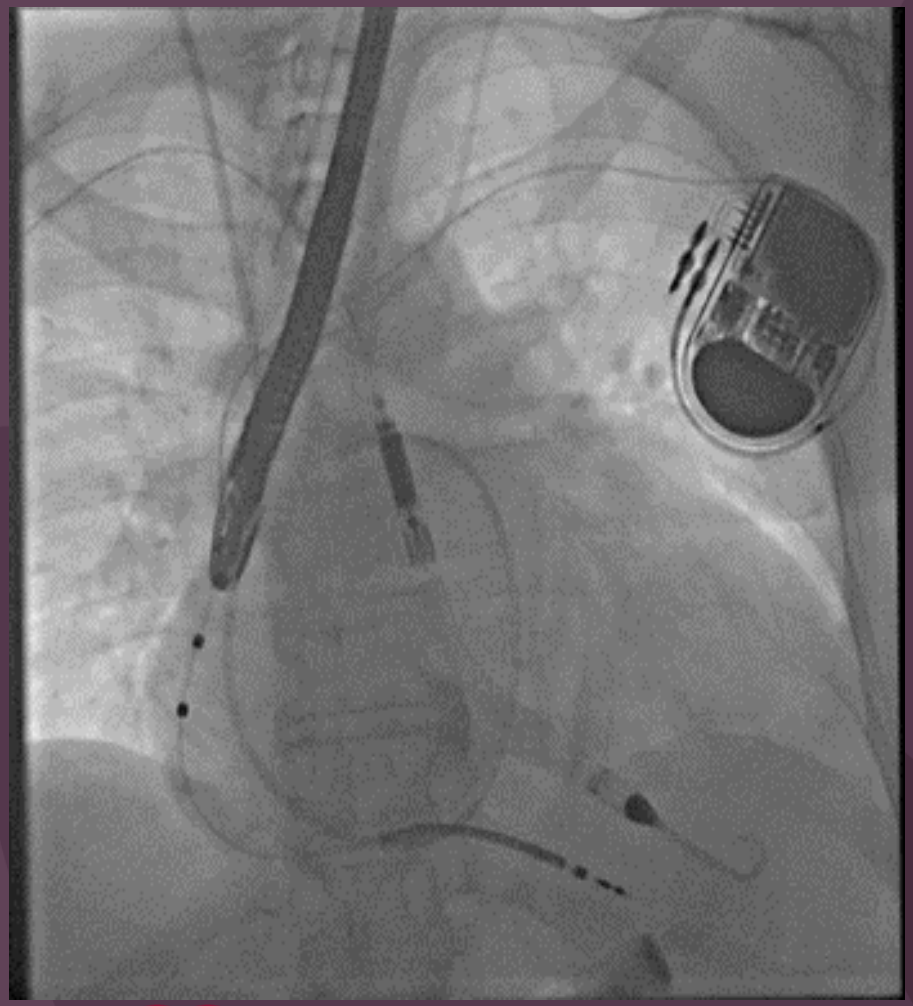
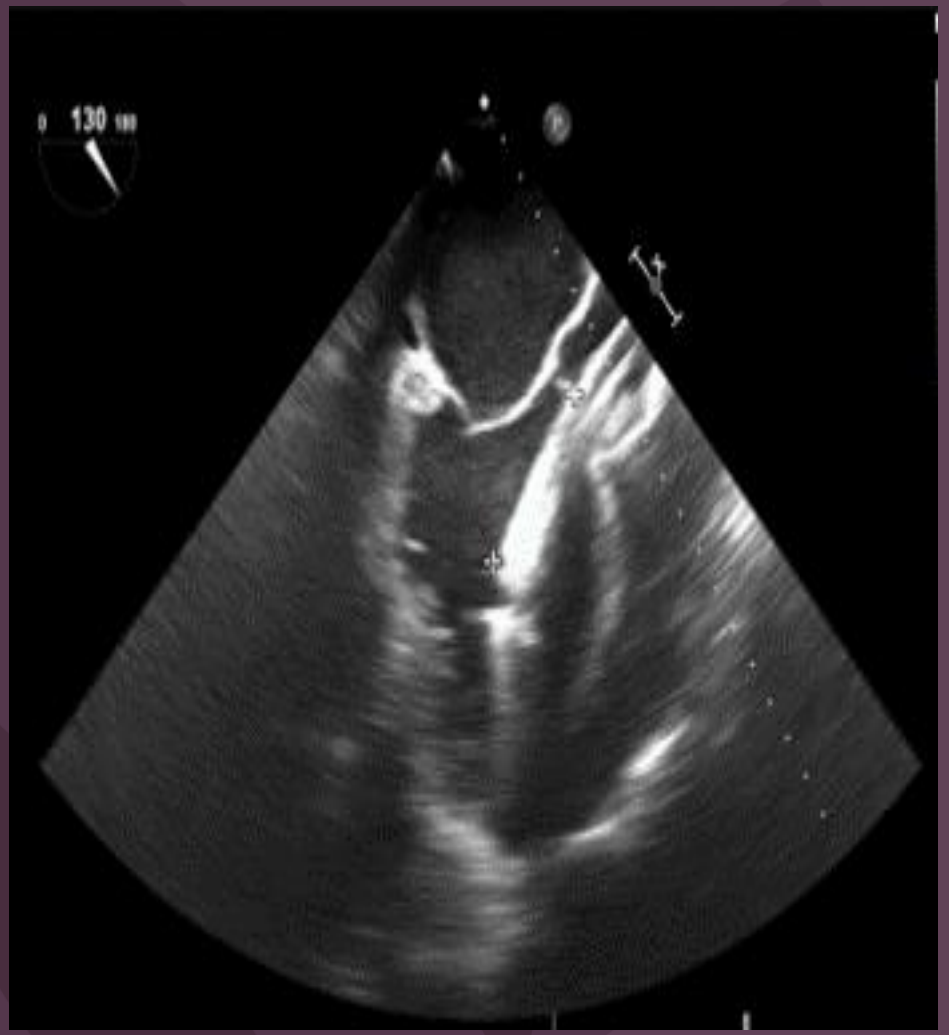
Impella Position in LV

CXR/fluoro & Echo





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Percutaneous VADs

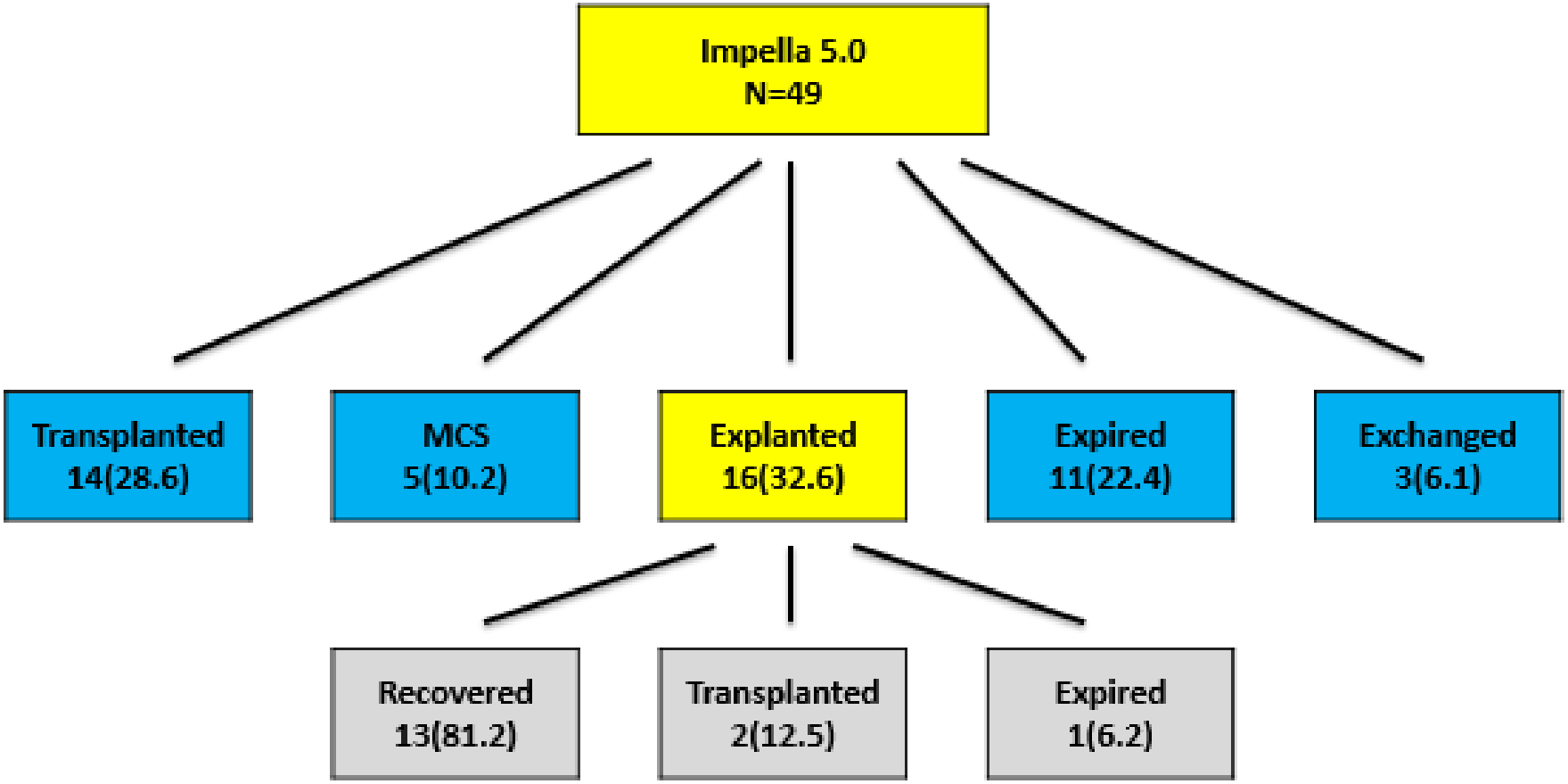
Indications & Advantages

- Short-term management of cardiogenic shock
- FDA approved for left heart failure (Impella 5.0/CP 6/4d)
- Impella 5.0 requires vascular access/graft; CP percut.
- Easy to place (subclavian/femoral) rapidly deployed
- Hemodynamically superior to IABP (flow 3-5 l/min)
- Potential for short term bridge to heart transplant
- Subclavian approach allows ambulation
- Works best with dilated LV **- unloads LV**; reduces MR
- Contra: severe PAD, LVT, severe AS/AI, VT storm; VSD, severe RHF (use w/ TandemHeart RVAD = “Tandella”)

