PATIENT SELECTION FOR ADVANCED HEART FAILURE THERAPIES

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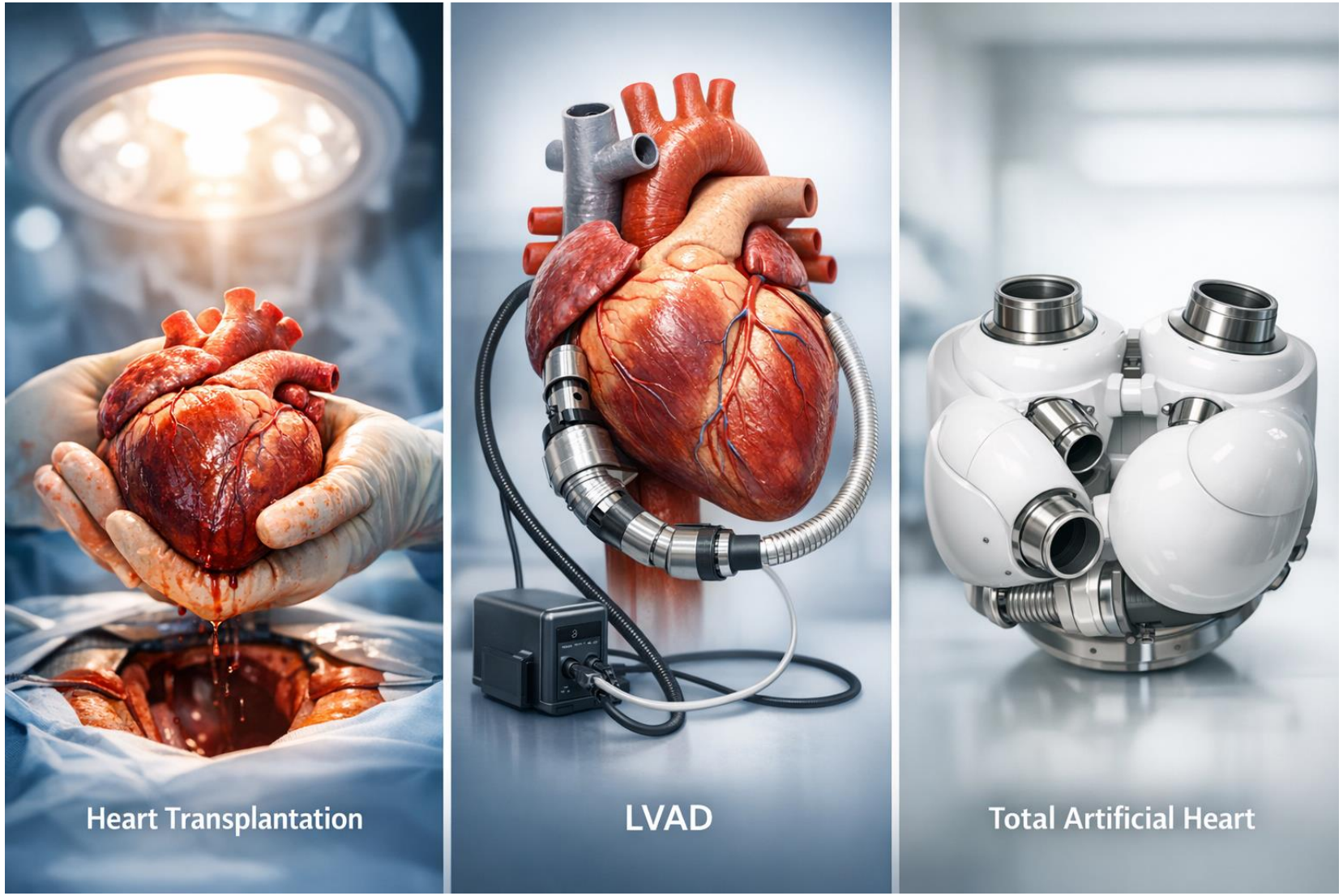
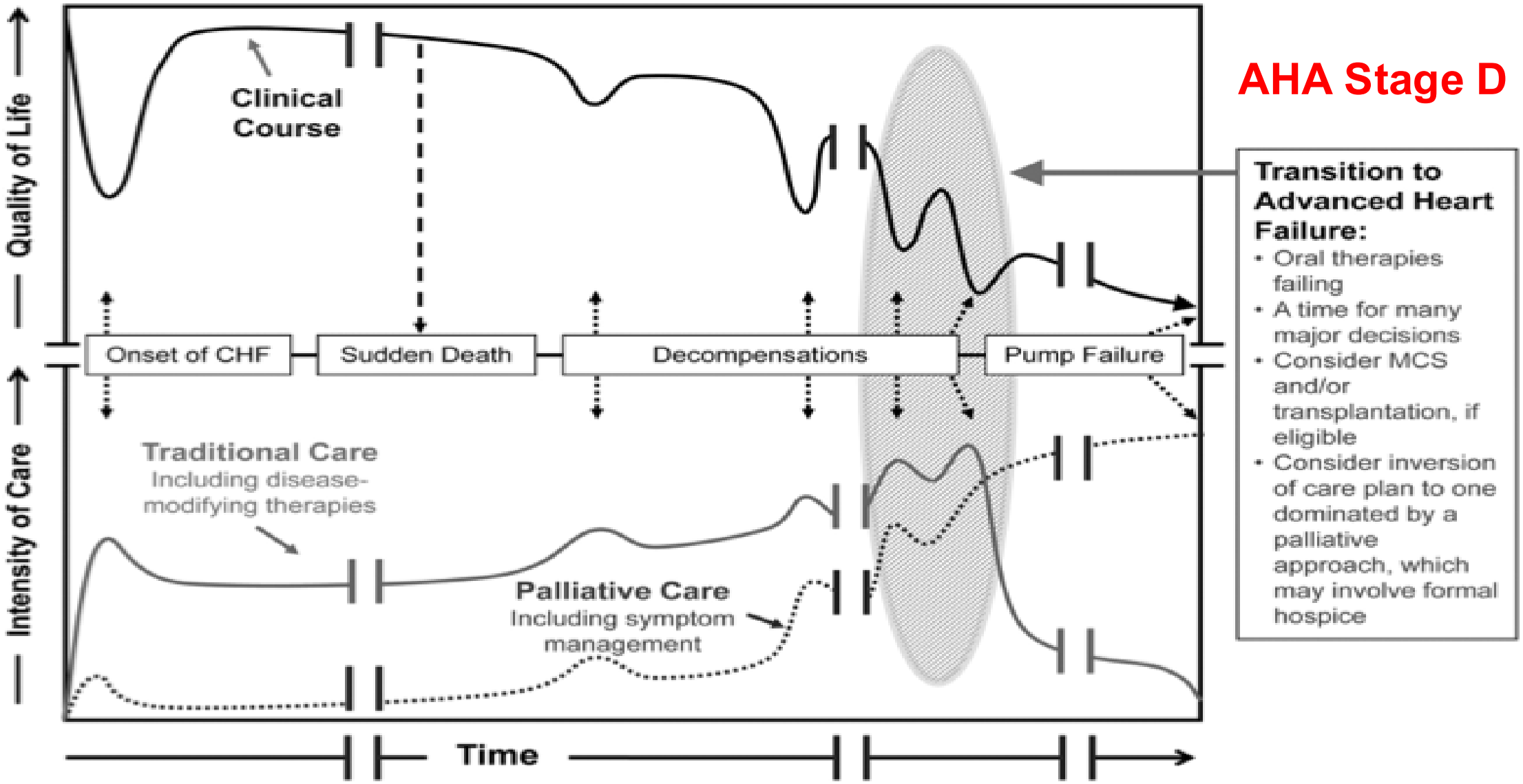
ADVANCED HEART FAILURE THERAPIES



NATURAL COURSE OF HEART FAILURE



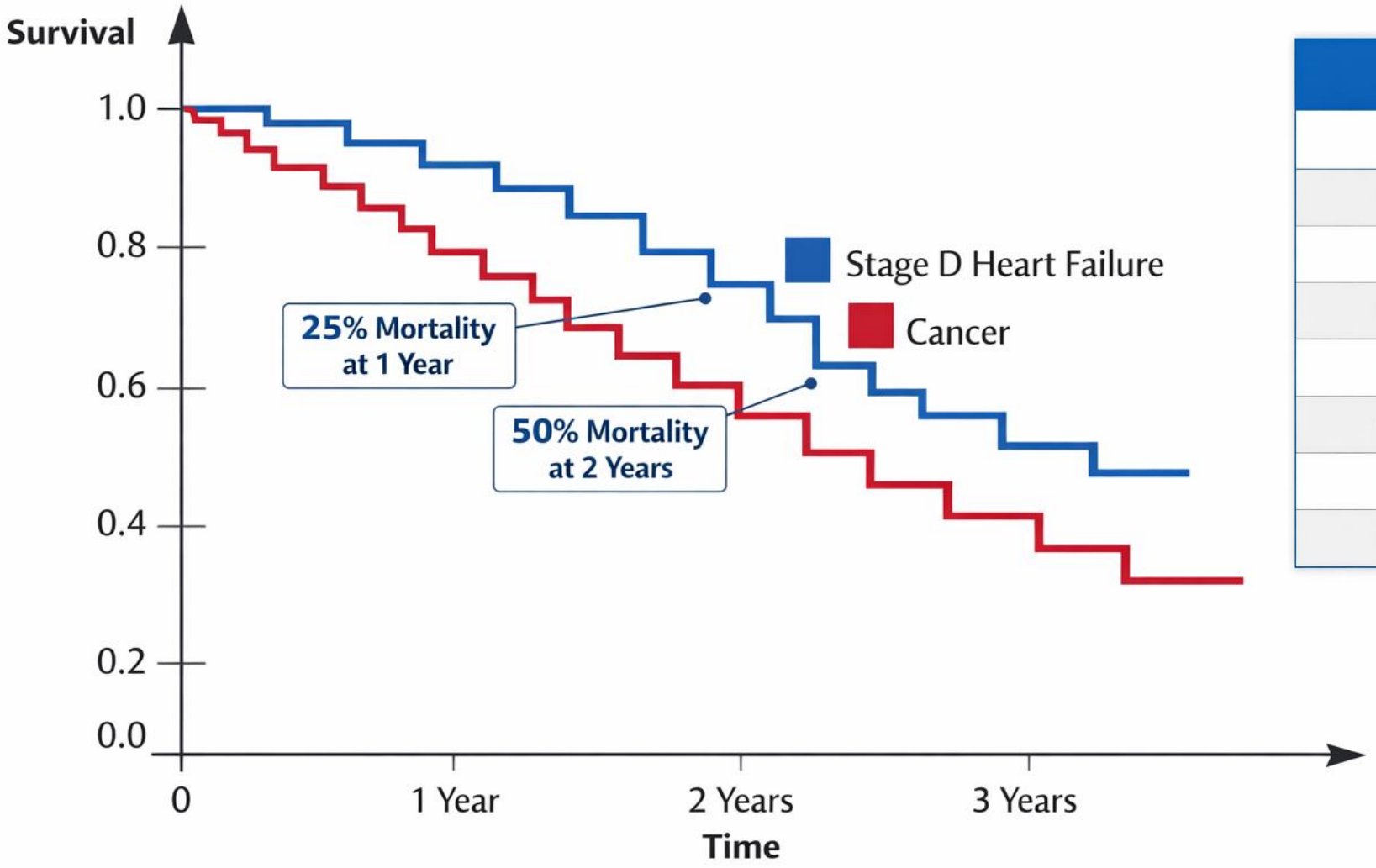
AHA Stage D

Transition to Advanced Heart Failure:

- Oral therapies failing
- A time for many major decisions
- Consider MCS and/or transplantation, if eligible
- Consider inversion of care plan to one dominated by a palliative approach, which may involve formal hospice

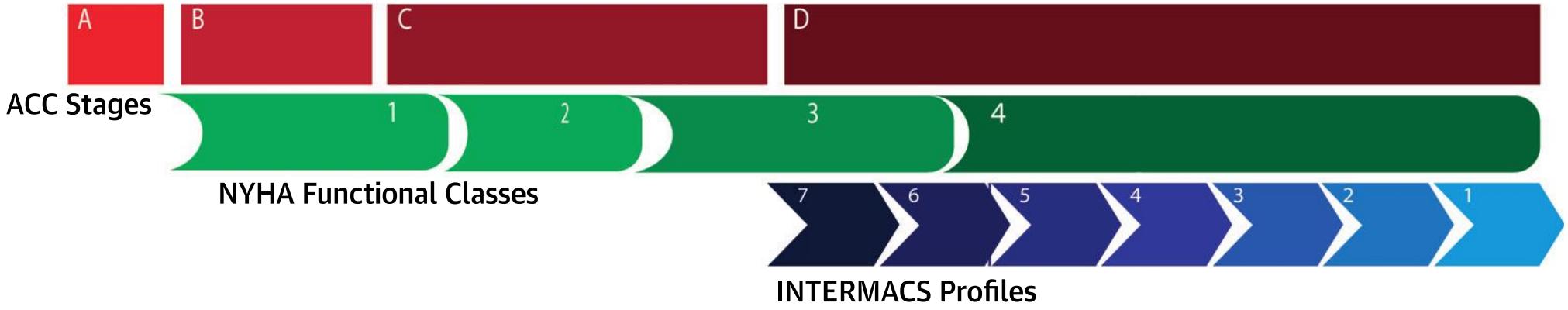
Allen et al. Circulation 2012; 125;1928-52

STAGE D HF MORTALITY RIVALS CANCER



2-Year Mortality Rates (U.S. Adults)	
Cancer Type	2-Year Mortality
Pancreatic	≈ 65–70%
Lung	≈ 45–50%
Brain	≈ 40–45%
Head & Neck	≈ 30–35%
Colon	≈ 20–25%
Breast	≈ 8–10%
Prostate	≈ 2–4%

HF CLASSIFICATION



ACC Stages

A: Patient is at high risk for developing heart failure but has no functional or structural heart disorder

B: Structural heart disorder without symptoms

C: Past or current symptoms or heart failure associated with structural disorder

D: Advanced heart disease requiring hospital-based support, transplant, or palliative care

NYHA Functional Classes

I: No limitation in normal physical activity

II: Mild symptoms with normal activity

III: Markedly symptomatic during daily activities, asymptomatic only at rest

IV: Severe limitations, symptoms even at rest

INTERMACS Profiles

Profile 1: Critical Cardiogenic Shock

Profile 2: Progressive Decline

Profile 3: Stable, But Inotrope Dependent

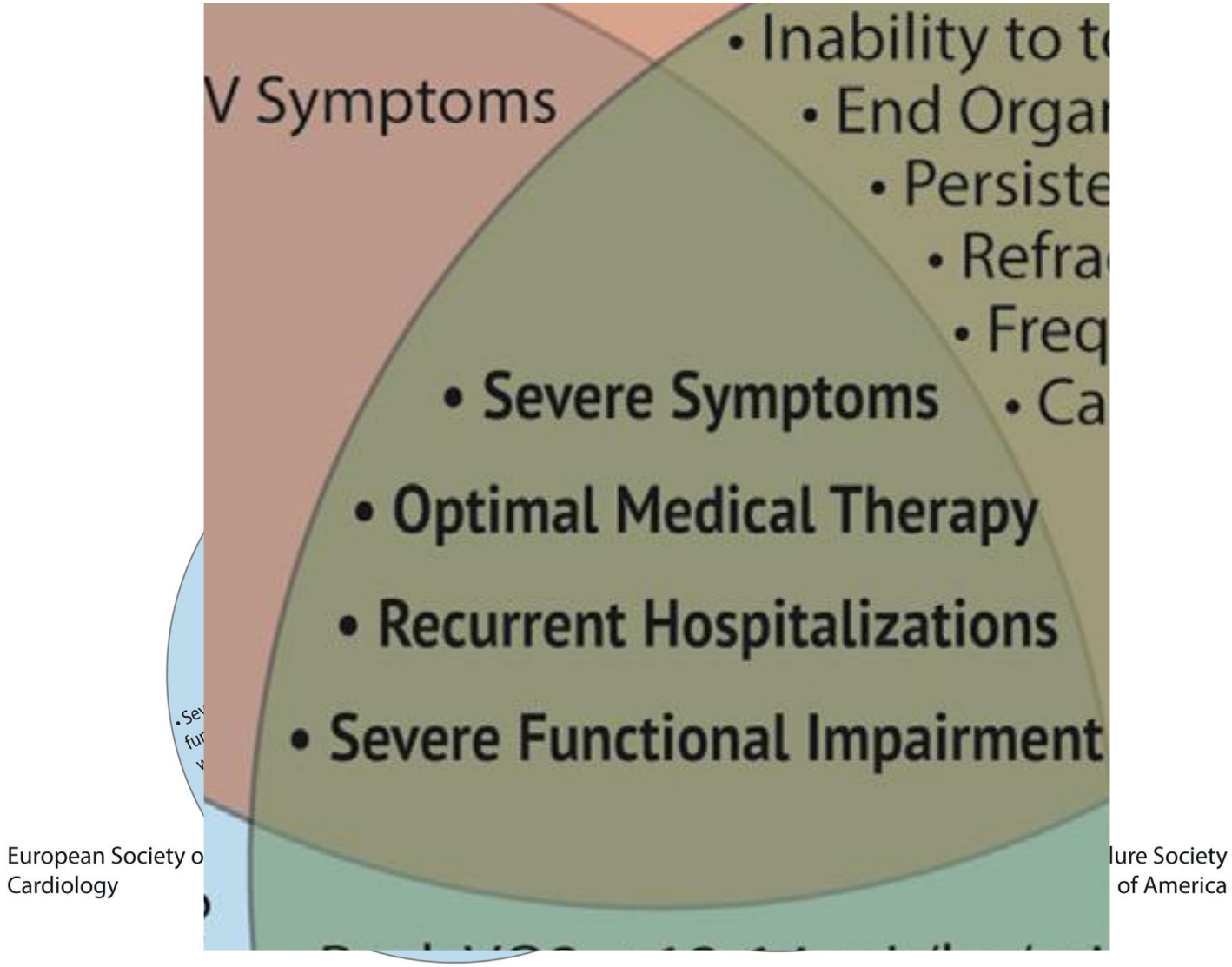
Profile 4: Resting Symptoms

Profile 5: Exertion Intolerant

Profile 6: Exertion Limited

Profile 7: Advanced NYHA Class III

STAGE D - ADVANCED HEART FAILURE CHARACTERISTICS



- Symptoms
  - NYHA class IIIB & IV
- Substrate
  - Cardiomyopathy, Valve disease, Arrhythmias, CAD
- Hemodynamics
  - Elevated intracardiac filling pressures
  - Low cardiac output
- Risk Factors
  - Recurrent HF admissions, ICD shocks, CPET results, Biomarkers

ADVANCED HEART FAILURE PATIENTS

“Crash & Burn”- Profiles 1,2

“Walking Wounded” – Profiles 4-7

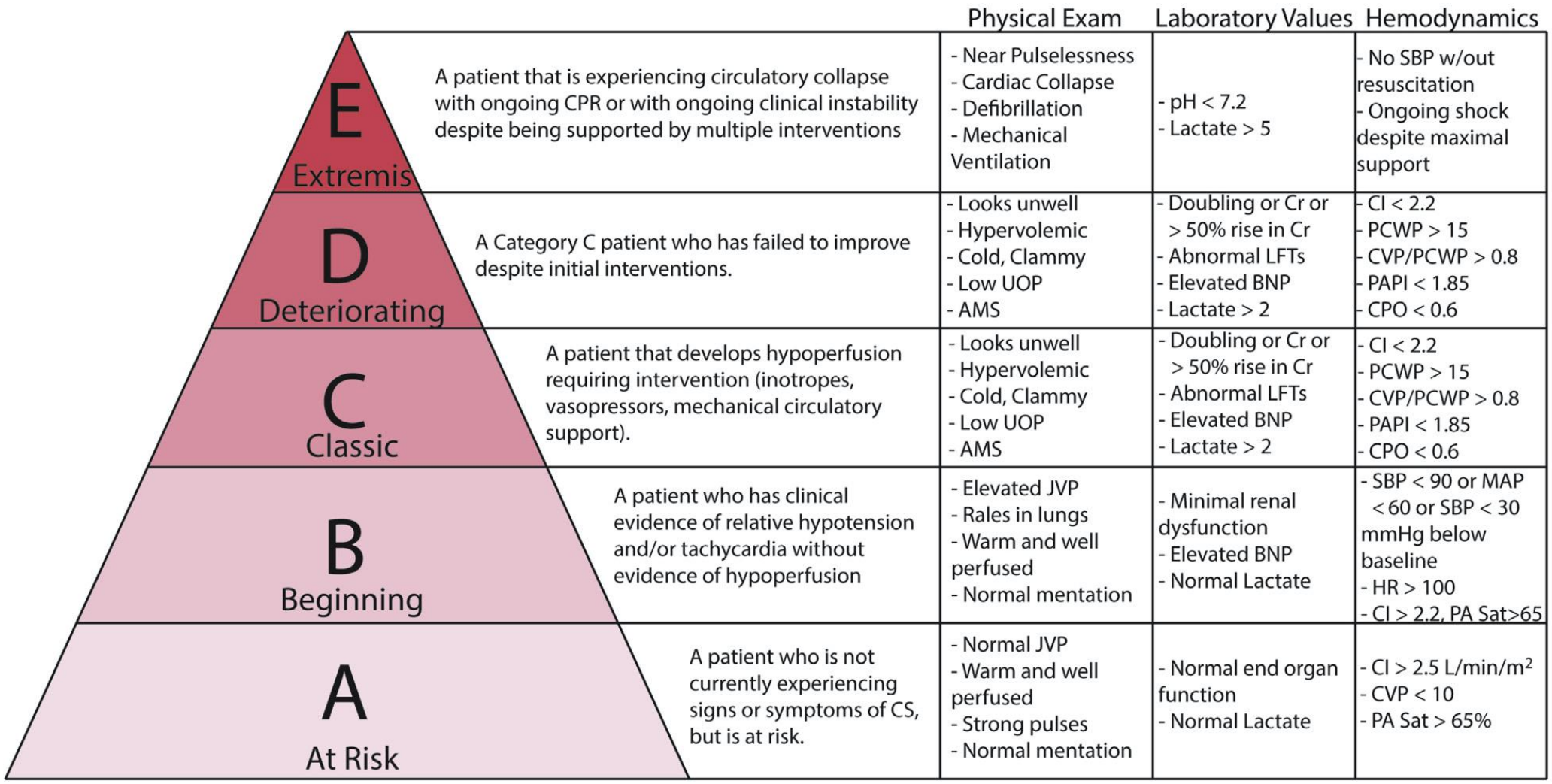
Table 2 **INTERMACS Patient Profiles (20)**