Potential Complications of pVADS

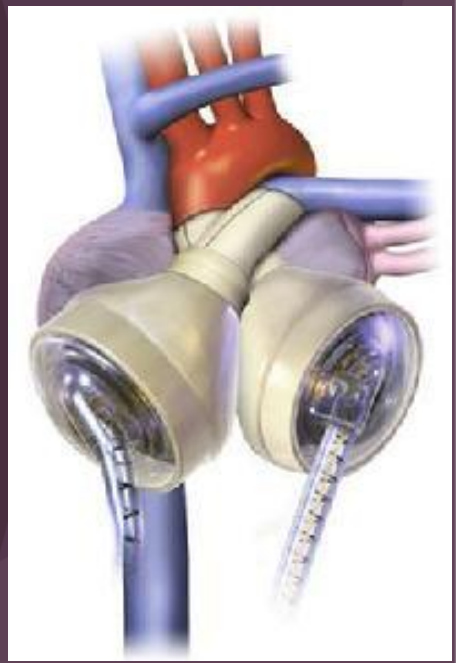
- Vascular injury / occlusion /dissection
- Bleeding (transfusion requirements)
- Hemolysis
- Infection
- CVA
- Ventricular arrhythmias (VT)
- Mitral insufficiency (chordal rupture)
- Tricuspid insufficiency (TandemHeart RVAD)
- Device thrombosis / failure

Impella 5.0 Outcomes (2017)



37/49 = 75% successful outcome

Right, Left or BiVentricular MCS?



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Evaluating RV function

Parameter	Favors LVAD alone
•CVP on OMM	< 10 mm Hg (OMM)
•RVSWI (MPA – RA x SV/BSA)	> 300 mm Hg ml/m2
•Tricuspid regurgitation	minimal to moderate
•PVR (PAPi)	< 4 WU (> 1)
•Transpulmonary gradient	< 15 mm Hg
•RV size / RVEF	
–RVEDV	< 200 ml
–RVESV	< 177 ml
–RVEF	> 30%
•Need for pre-op vent. support	none

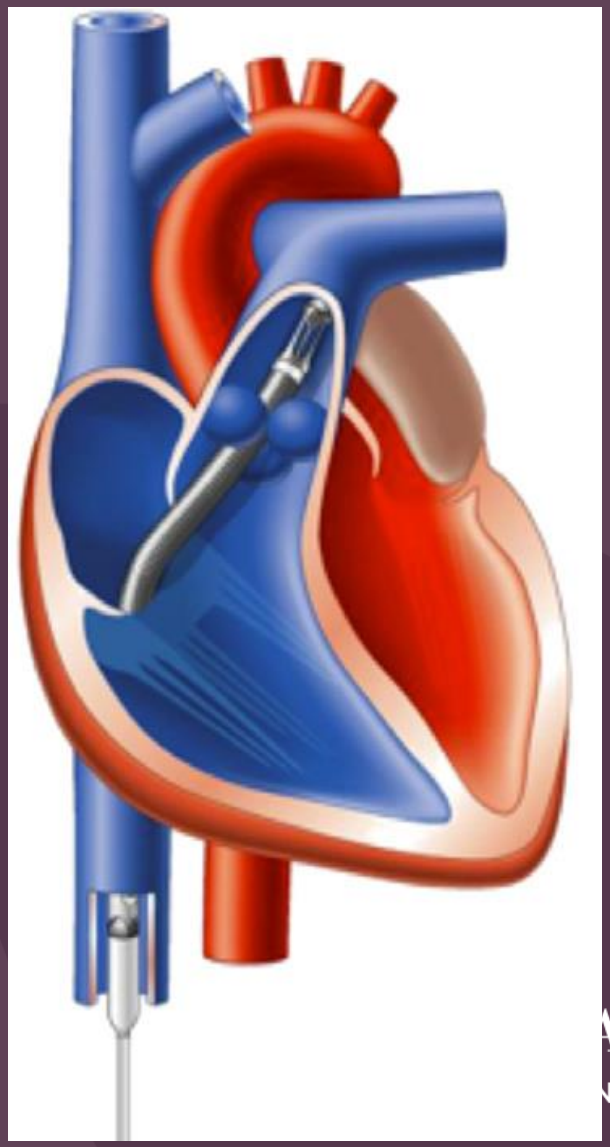
RV failure post-LVAD implant inc mortality 19 to 49%

Which Device?

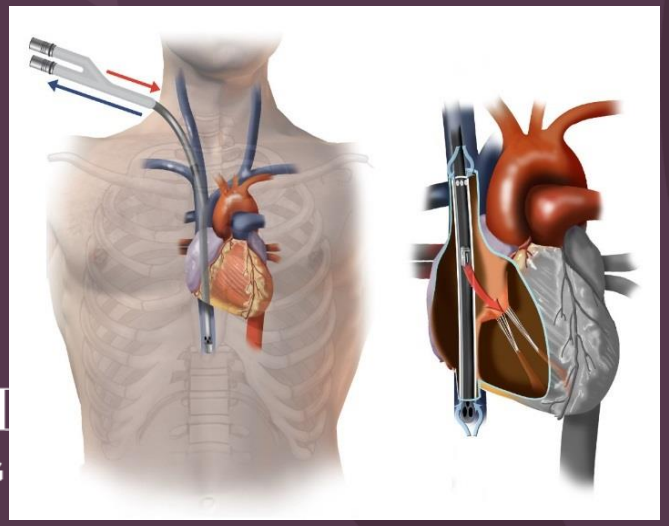
Parameter	Favors LVAD	Favors BiVAD/TAH
Echo RV dysfunction	None-mild (mod)	severe
TAPSE/PAPI	> 1 cm / > 1.5	< 1 cm / < 1.4
TR / MR	Mild-mod / severe	Severe / severe
Hemodyn: RAP	< 10 mmHg OMM	> 15 mmHg
RVSWI	High (>200)	Low (<100)
INTERMACS Profile	3-6 (2)	1-2
Etiology	Dilated/ischemic	Restrictive/anatomic
Arrhythmia (refract VT)	----	TAH/BiVAD preferred
End-organ dysfx/TCS	----	TAH/BiVAD preferred

MCS -Temporary RV support

Impella-RP



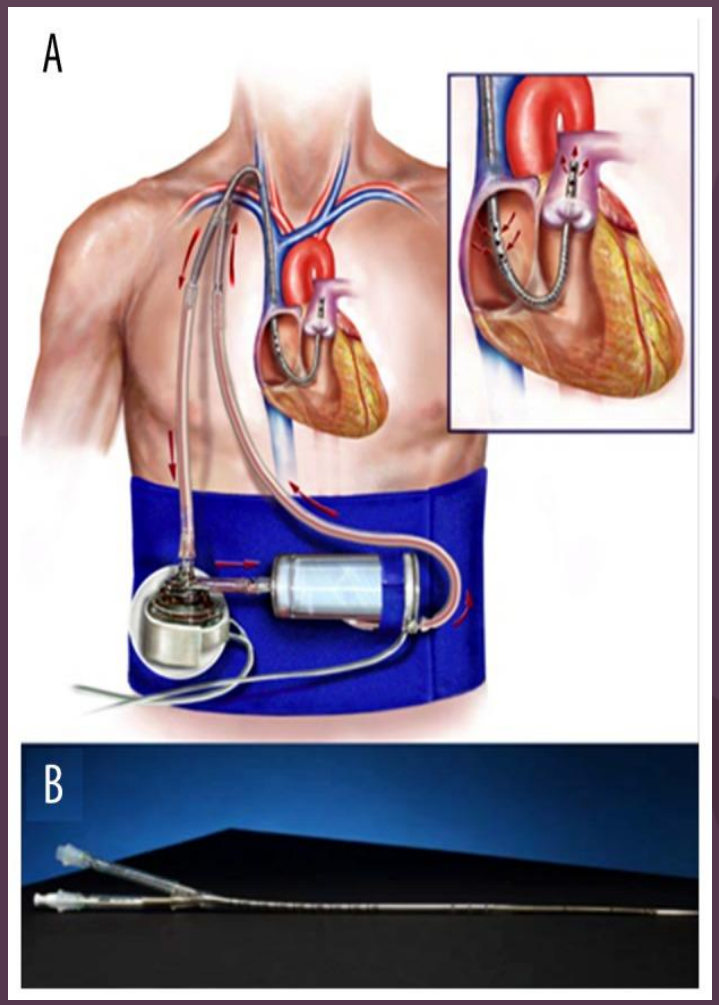
Protekduo catheter

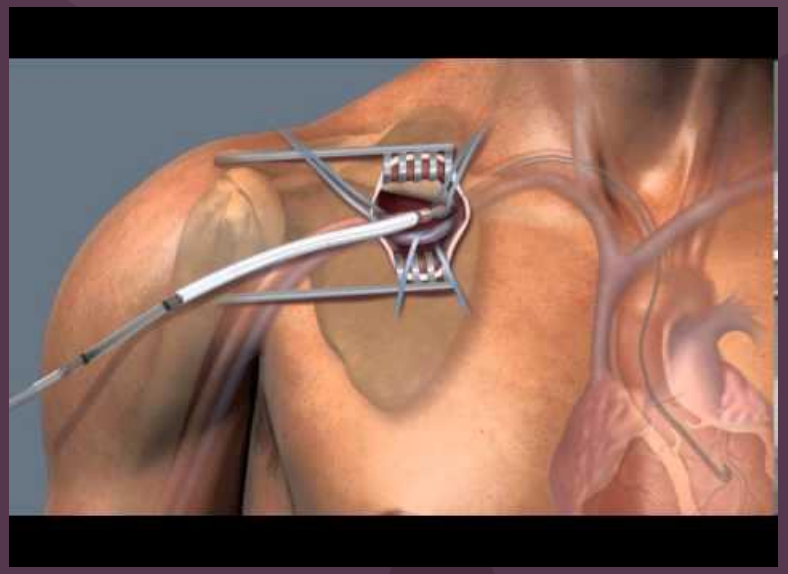


TandemHeart

CentriMag

TandemHeart RVAD + Impella LVAD = "Tandella"