Level	Definition	Description
1	Critical cardiogenic shock	"Crash and burn"
2	Progressive decline	"Sliding fast"
3	Stable but inotrope dependent	Stable but dependent
4	Recurrent advanced HF	"Frequent flyer"
5	Exertion intolerant	"Housebound"
6	Exertion limited	"Walking wounded"
7	Advanced NYHA class III	Advanced NYHA class III

HF = heart failure; NYHA = New York Heart Association.

CARDIOGENIC SHOCK – PROFILES 1-3

FIGURE 4 SCAI Classification of CS



	Physical Exam	Laboratory Values	Hemodynamics
A patient that is experiencing circulatory collapse with ongoing CPR or with ongoing clinical instability despite being supported by multiple interventions	- Near Pulselessness - Cardiac Collapse - Defibrillation - Mechanical Ventilation	- pH < 7.2 - Lactate > 5	- No SBP w/out resuscitation - Ongoing shock despite maximal support
A Category C patient who has failed to improve despite initial interventions.	- Looks unwell - Hypervolemic - Cold, Clammy - Low UOP - AMS	- Doubling or Cr or > 50% rise in Cr - Abnormal LFTs - Elevated BNP - Lactate > 2	- CI < 2.2 - PCWP > 15 - CVP/PCWP > 0.8 - PAPI < 1.85 - CPO < 0.6
A patient that develops hypoperfusion requiring intervention (inotropes, vasopressors, mechanical circulatory support).	- Looks unwell - Hypervolemic - Cold, Clammy - Low UOP - AMS	- Doubling or Cr or > 50% rise in Cr - Abnormal LFTs - Elevated BNP - Lactate > 2	- CI < 2.2 - PCWP > 15 - CVP/PCWP > 0.8 - PAPI < 1.85 - CPO < 0.6
A patient who has clinical evidence of relative hypotension and/or tachycardia without evidence of hypoperfusion	- Elevated JVP - Rales in lungs - Warm and well perfused - Normal mentation	- Minimal renal dysfunction - Elevated BNP - Normal Lactate	- SBP < 90 or MAP < 60 or SBP < 30 mmHg below baseline - HR > 100 - CI > 2.2, PA Sat>65
A patient who is not currently experiencing signs or symptoms of CS, but is at risk.	- Normal JVP - Warm and well perfused - Strong pulses - Normal mentation	- Normal end organ function - Normal Lactate	- CI > 2.5 L/min/m^2 - CVP < 10 - PA Sat > 65%

Jentzer et al. JACC 2019

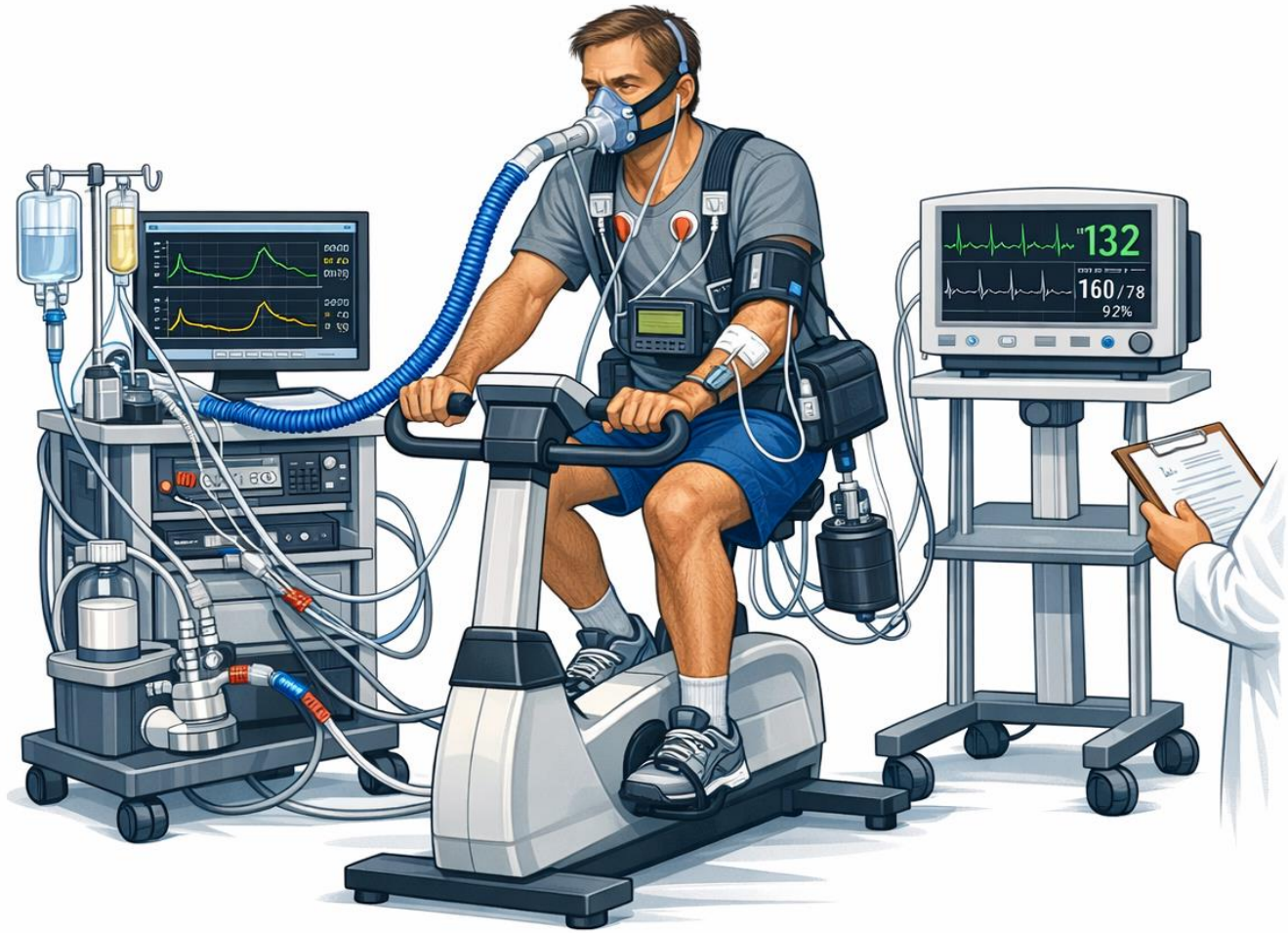
ADVANCED HF – THE WALKING WOUNDED

- Recurrent HF Hospitalizations
- CRT Non-Responders
- Need for Inotropes
- Neuro-hormonal antagonist doses limited by hypotension and renal dysfunction
- Diuretic Resistance
- Persistent symptoms with ADLs
- Cardio-renal syndrome

HF HOSPITALIZATION – A SENTINEL EVENT

Timeframe	Estimated Mortality Rate	Key Details
In-Hospital	**3% – 8%**	Rates vary by age and severity; recent trends show a decrease in-hospital but not post-discharge.
30 Days	**6% – 10%**	The first 30 days are considered a "vulnerable phase" with high risks of readmission and death.
90 Days	**11% – 15%**	Risks are nearly tripled for patients with social determinants of health (SDOH) like social isolation.
1 Year	**27% – 37%**	Mortality is higher than many common cancers and often linked to high readmission rates (up to 53%).
5 Years	**~69%**	Median survival for newly hospitalized HF patients is approximately **2.4 years**.
10 Years	**~83%**	Less than 1 in 5 patients survive 10 years post-hospitalization.

CARDIOPULMONARY EXERCISE TEST



CPET Parameter	Threshold Supporting Transplant Candidacy
Peak VO_2 (mL/kg/min)	**< 14 mL/kg/min**
Percent-predicted Peak VO_2	**≤ 50% predicted**
VE/VCO_2 Slope	**> 35**
Exercise Oscillatory Ventilation	**Present**
Anaerobic Threshold (VO_2 at AT)	**< 11 mL/kg/min**
Respiratory Exchange Ratio (RER)	**≥ 1.05**

ADVANCED HEART FAILURE PATIENTS

I	IV inotropes
N	NYHA IIIB/IV or persistently elevated natriuretic peptides
E	End-organ dysfunction (Cr > 1.8 mg/dL or BUN > 43 mg/dL)
E	EF ≤ 35%
D	Defibrillator shocks
H	Hospitalizations > 1
E	Edema (or elevated PA pressure) despite escalating diuretics
L	Low blood pressure, high heart rate
P	Prognostic medication — progressive intolerance or down-titration GDMT