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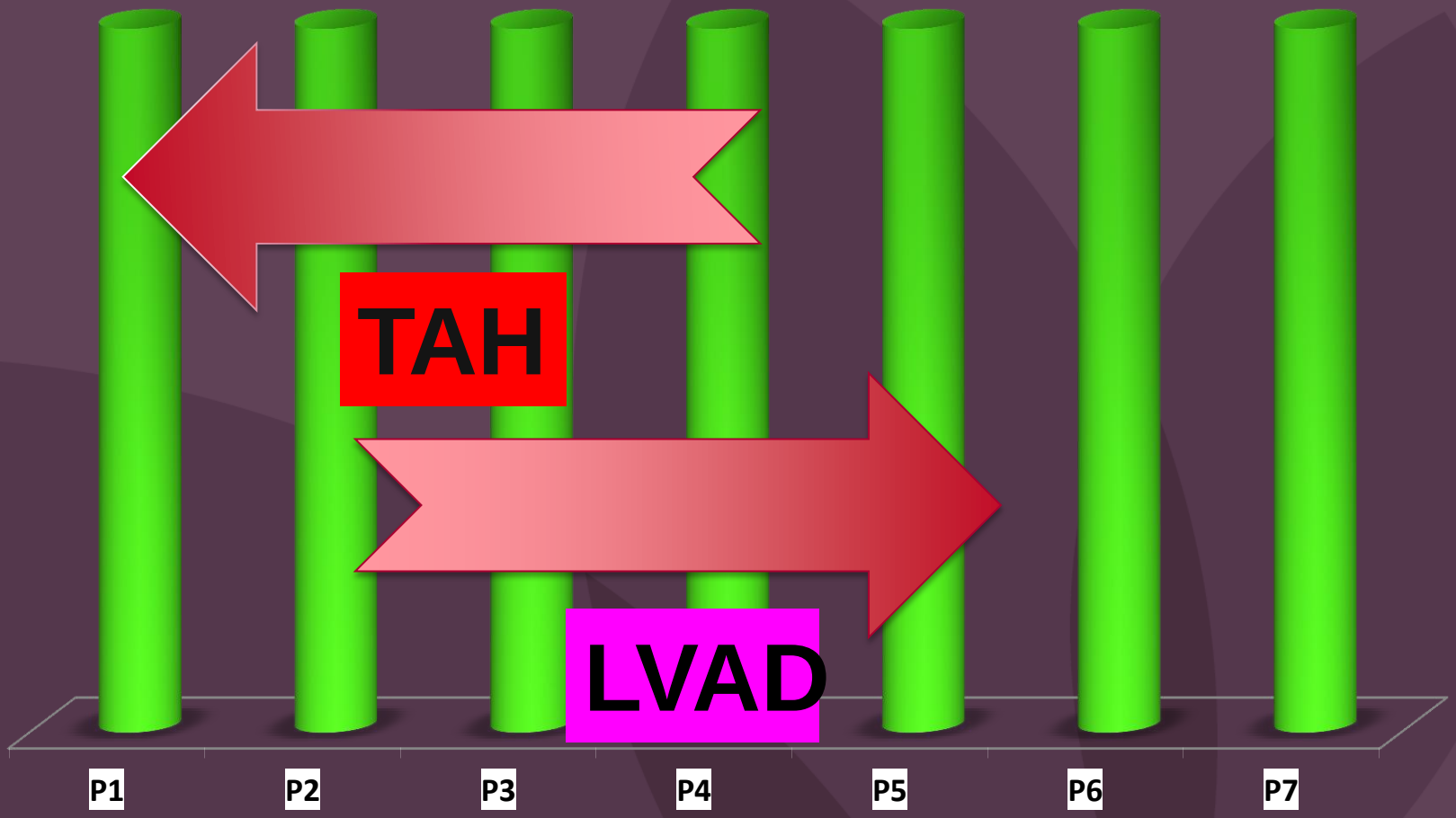
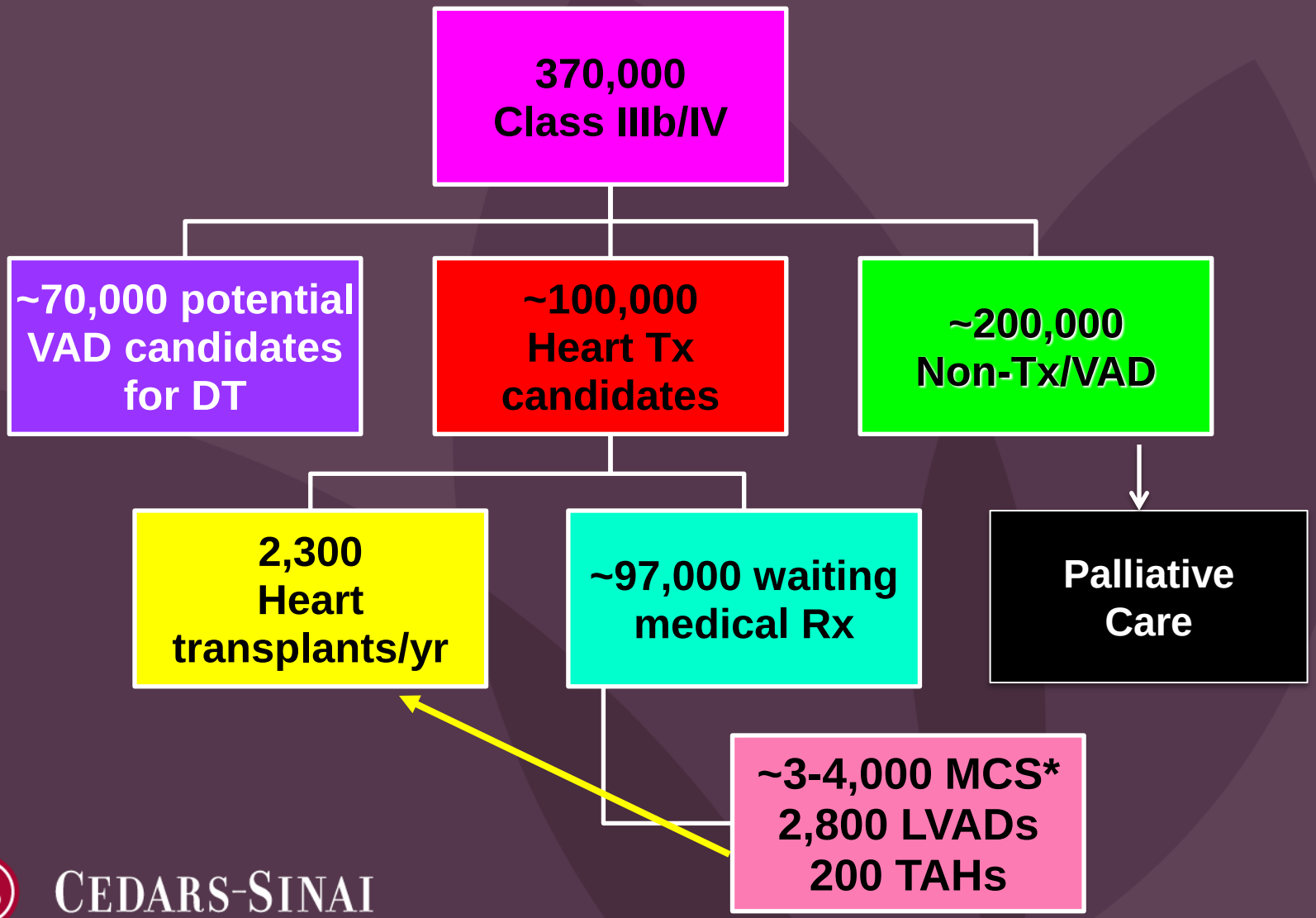
“Tandella”
Percutaneous BiVentricular Temp MCS

Devices by INTERMACS Profiles



Durable MCS Options for ESHD



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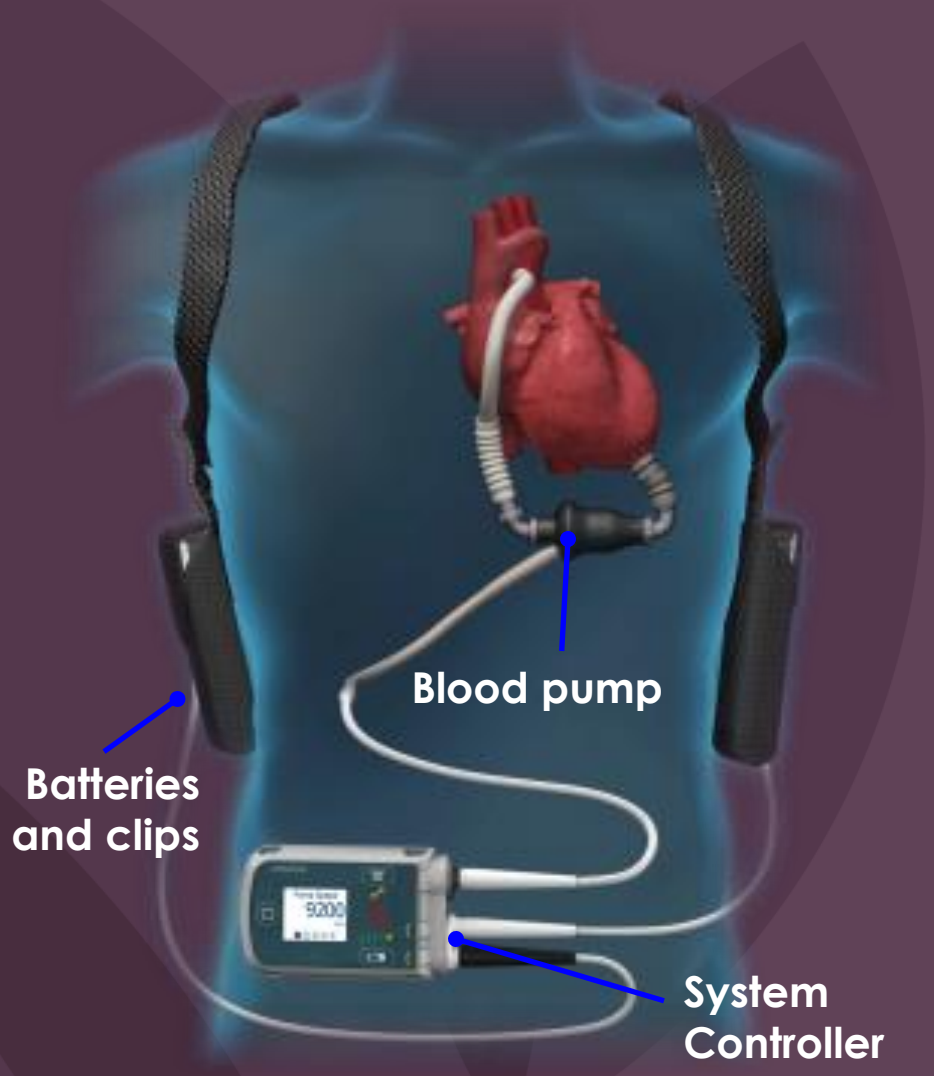
HeartMate II LVAD

- Axial continuous flow
- Silent; 3-8 liters/min flow
- Single moving part
- 2 industrial ruby bearings
- Valveless
- Durable (5-10 yrs)
- > 20,000 implanted
- Electrically powered percutaneous driveline
- FDA approved for BTT, DT



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The HeartWare Ventricular Assist System

- HVAD™ smallest implantable pump
  - Up to 10 liters of flow
  - Centrifugal pump (vs axial)
  - Hybrid magnetic / hydrodynamic suspension (bearingless system)
  - No pump pocket
  - > 14,000 implanted WW / CE mark
- *ADVANCE Trial* (BTT)
  - FDA approved for BTT
- *ENDURANCE* (DT) SupplementTrial: ongoing

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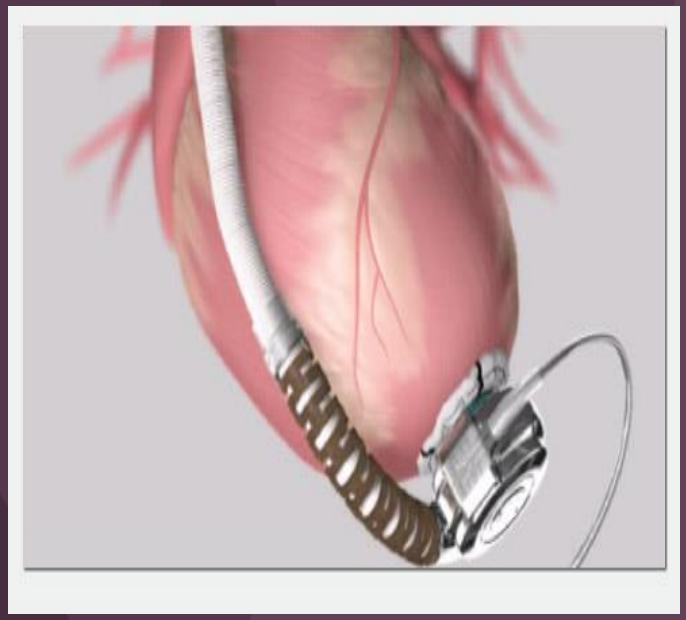

HeartMate III LVAD

- Centrifugal pump – full mag-lev technology: no bearings
- Flow: 2.5 – 10 l/min
- Enhanced AE profile
  - –Larger channels
  - –Built in pulsatility
- Ease of implant-no pocket
- Durable- single moving part
- Enhanced longevity-no contact/valves
- MOMENTUM: lowest pump thrombosis rate

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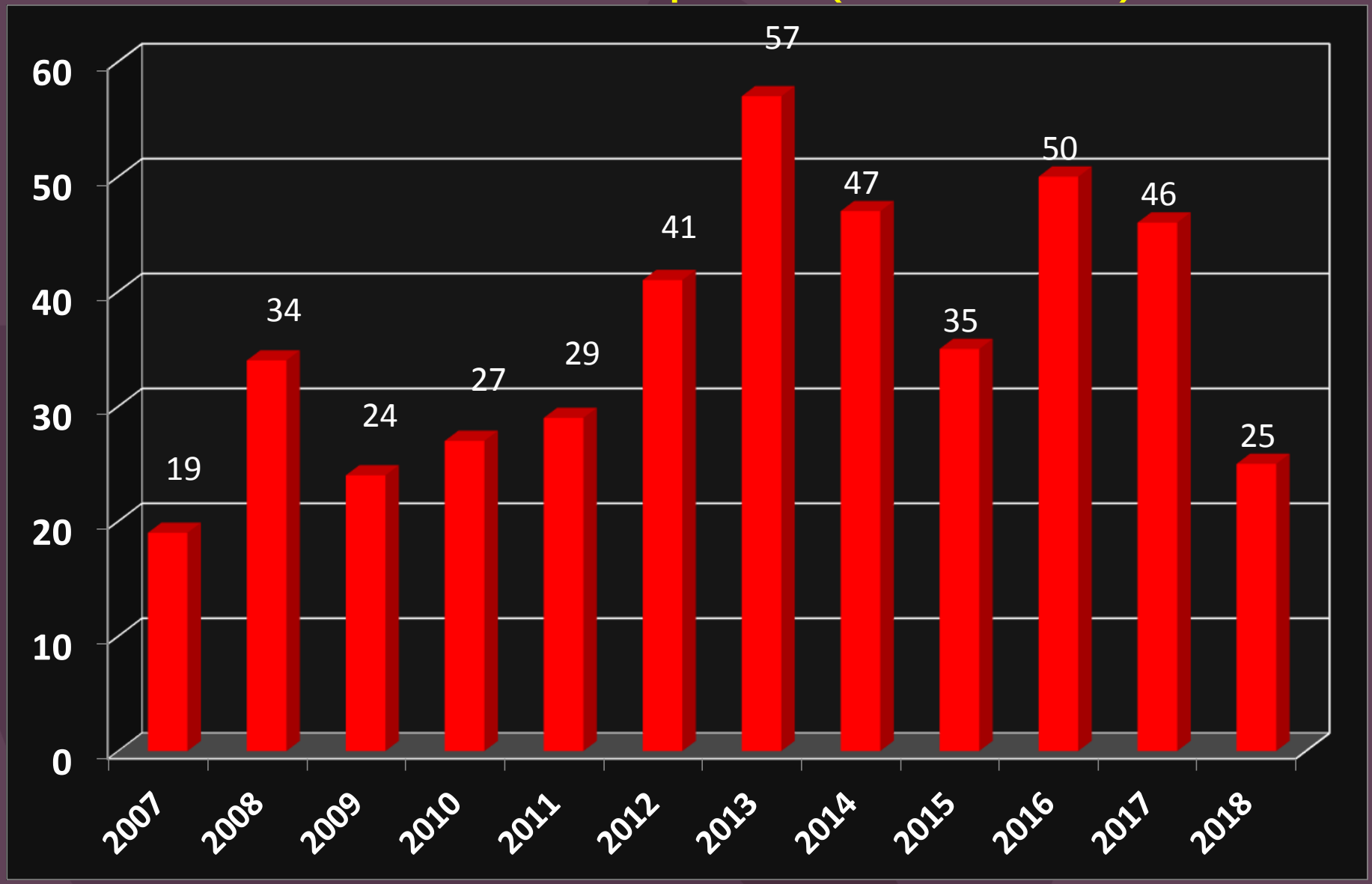
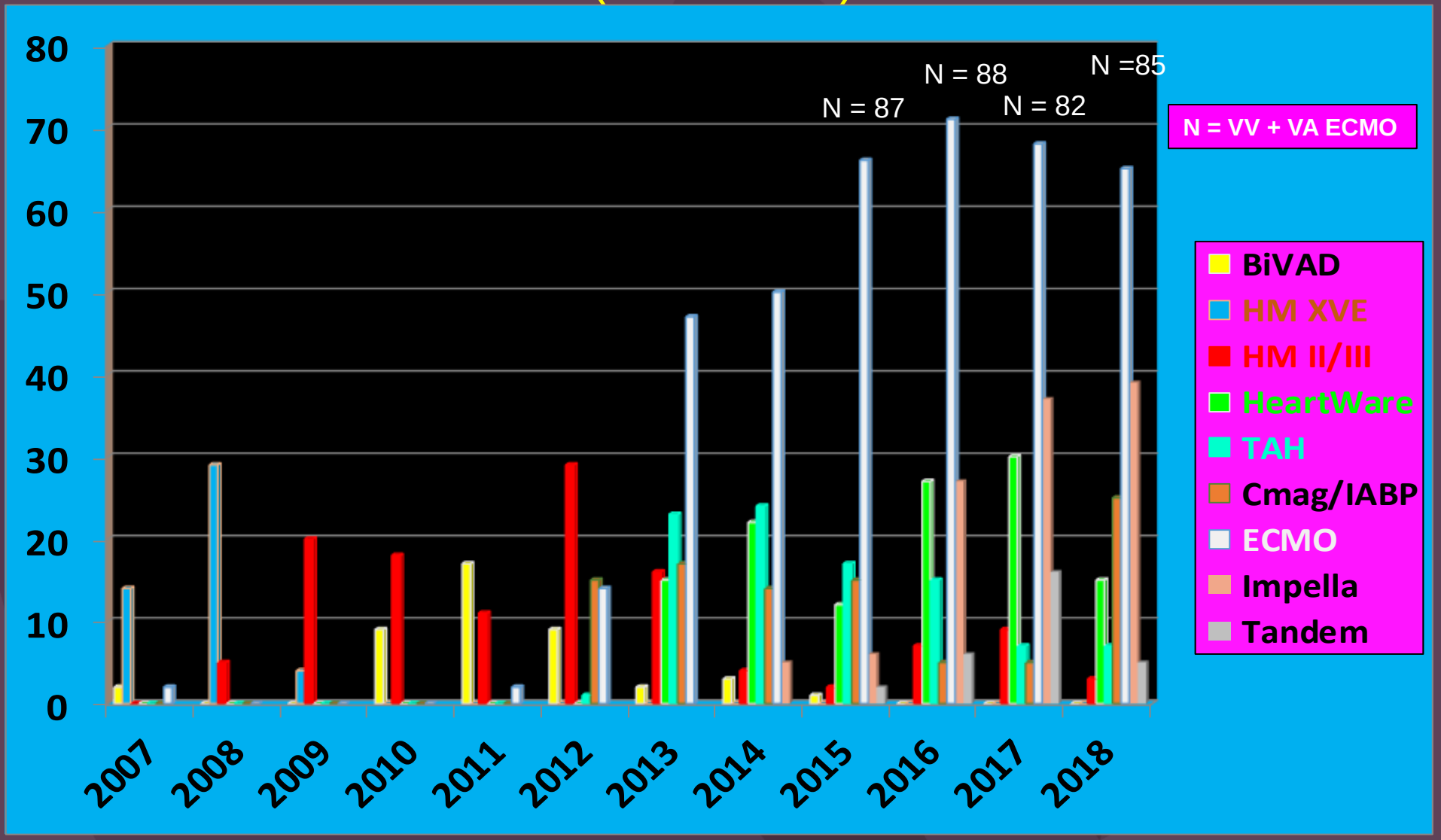
Cedars-Sinai MCS Program
Durable MCS Implants(2007-2018)