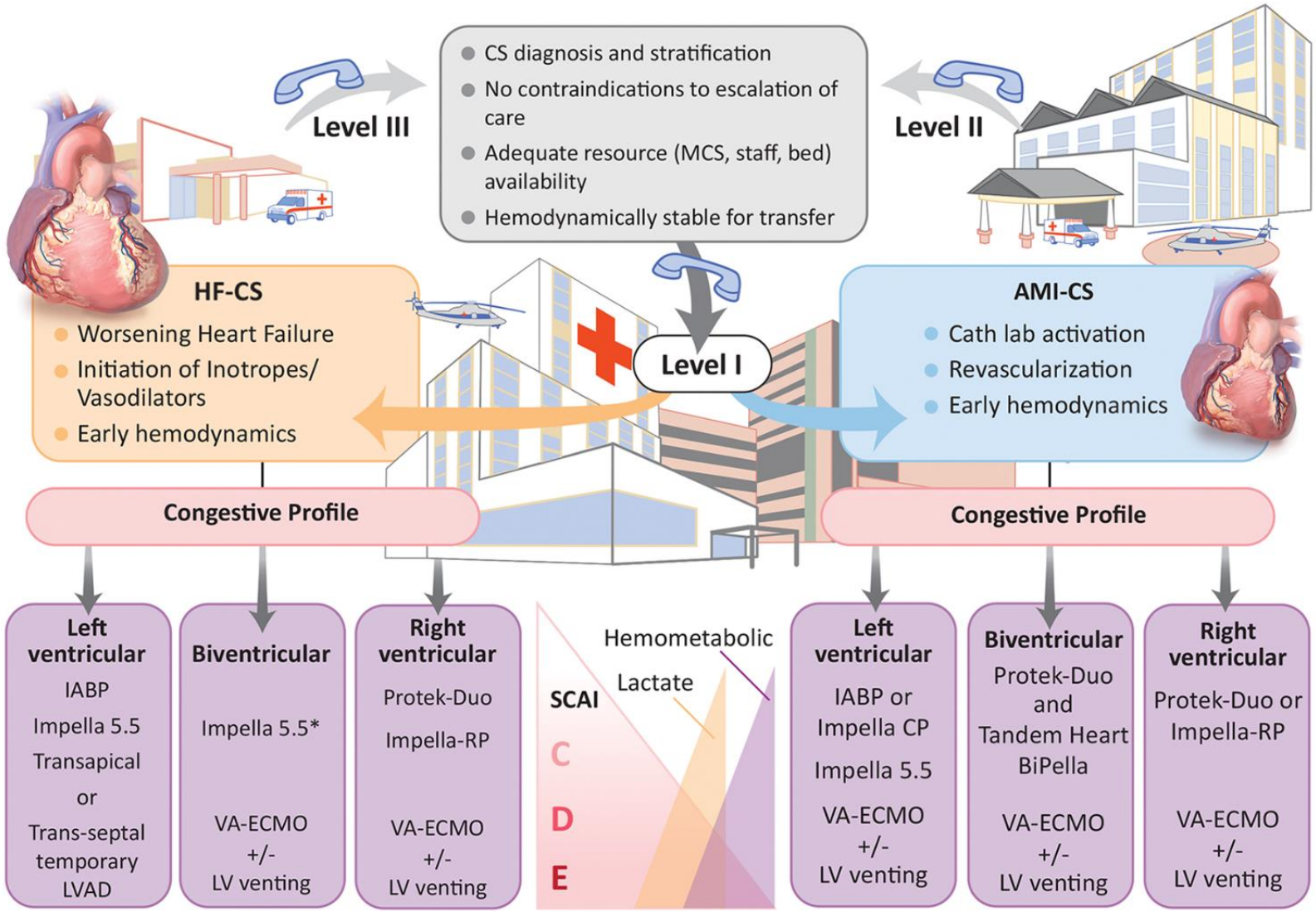
ADDITIONAL CONSIDERATIONS FOR REFERRAL:

- CRT non-responder
- Physical activity limited or impaired QOL

Yancy CW, et al. *J Am Coll Cardiol*. 2018.

TEMPORARY MCS TO RESCUE CARDIOGENIC SHOCK

- Recognition
- Initiation of vasopressors and inotropes
- Evaluation with Swan-ganz catheter and bloodwork
- Insertion of temporary MCS device



Mehta et al. Front CV Medicine 2024

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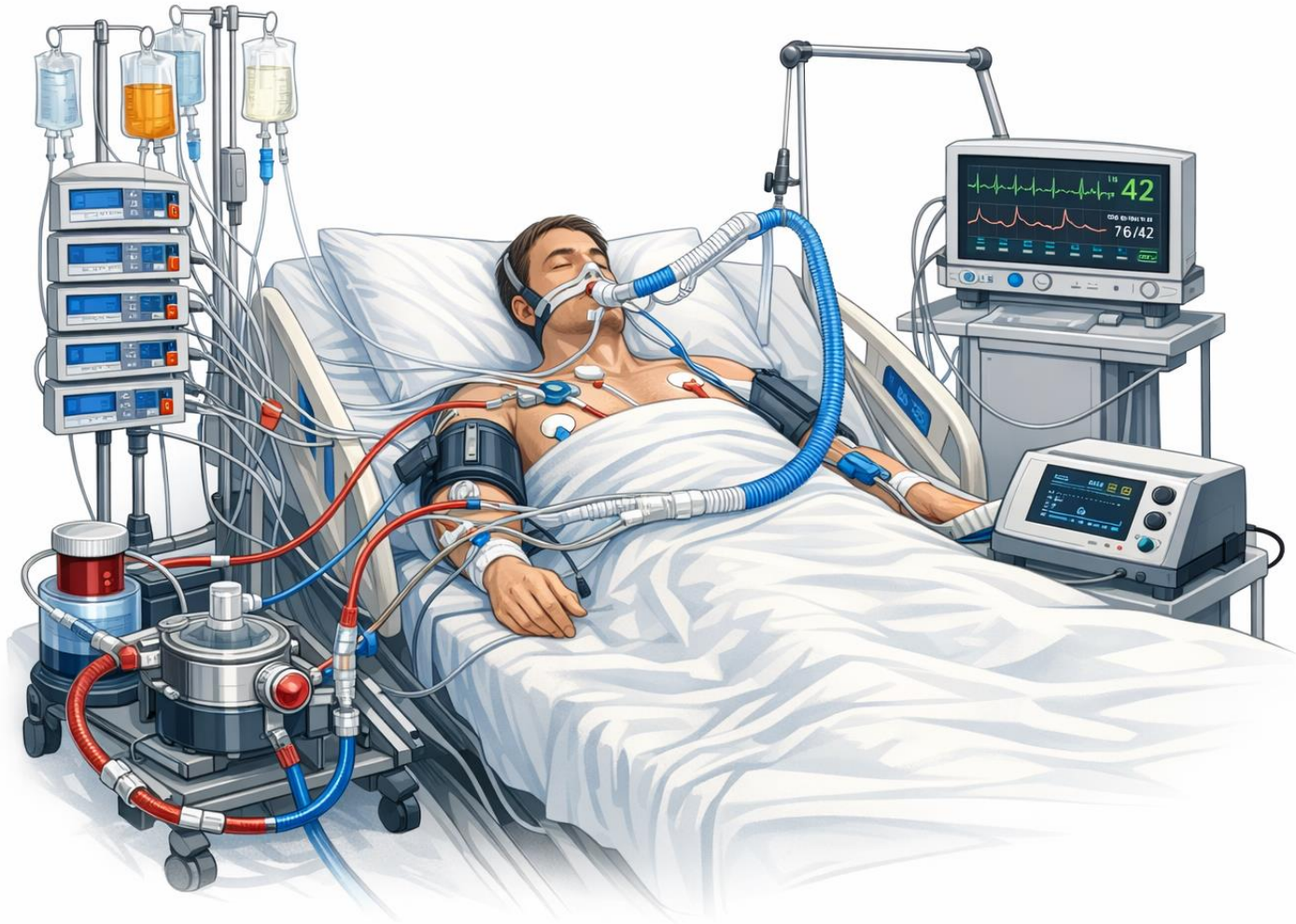
INTERMACS 1-3 – CARDIOGENIC SHOCK

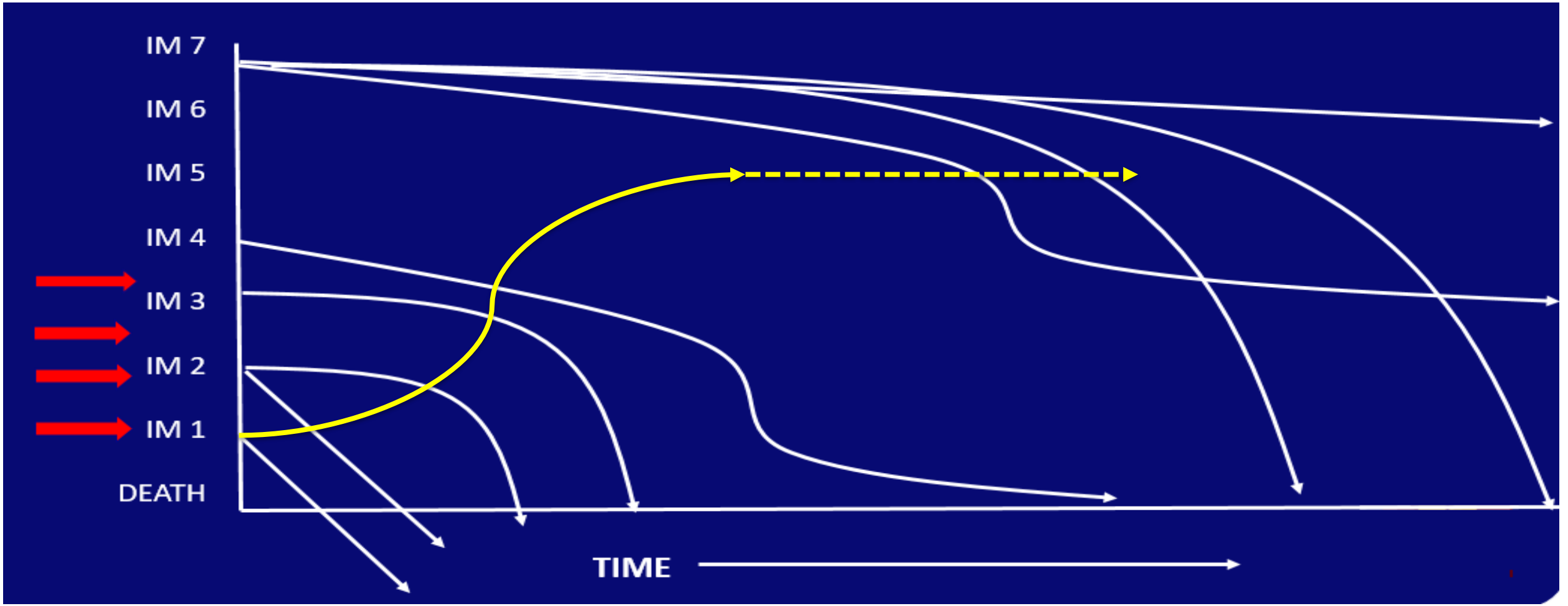


Will ventricular function RECOVER?

If not requires

- Heart Transplant
- LVAD
- Total Artificial Heart

UNPREDICTABLE COURSE OF ADVANCED HEART FAILURE



PREDICTORS OF RECOVERY

Category	High Recovery Likelihood	Poor Recovery Likelihood
Cardiac Etiology	**Reversible/Acute Insults:** • **Newly diagnosed** (de novo) HF • **Tachy-related** cardiomyopathy • **EtOH-induced** cardiomyopathy • **Takotsubo** syndrome • Acute Myocarditis	**Chronic/Refractory Disease:** • Established HF **on GDMT prior to admission** • Known low LVEF with chronic remodeling • Prior failed attempts at weaning
Hemodynamics	• CPO ≥0.6 W • Pulse Pressure ≥52 mmHg • PAPI ≥1.0 (RV health)	• PAWP ≥20 mmHg • CPO <0.5 W • High filling pressures despite support
Metabolic	• Lactate <2.0 mmol/L • Rapid lactate clearance • Improving renal/hepatic function	• Persistently high lactate (>4.0) • Developing multi-organ failure
Imaging	• LVOT VTI ≥12 cm • LVEF >25% during weaning trial • Restoration of TIMI 3 flow (if MI)	• Severe, fixed RV dysfunction • Severe LV dilatation (LVEDD >6.5 cm) • Residual multivessel CAD

TIMING OF REFERRAL - RECOGNIZING STAGE D

Referral Timing is critical

HOSPICE/COMFORT MEASURES

STAGE D: Advanced Heart Failure with symptoms that are no longer relieved by standard medications and other therapies

-Long-term inotropes or IV heart medications, mechanical circulatory support in form of LVAD or total artificial heart, heart transplantation

STAGE C: Heart failure with symptoms (Shortness of breath, swelling, fatigue, possibly limitation in activity)

-Water pills, heart failure medications, pacemaker/ICD, valve surgery, cardiac bypass or stent placement, sodium restrictions

STAGE B: Heart Failure with no symptoms

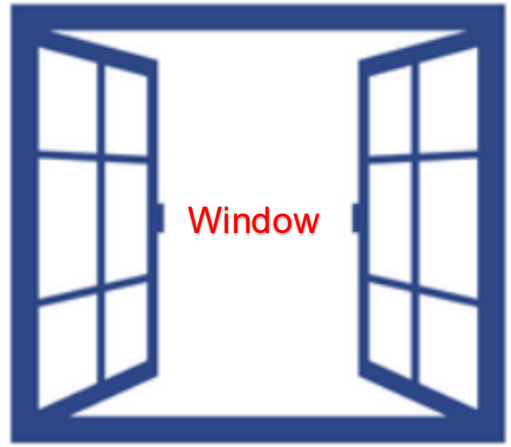
-Some patients may start one or two heart failure medications at this stage

STAGE A: Patient at risk of Heart Failure

-Blood pressure management, healthy lifestyle (healthy diet, activity, diabetes or other comorbity management)

TIME

THERE IS A



FOR ADV HF REFERRALS!

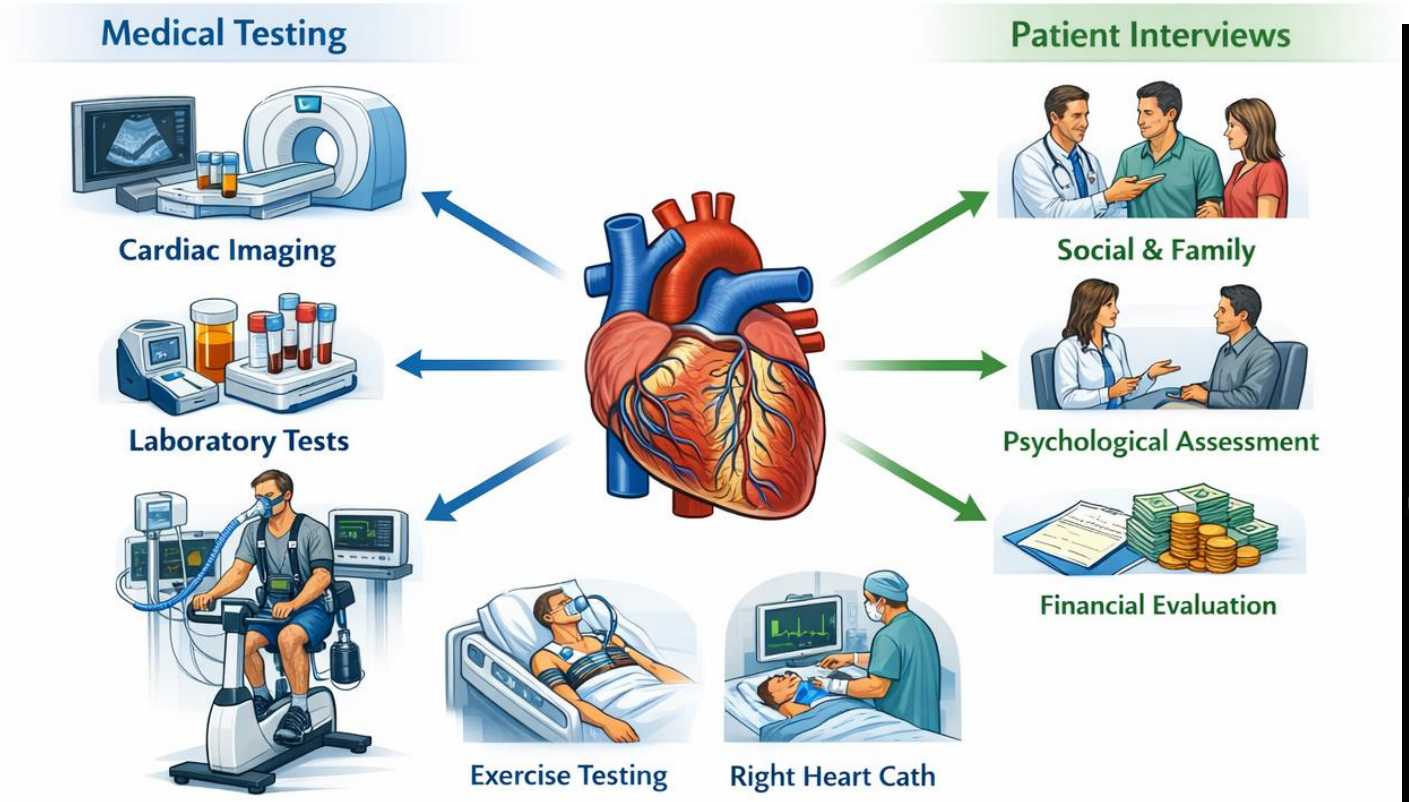
TIMING OF REFERRAL

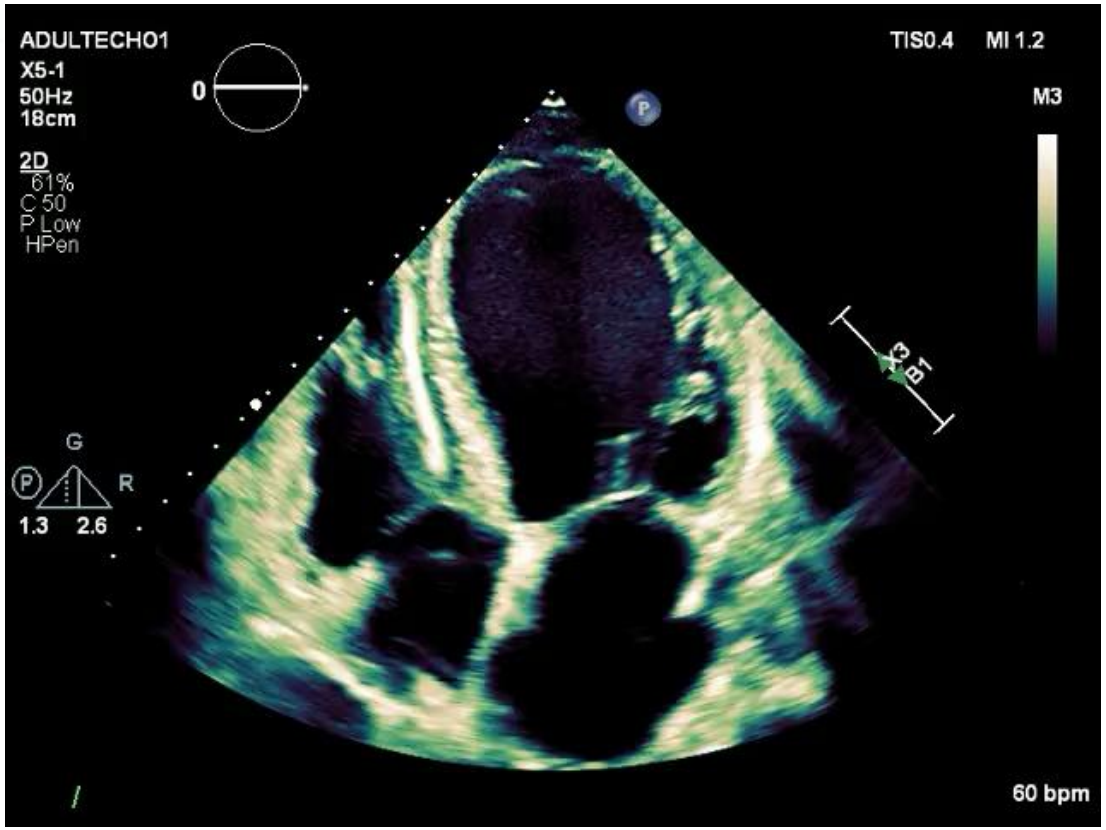
INTERMACS 1-3

Higher post HT & LVAD mortality
Longer stays in the hospital
More RV failure pre and post LVAD

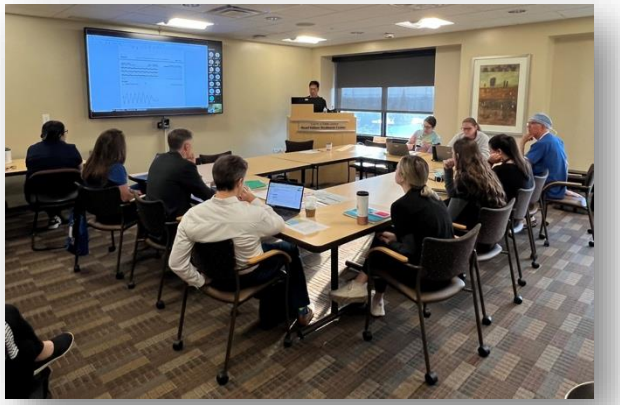
INTERMACS 4-7
More of an elective surgery
Too early? – subject patients to the constant
Hazard of adverse events post HT and LVAD

EVALUATION PROCESS





MULTIDISCIPLINARY TEAM SELECTION CONFERENCE



Heart Failure MD or NP
Optimizes medical management, assess patient to see if good medical candidate, follows throughout continuum of care.

Other Specialists:
- Hematology/Oncology
- Endocrinology
- Infectious Disease
- Gastroenterology
- Pulmonology

Palliative Care
QOL focus, pain & symptom management, psychosocial support, advance directives & care planning. Follows during hospitalization, includes chaplains.