As of Dec 31, 2018

Cedars-Sinai MCS Volume by Device
(2007-2018)



Dec 31, 2018

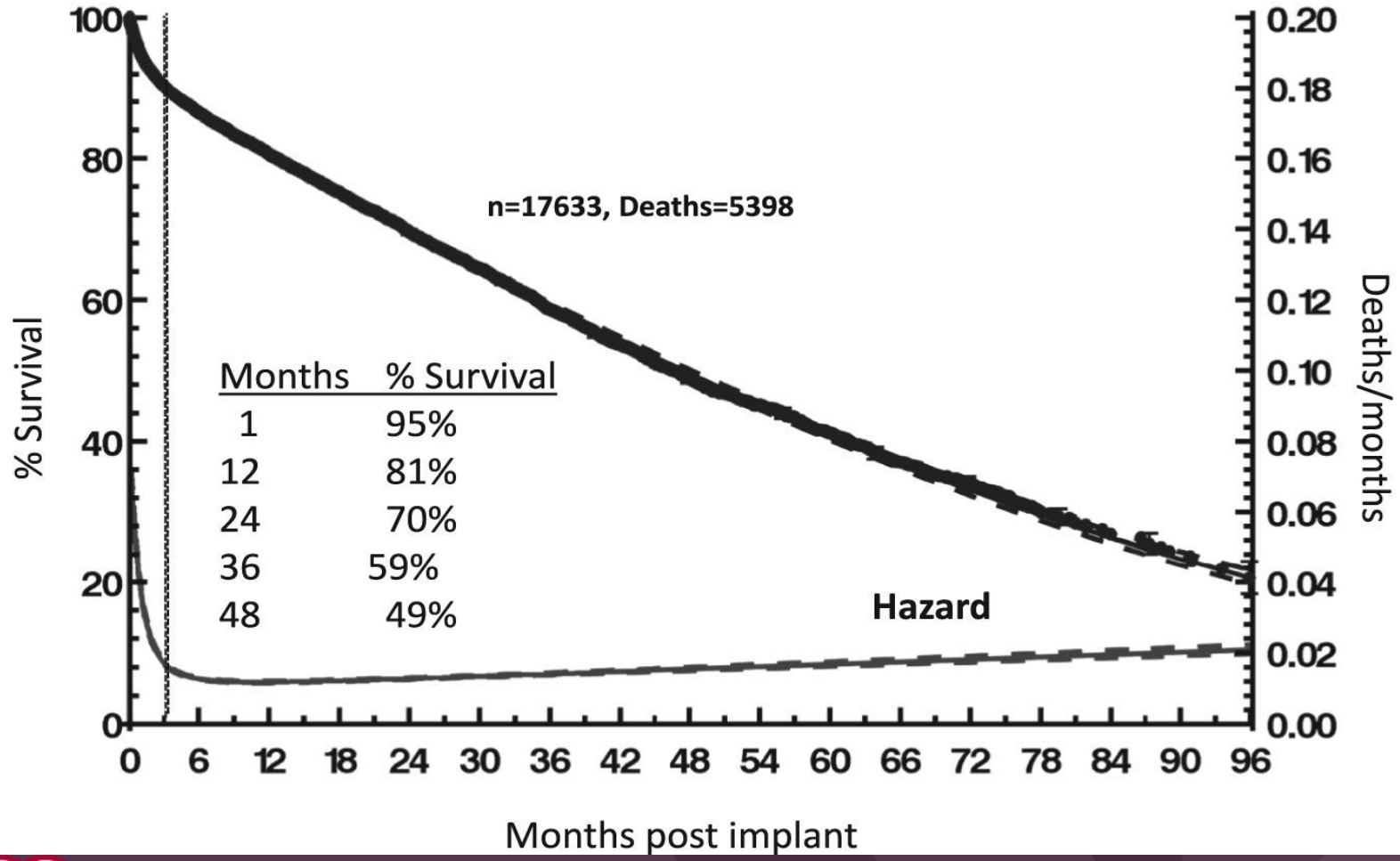
Percentage of Tx Patients Bridged by MCS

Year	2011	2012	2013	2014	2015	2016	2017	Total
MCS/Tx	18/89	24/95	31/119	29/122	32/132	47/122	28/103 42/103*	208/782
% Tx Pts bridged by MCS	20.2%	25.3%	26.1%	23.8%	23.5%	38.5%	27.8% 40.8%*	26.6% 28.4%*

* 14 pts bridged to Tx w/ Impella 5.0

Intermacs

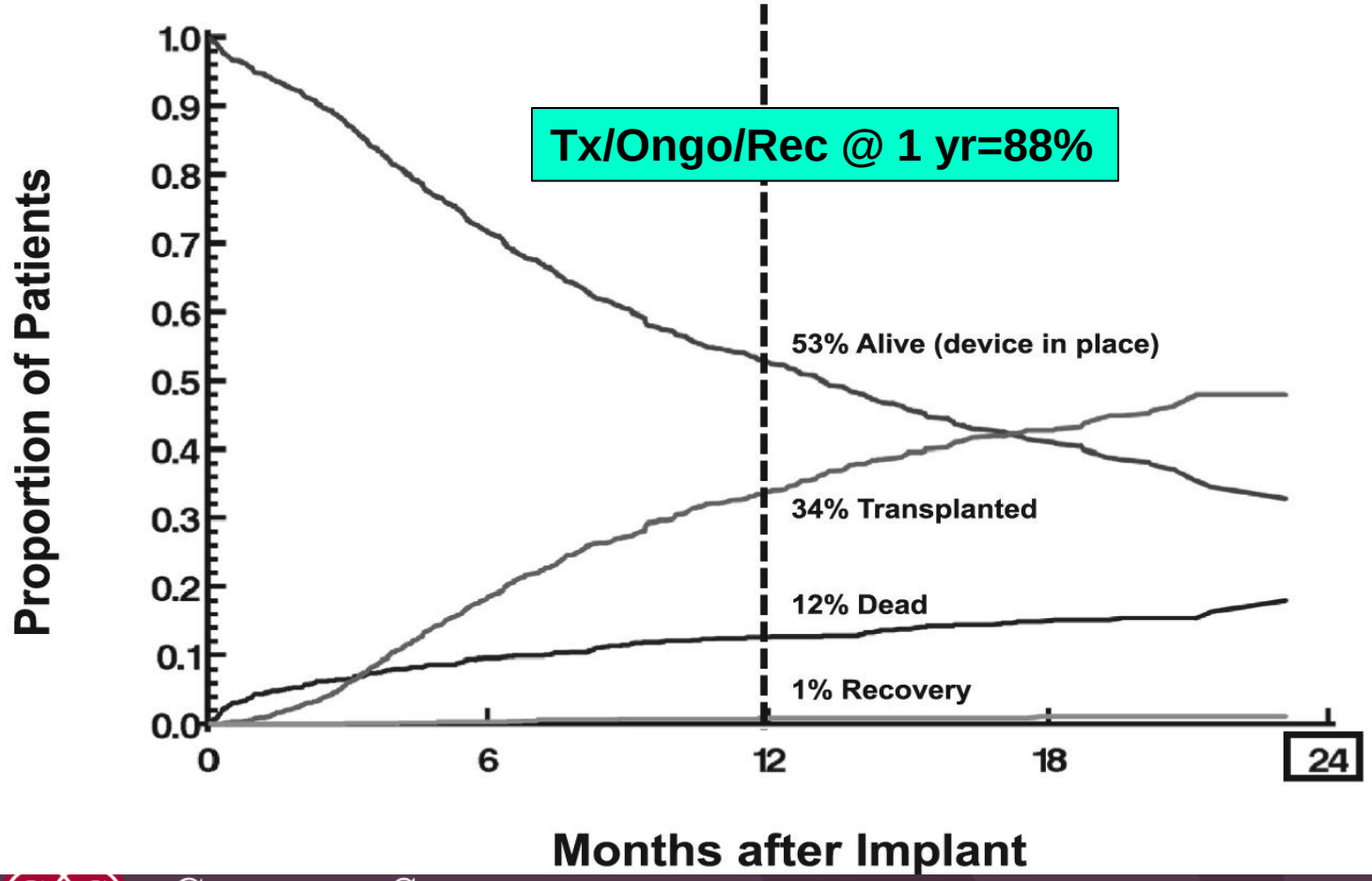
Continuous Flow LVAD/BiVAD Implants: 2008 – 2016, n=17633