LVAD Coordinators/RN
Coordinate VAD testing, introduce & maintain equipment, lab work, insurance approval, continues education throughout continuum.

Procedures:
- EGD
- Colonoscopy
- Echo
- EKG
- Left/right heart catheterization
- Chest X--rays, CT/ other scans
- Blood tests

Cardiac Surgeon
Assess if good surgical candidate, explains risks of surgery, recovery.

Social Worker
Assess patient & family with community resources, discharge planning, ongoing support with medications, driveline supplies, placement needs.

- Coordinates LVAD support group
- Coordinates meeting LVAD patient
- Assess patient & family, psychosocial & financial support, barriers to living with LVAD.

Psychologist
Assess patient & family for psychological strengths & barriers to LVAD.

CONTRAINDICATIONS TO OHT & LVAD

Absolute Contraindications	Relative Contraindications	Relative Contraindications	Absolute Contraindications
• Systemic Illness with a life expectancy < 2 years • Fixed Pulmonary Hypertension	• Age > 72 years old • Any active infection (with the exception of device related infections in VAD) • Severe diabetes with end-organ damage • Severe peripheral vascular disease or cerebrovascular disease • Active peptic ulcer disease • Morbid obesity or cachexia • Creatinine > 2.5 or creatinine clearance < 25 • FEV1 < 40% expected • Difficult to control hypertension • Irreversible neurologic or neuromuscular disorder • Active mental illness or psychosocial instability • Medical nonadherence • Drug, tobacco, alcohol use within 6 mos. • Liver dysfunction with total bilirubin > 2.5, serum transaminases > 3x normal, and/or INR >1.5 off warfarin • Heparin induced thrombocytopenia within 100 days	• Age > 80 • Morbid obesity or cachexia • Musculoskeletal disease that impairs rehabilitation • Active systemic infection or prolonged intubation • Untreated malignancy • Severe peripheral vascular disease or cerebrovascular disease • Drug, tobacco, alcohol use within 6 mos. • Impaired cognitive function • Psychosocial instability	• Irreversible hepatic disease • Irreversible renal disease • Irreversible neurologic or neuromuscular disorder • Medical nonadherence • Active mental illness or psychosocial instability

Heart Transplantation **Left Ventricular Assist Device**

These patients might be eligible for an LVAD!

+ Drug Screen

- Illicit substances
- Marijuana (inhaled)
- Nicotine

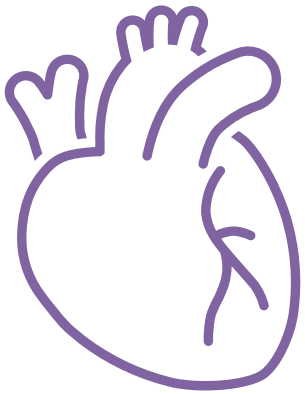
Age >72 years old

Morbid Obesity (BMI above 40)

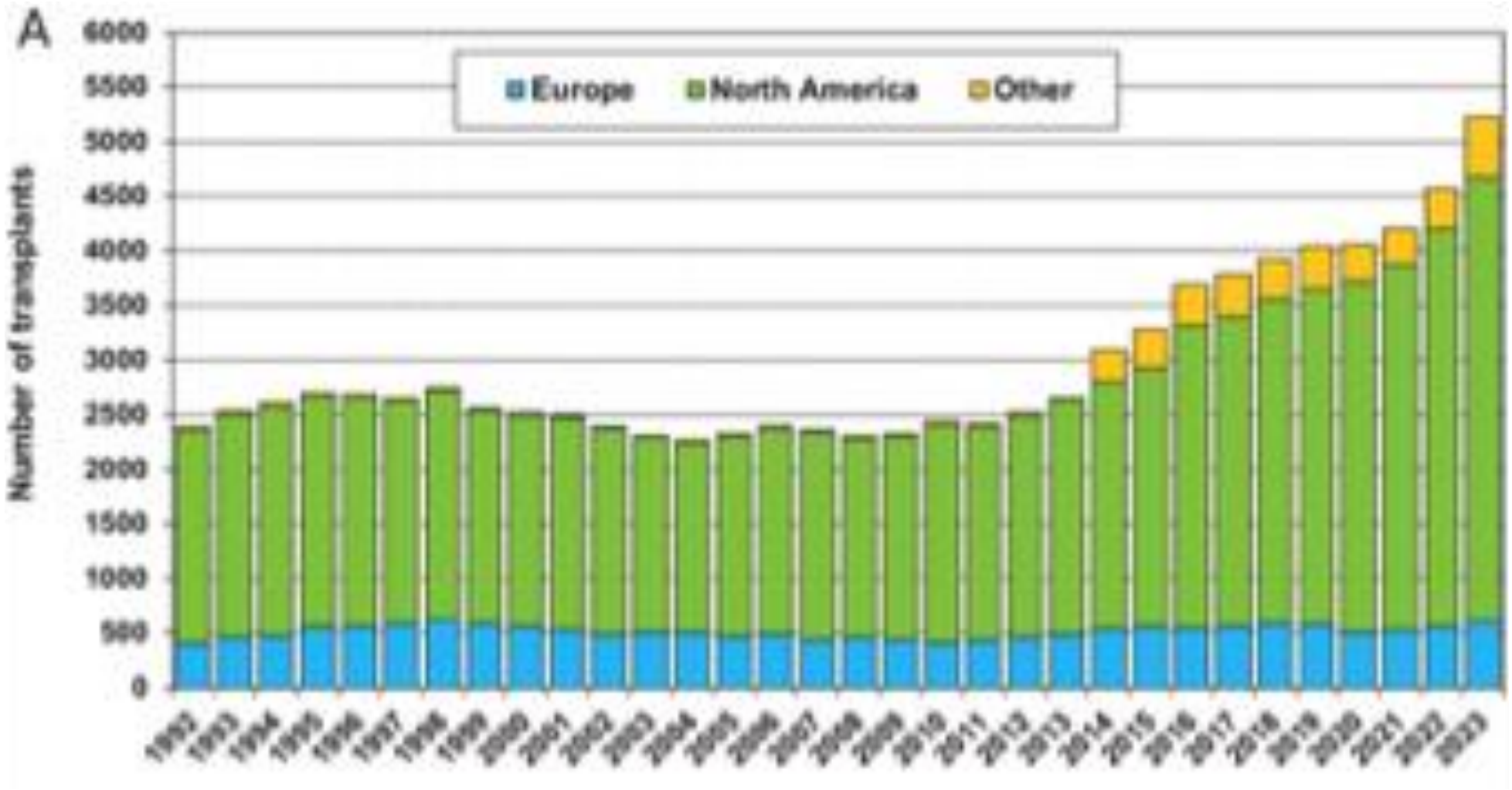
Uncontrolled Diabetes

Severe Pulmonary Hypertension

Most Common Exclusions for Transplant



HEART TRANSPLANT NUMBERS



Singh et al. JHLT 2025; 44(12):1857-1873

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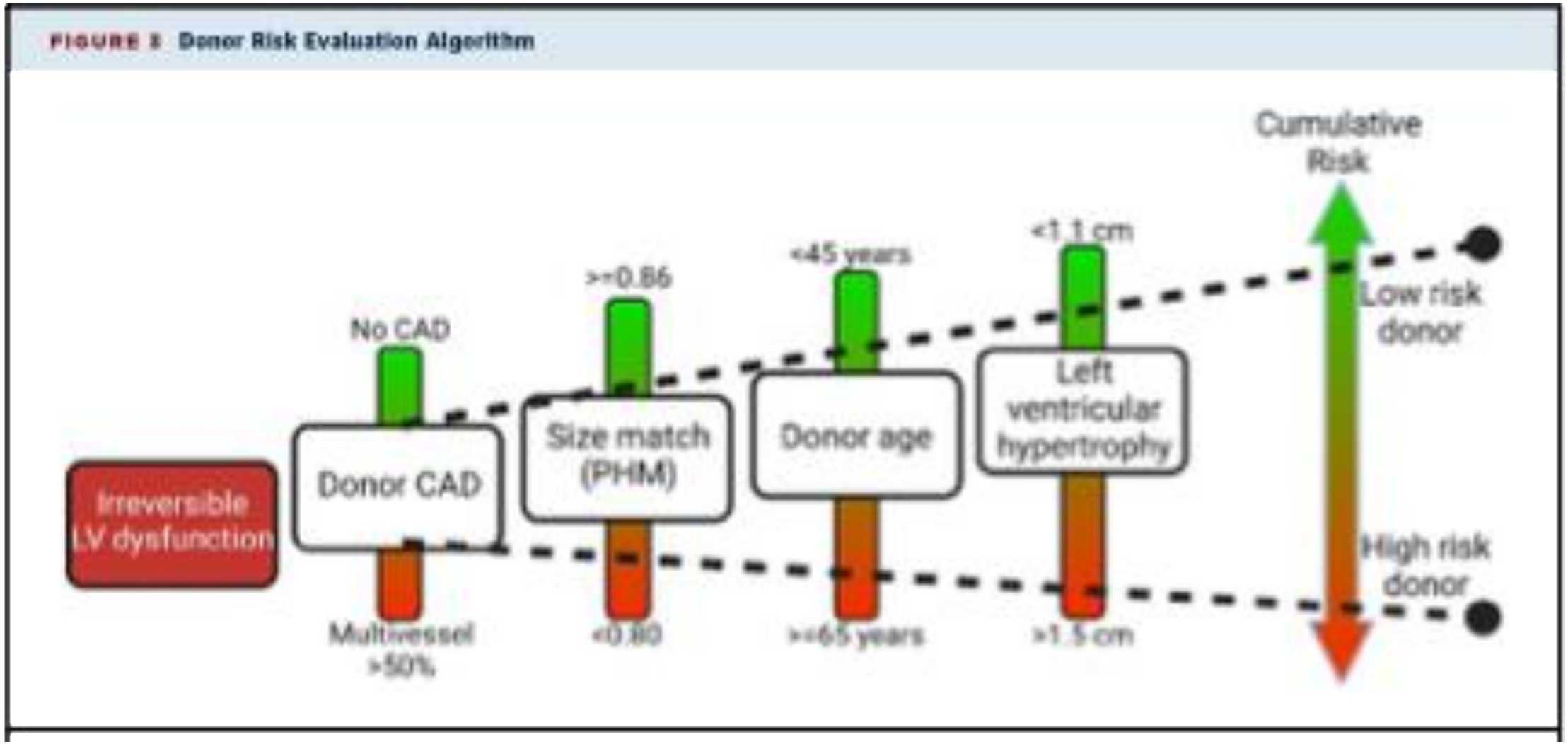
WAITLIST PATIENTS EXCEED NUMBER OF TRANSPLANTS

FIGURE 1 Numbers of patients on the United States Heart Transplant Waiting List vs Those Transplanted Between 2000 and 2023