The Journal of Heart and Lung Transplantation 2017 36, 1080-1086DOI: (10.1016/j.healun.2017.07.005)

Implants: June 2006 – December 2016, n=18987

BTT: Listed CFLVADs implants 2015-2016, n=1375



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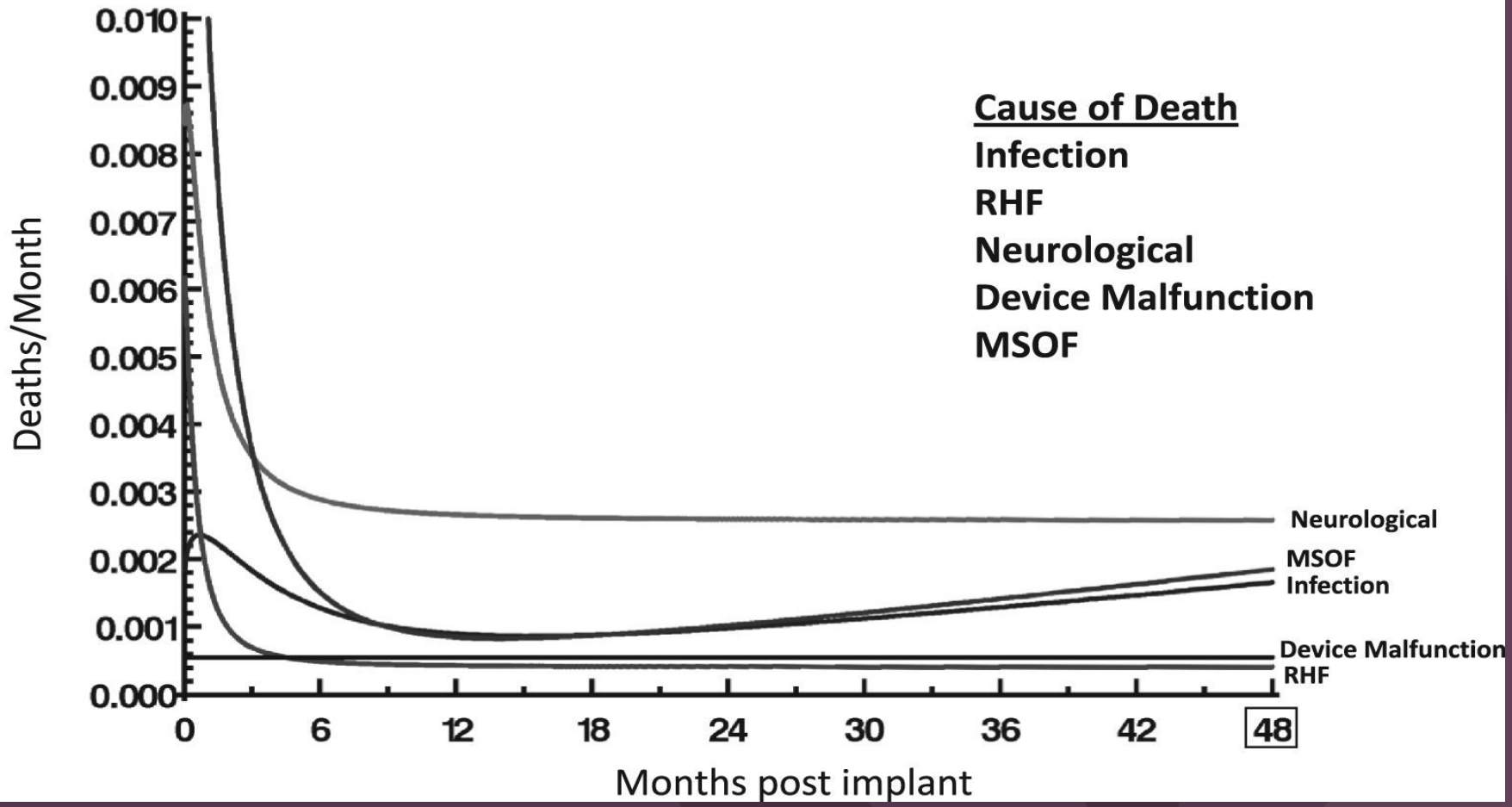

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RC with HM II LVAD

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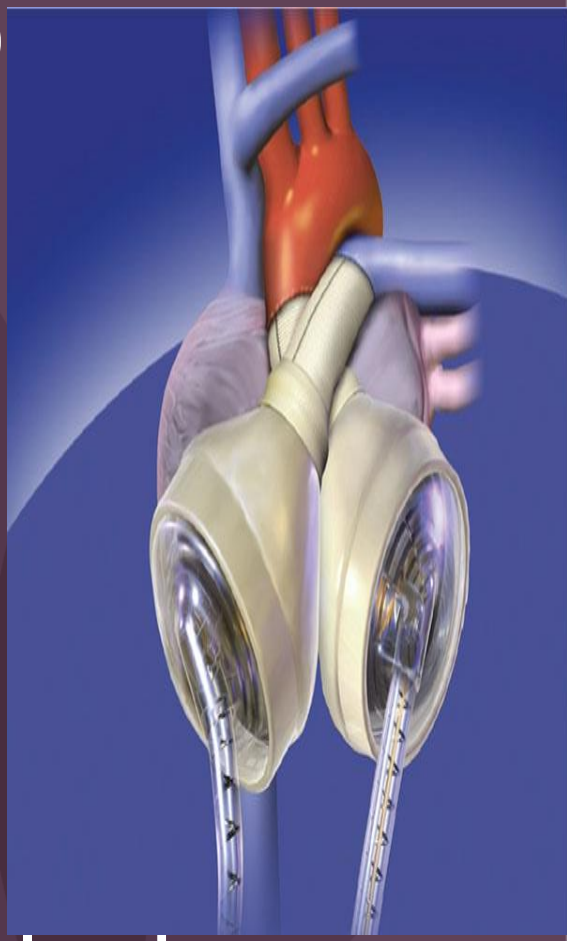
Implanted July 2010 Inova-Fairfax

Syncardia t-TAH

- **Class: implantable pulsatile(pneumatic)**
- **Indications: (temp. bivent. *replacement*)**
  - **bridge to OHT (FDA approved)**
  - **severe irrev. bivent failure**
- **Limitations:**
  - **Requires full anticoagulation**
  - **Size requirement BSA ≥ 1.6 m2***
- **"Freedom" portable driver available**
- **Only TAH approved by FDA/CMS BTT**
- **79% successfully transplanted***
- **Nearly 1,600 implanted WW**
- **70 cc DT Trial (Jan 2015); 50 cc TAH trial underway**



*Copeland J, Arabia F et al; NEJM 351: 859-867 2004

Candidates for TAH

- Irreversible, severe biventricular failure
- Larger, critically ill patients in cardiogenic shock w/ significant end-organ dysfunction
- Unique anatomic issues
- (LV thrombus, VSD, massive MI, primary cardiac malig, complex CHD
- Hypertrophic, amyloid, restrictive CMY
- Heart tx w/ severe CAV or refractory rejection
- Incessant VT/VF

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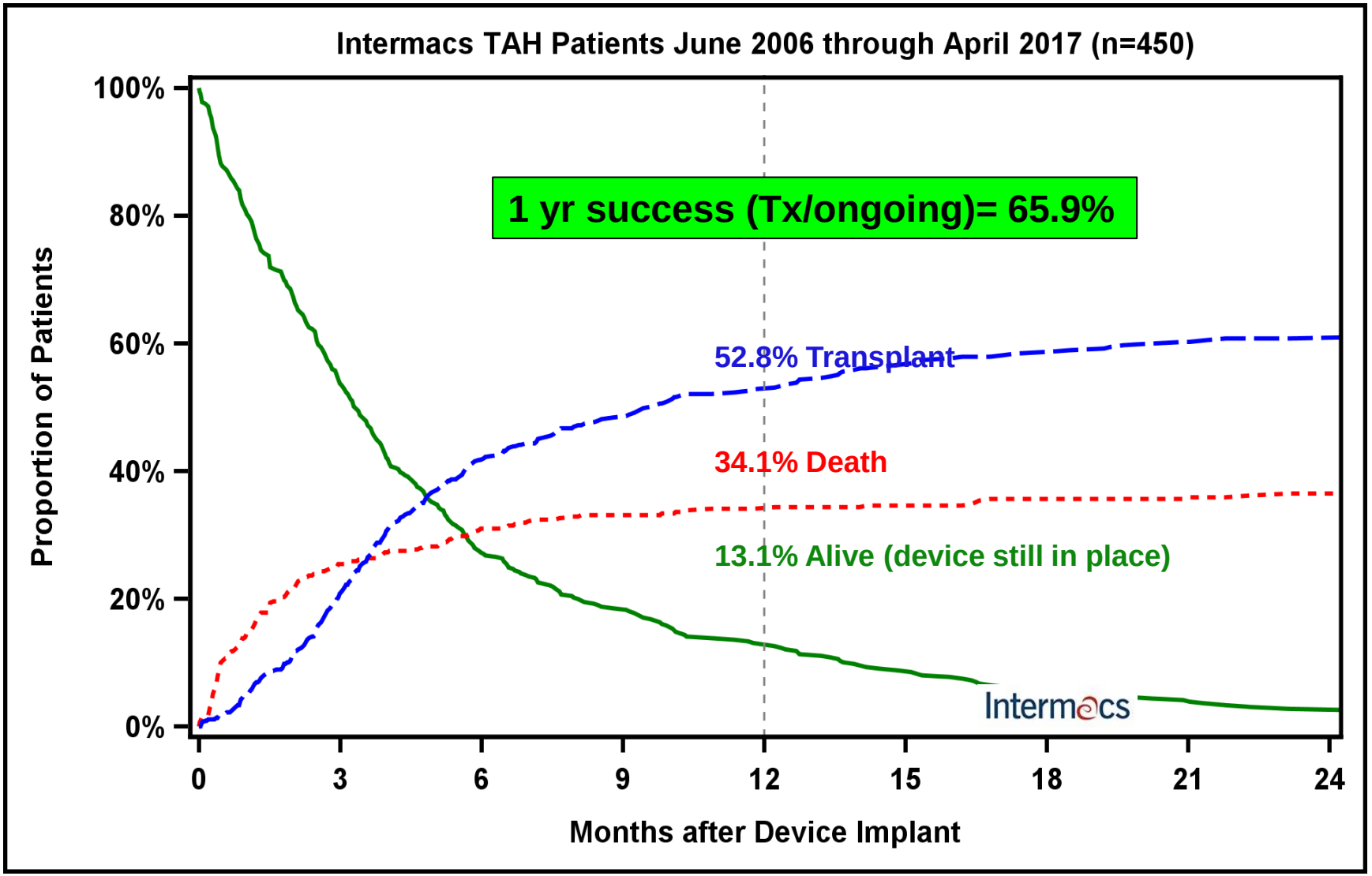
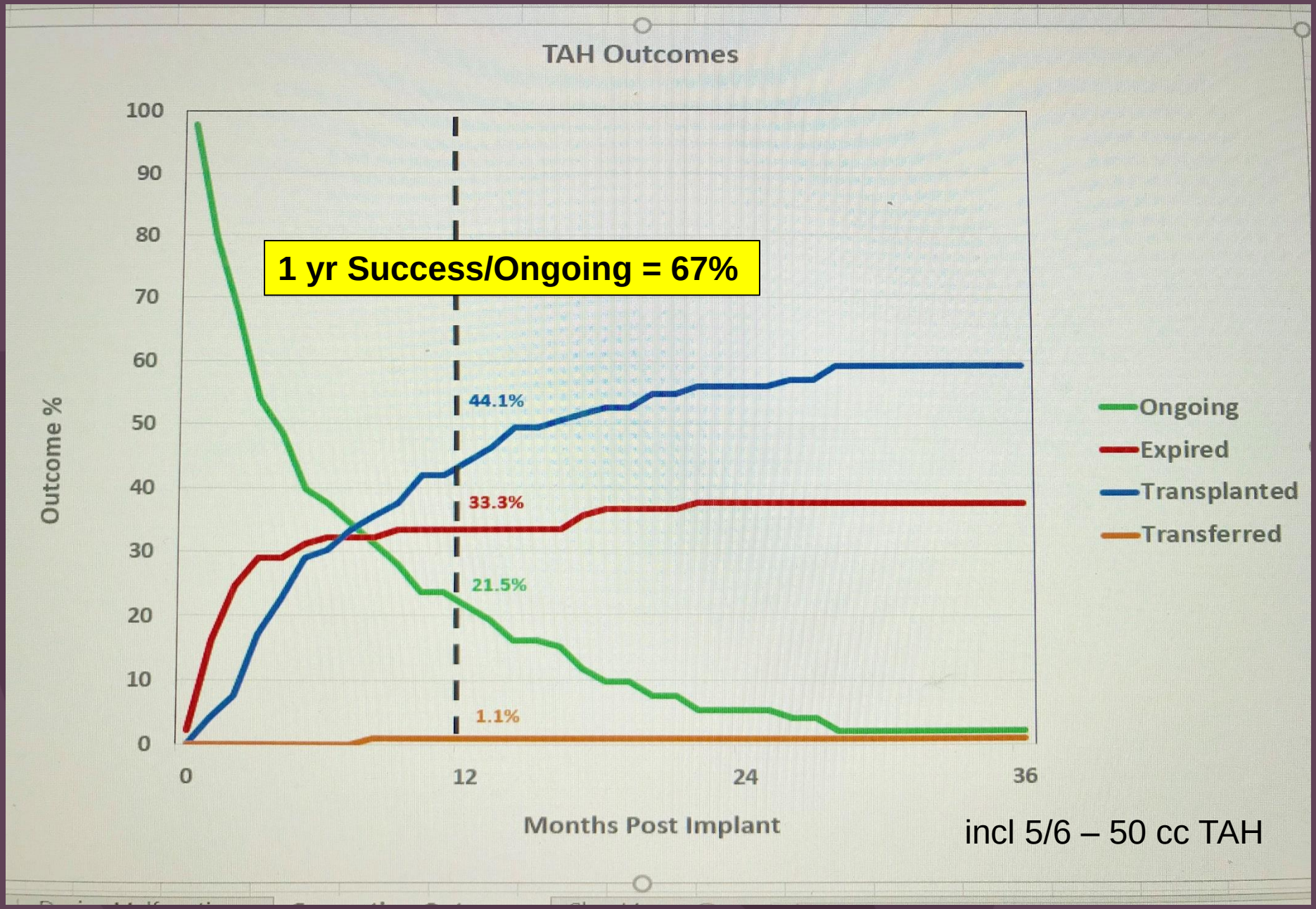
TAH Competing Outcomes

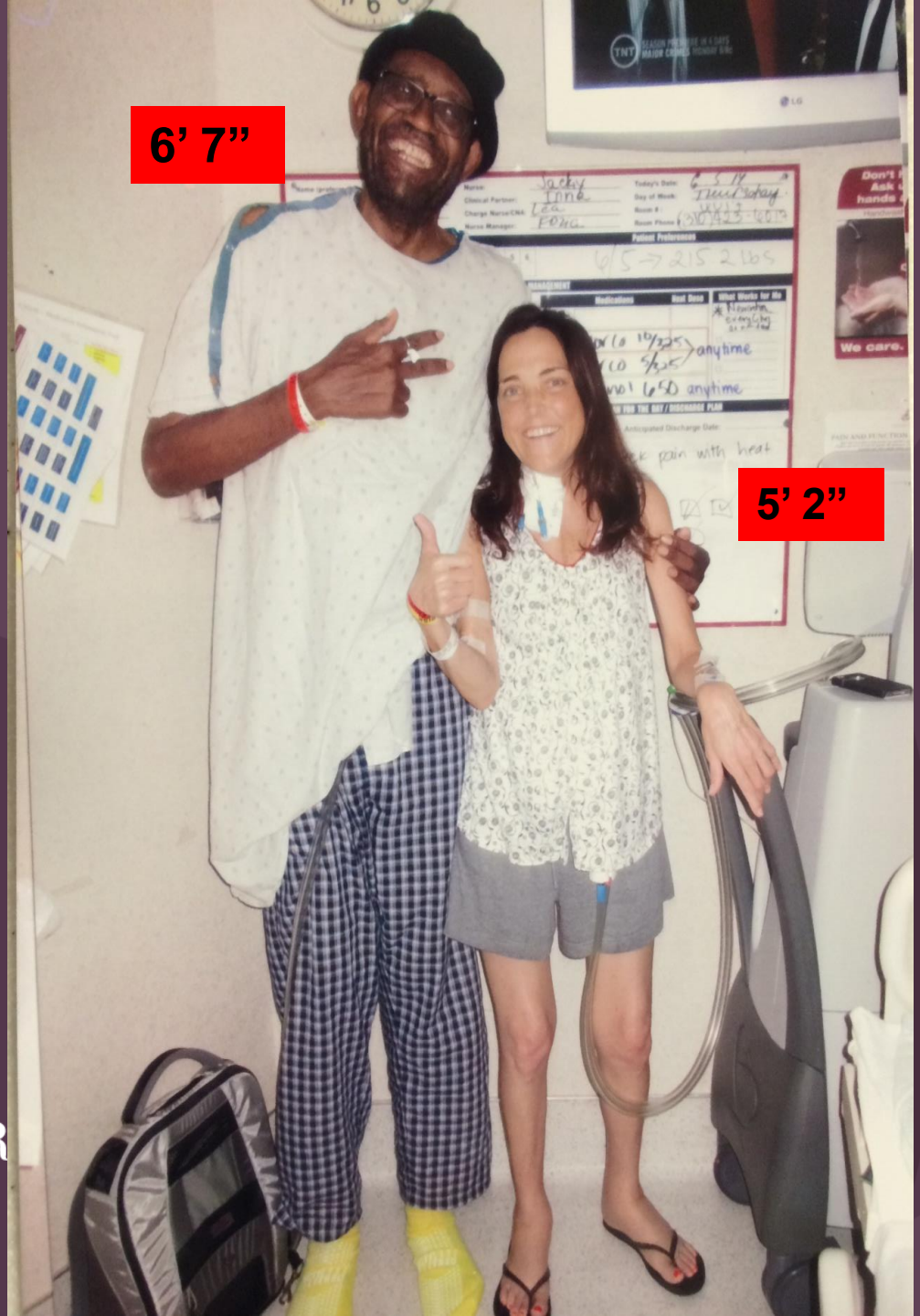


Intermacs - TAH Project

TAH Competing Outcomes (N=94)



incl 5/6 – 50 cc TAH



Range of pt size for 70 cc TAH

June 9, 2014

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MR - S/p 50 cc TAH (POD #35)