This is based on data made available by Organ Procurement and Transplantation Network.[87]

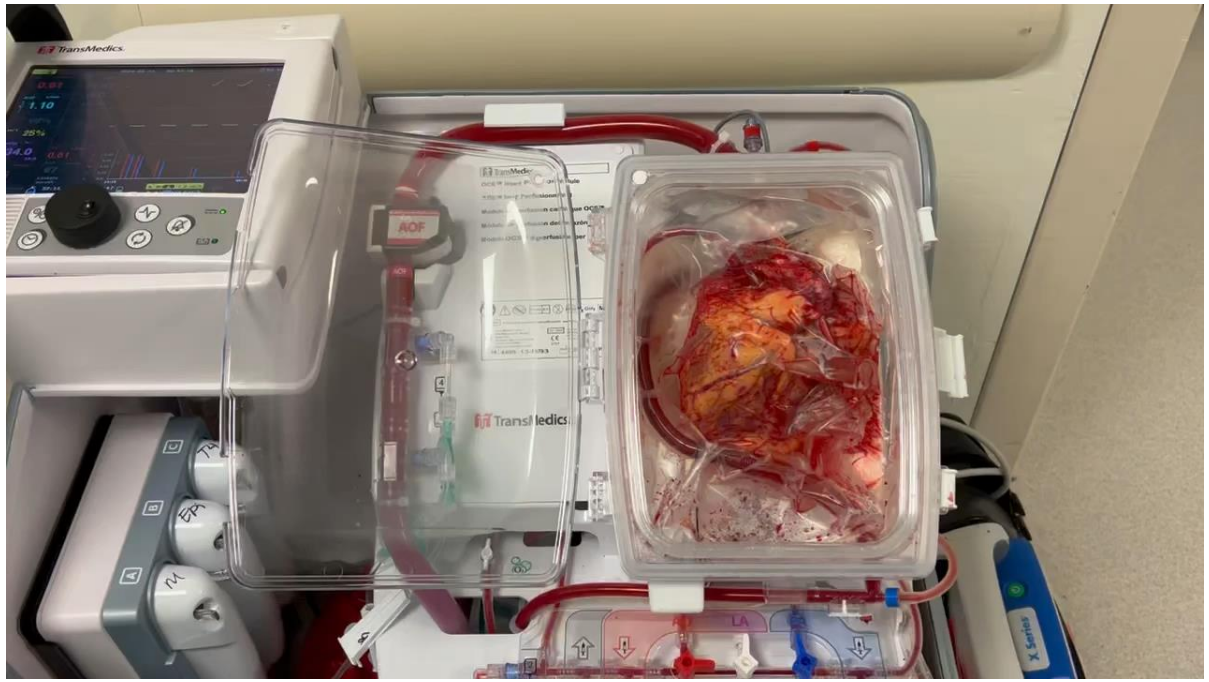
DONOR SELECTION



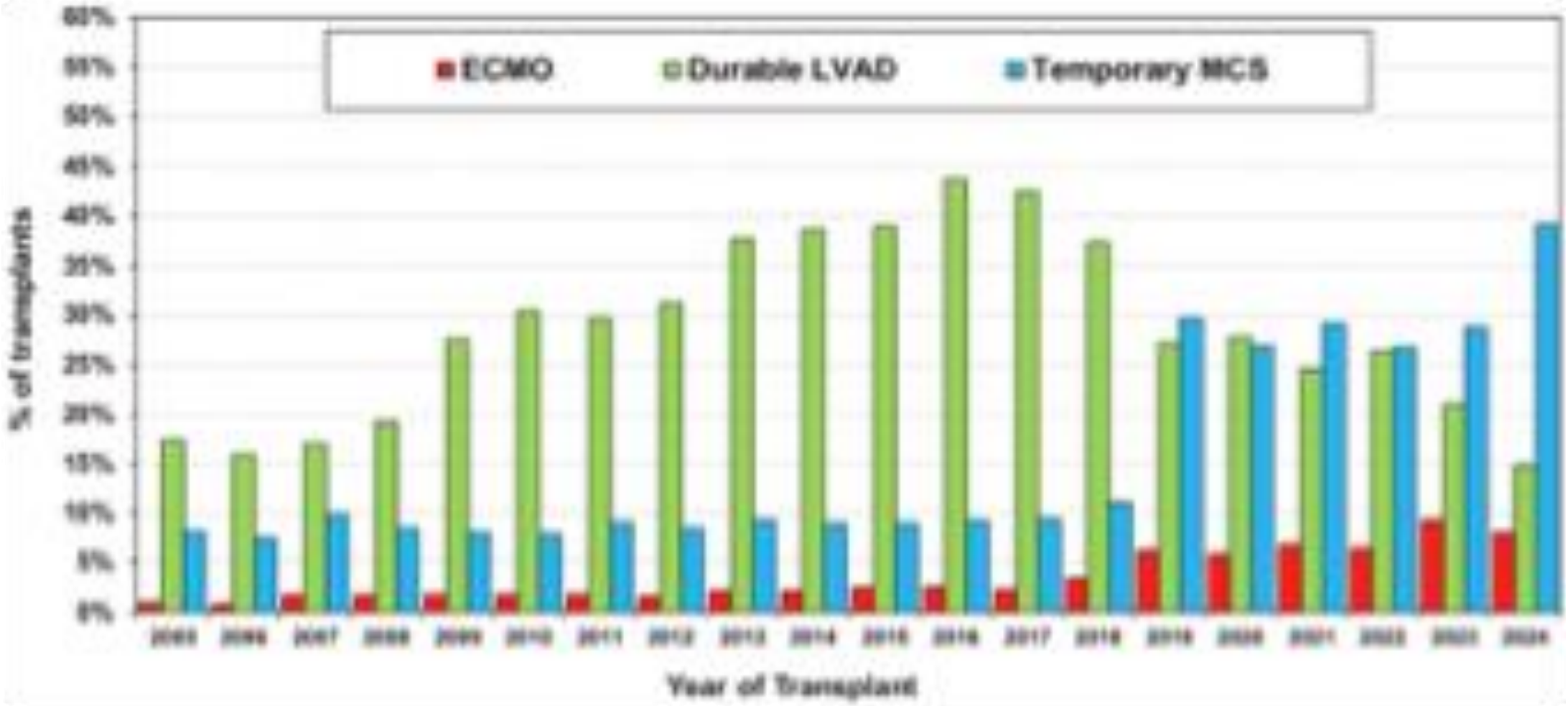
ORGAN PROCUREMENT

TABLE 2: Comparison of Different Organ Preservation Systems

Preservation Method	How It Works	Pros/Cons	Trials (If Applicable)
Static cold storage	Organ placed in preservation solution and 3 bags, and placed in a cooler with crushed ice	Inexpensive, simple Limited preservation time due to ischemic injury Risk of uneven cooling and cold injury	NA
SherpaPack	Sterile, pressure-controlled device that maintains temperature between 4° C and 8° C	Decreased risk of cold injury Allows longer ischemic times More expensive than ice	GUARDIAN Registry Studies
OCS	Extracorporeal perfusion system that keeps heart around physiological temperature in oxygen- and nutrient-rich solution	Decreased cold ischemia time Superior outcomes for longer ischemic times and extended criteria hearts Allows monitoring of several cardiac parameters Most expensive and resource/personnel-intensive option	PROCEED II trial OCS Heart EXPAND trials