August 16, 2018

1 yr Post-Tx Survival by Device

	Transplant Year - All Indications						
	2011	2012	2013	2014	2015	2016	Total
LVAD	1/1	6/6	15/16	10/10	7/8	14/15	53/56
TAH			8/9	8/8	14/16	12/13	42/46
BIVAD	8/9	6/8	5/5	1/1	0/1		20/24
All	9/10	12/14	28/30	19/19	21/25	26/28	115/126
						93%	91%

Destination Therapy

(DT)

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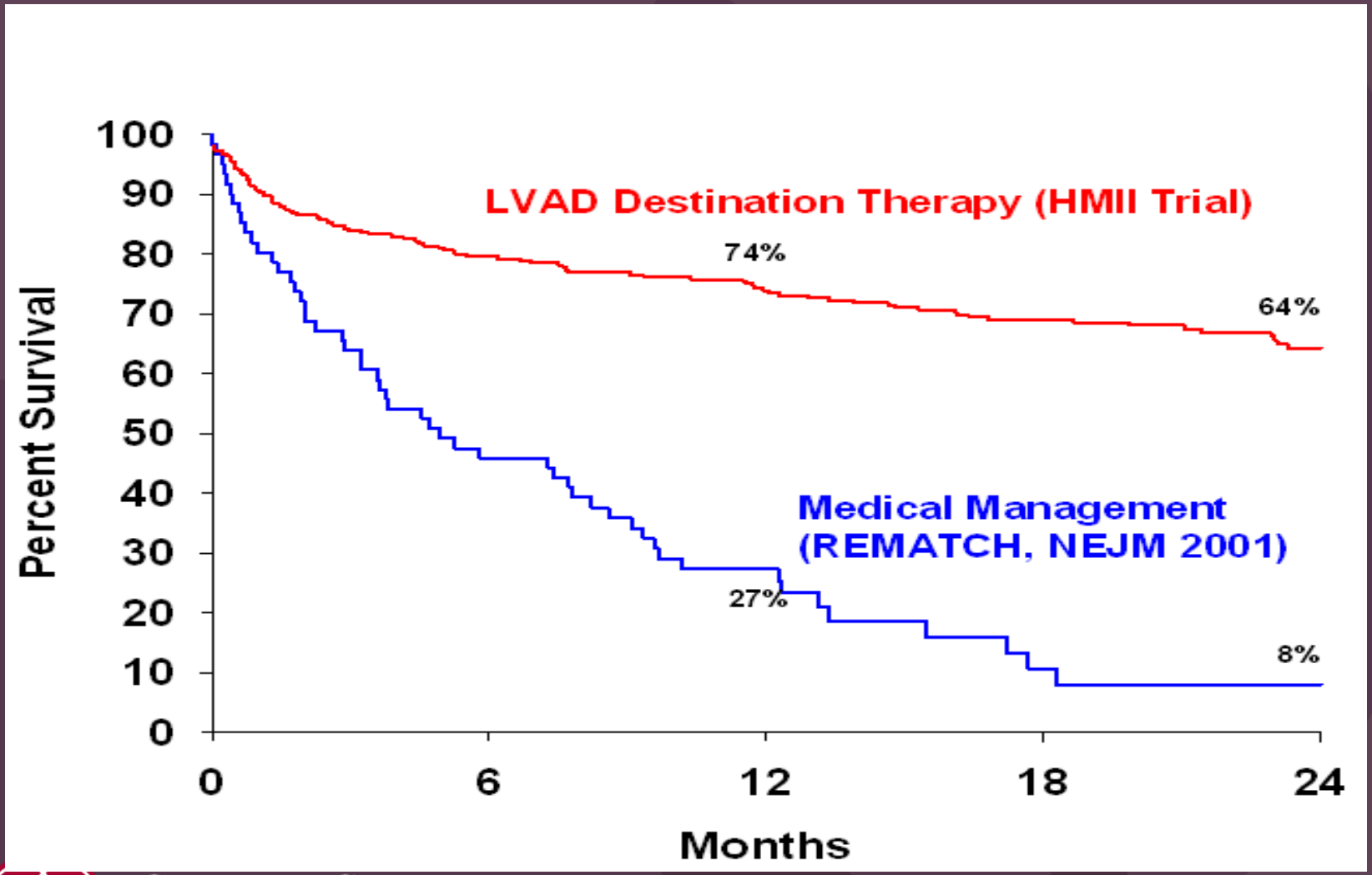
Criteria for Destination Therapy

- LVEF ≤ 25%
- Peak VO2 < 14 ml/kg/min (or 50% pred.age/sex)
- And either
  - NYHA Class IV heart failure symptoms despite optimal medical therapy for at least 45 of prior 60 days or
  - Dependence on IV inotropes for at least 14 days, or
  - Dependence on an IABP for at least 7 days
- Not a candidate for transplantation
- No irreversible renal, pulmonary or hepatic dysfunction or active infection
- Devices approved by FDA for DT: HM II HeartWare HVAD
- DT Trials ongoing with HM III, TAH

NEJM 2009;361(23):2241-51.

Magnitude of survival benefit with LVAD DT therapy?



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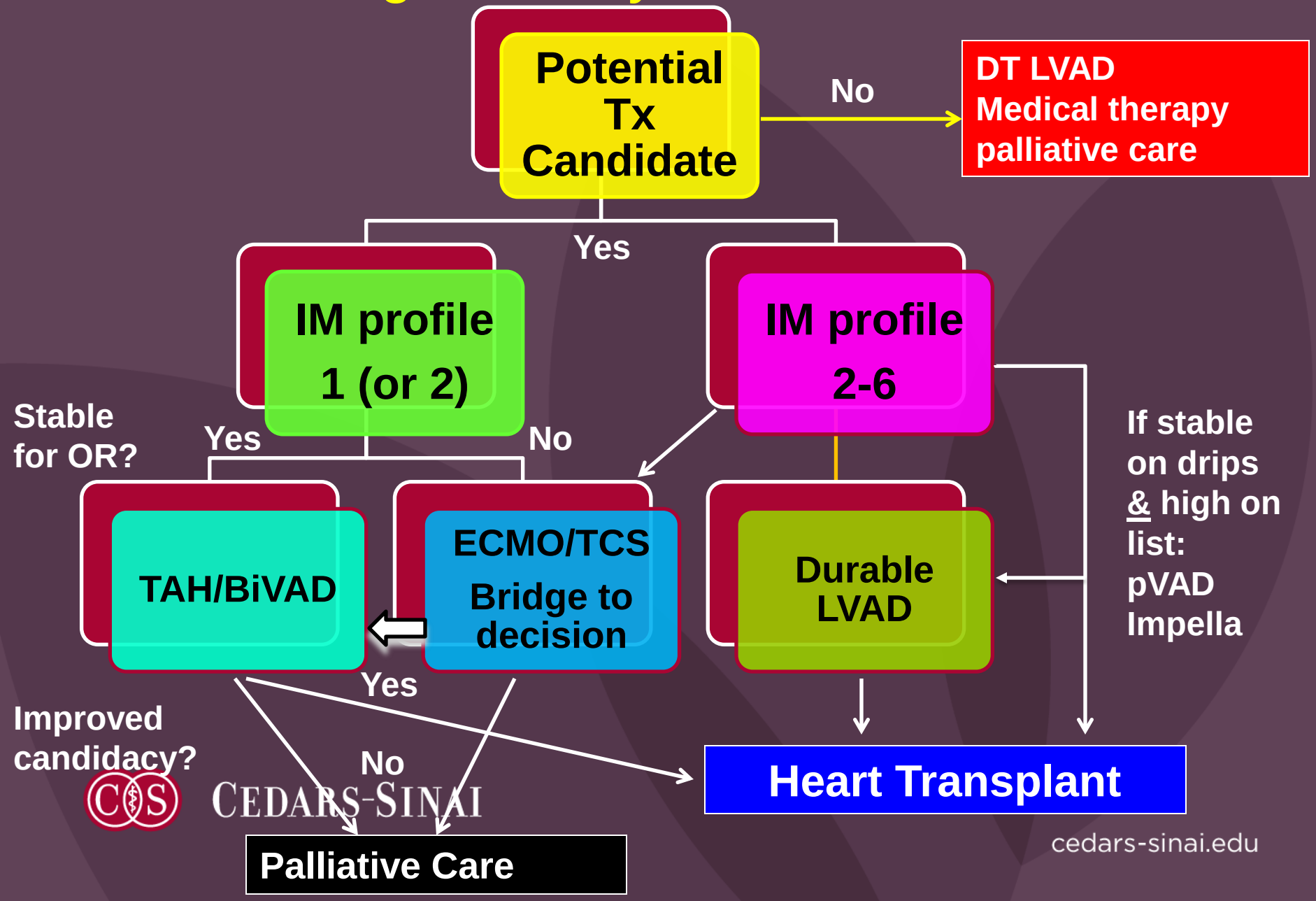
Source: Park SJ, AHA 2010

Device Algorithm by INTERMACS Profile



CONCLUSIONS

- In Adv HF and cardiogenic shock, successful outcomes depend upon appropriate patient and device selection along with expeditious referral
- MCS candidates should be ill enough to justify risks of implantation but not so ill to be associated with poor outcome (prefer IM 2-5 vs IM I)
- Continuous flow **LVADs** w/ extended durability are MCS **devices of choice;** Implant early!
- IM 1 may do better w/ BiVAD/TAH
- Inc utilization of percutaneous temporary MCS (Impella/Tandem) as BTT/BTD/BTB/BTR
- Consider DT LVAD for non-Tx candidate w/ ESHD