MCS AS BRIDGE TO TRANSPLANT



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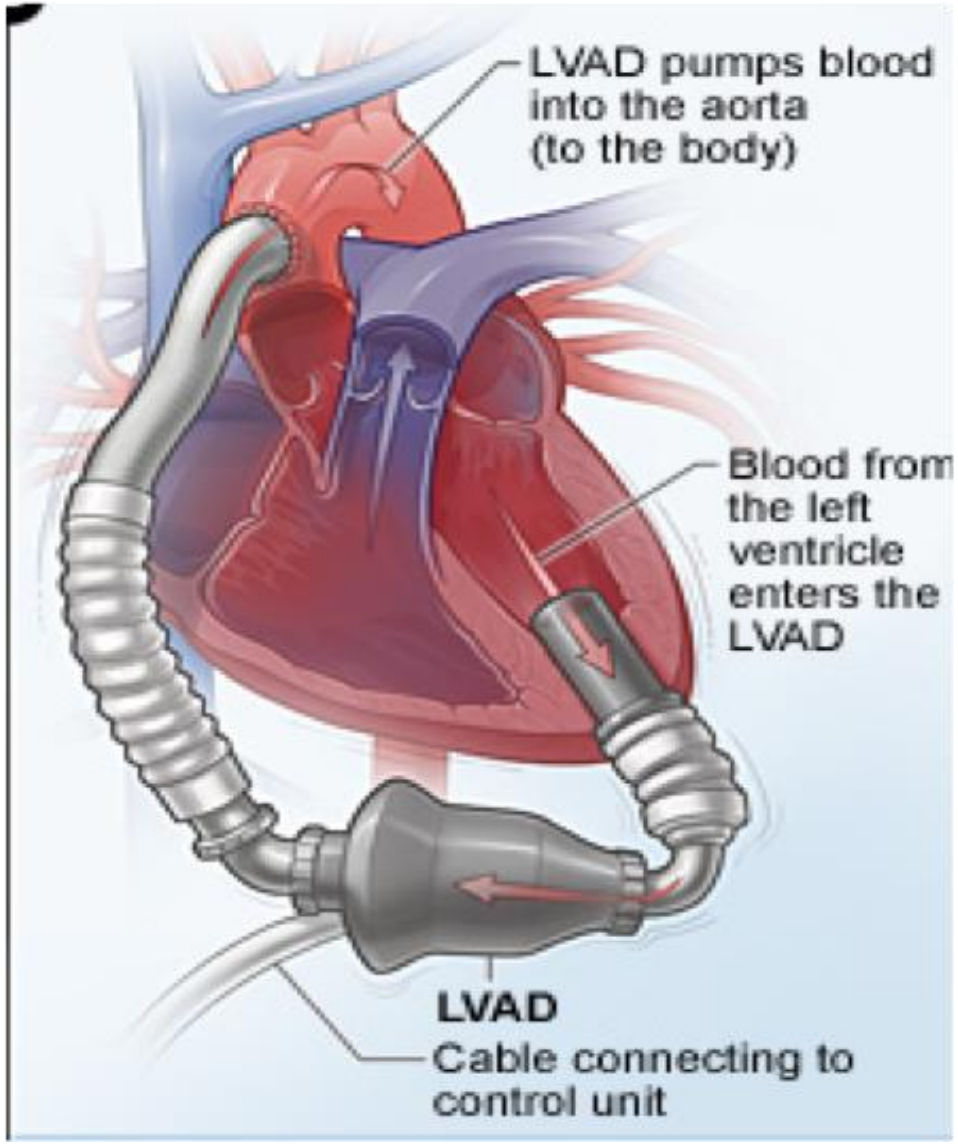
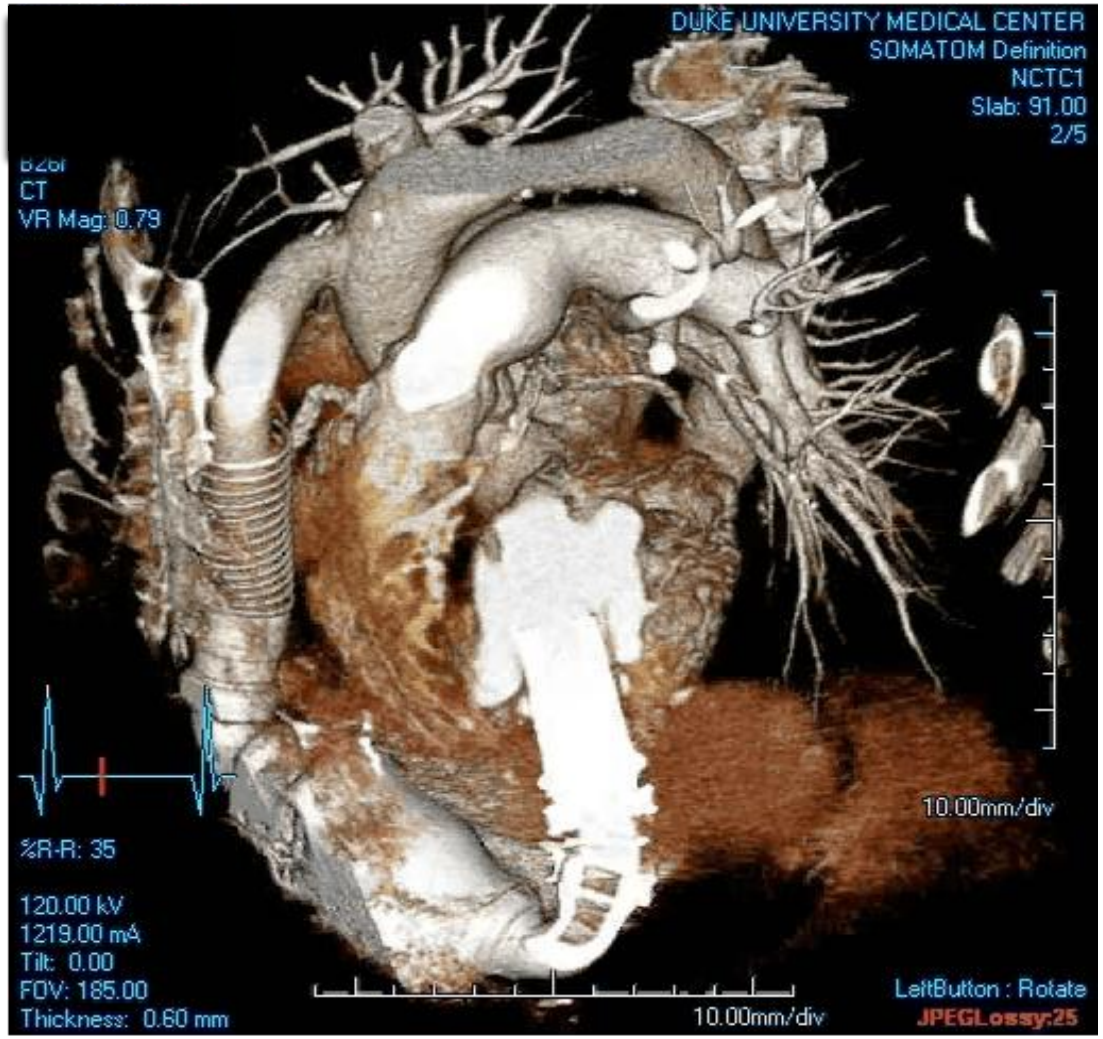
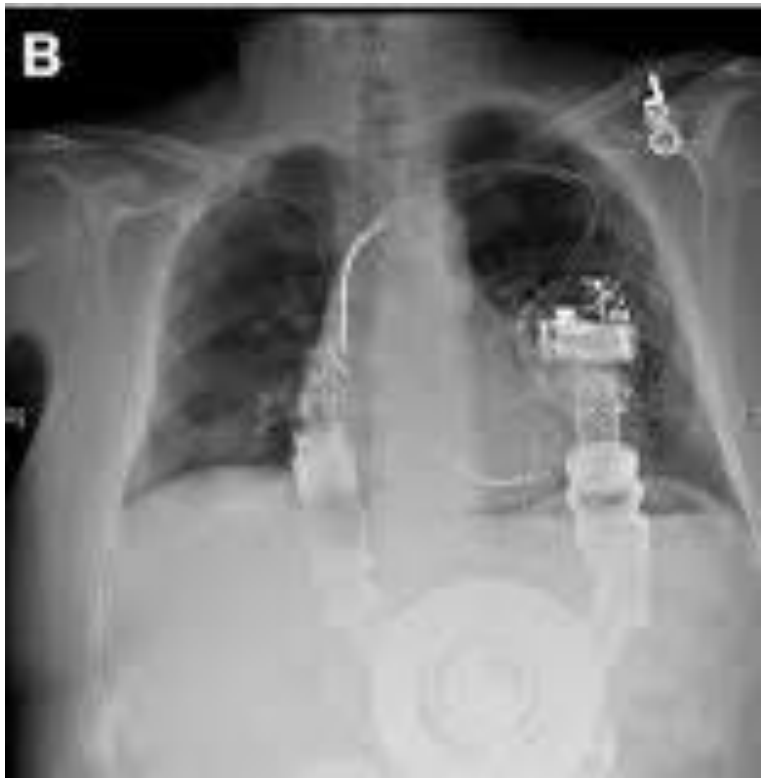
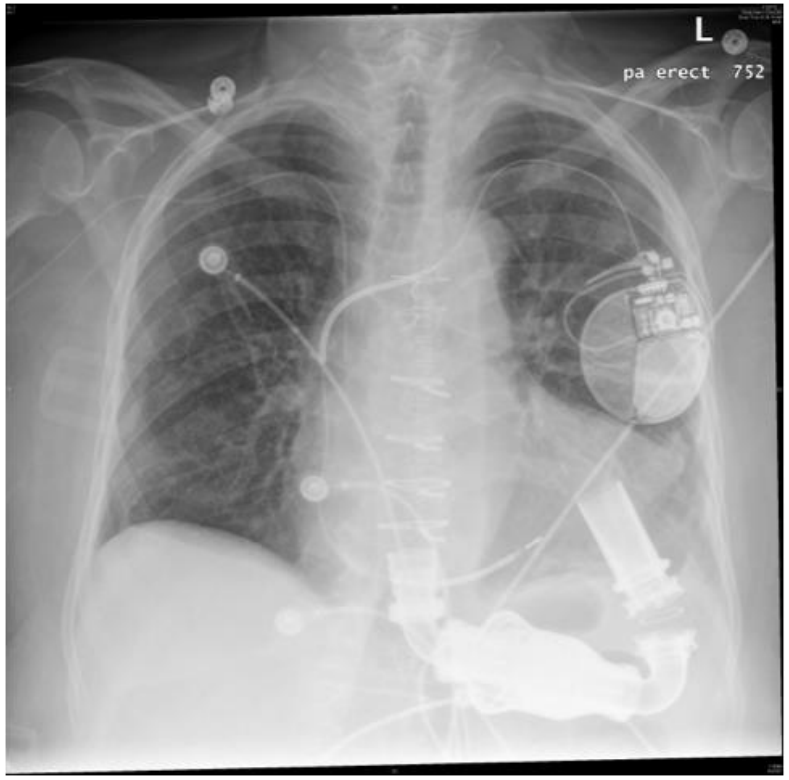
LVAD ANATOMY

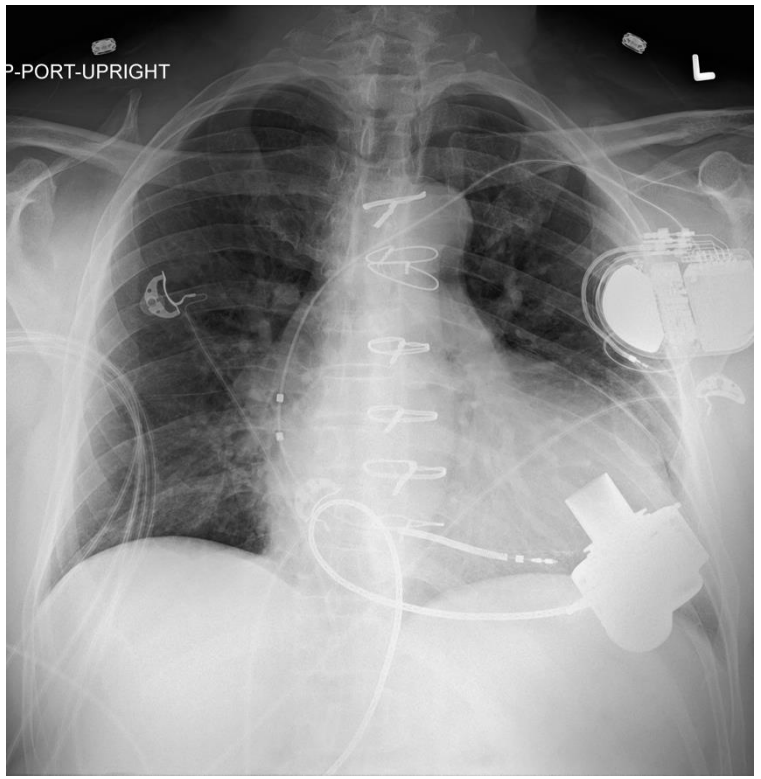


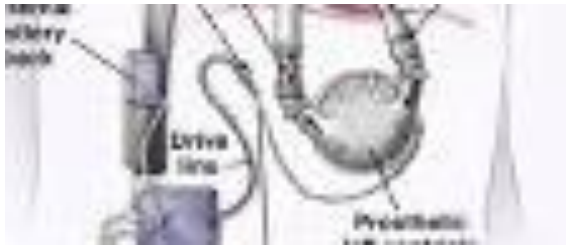


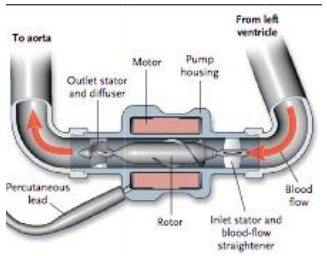
DEVICE EVOLUTION

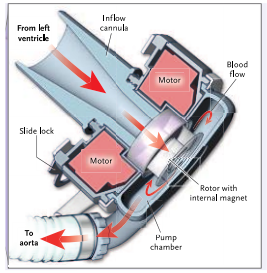








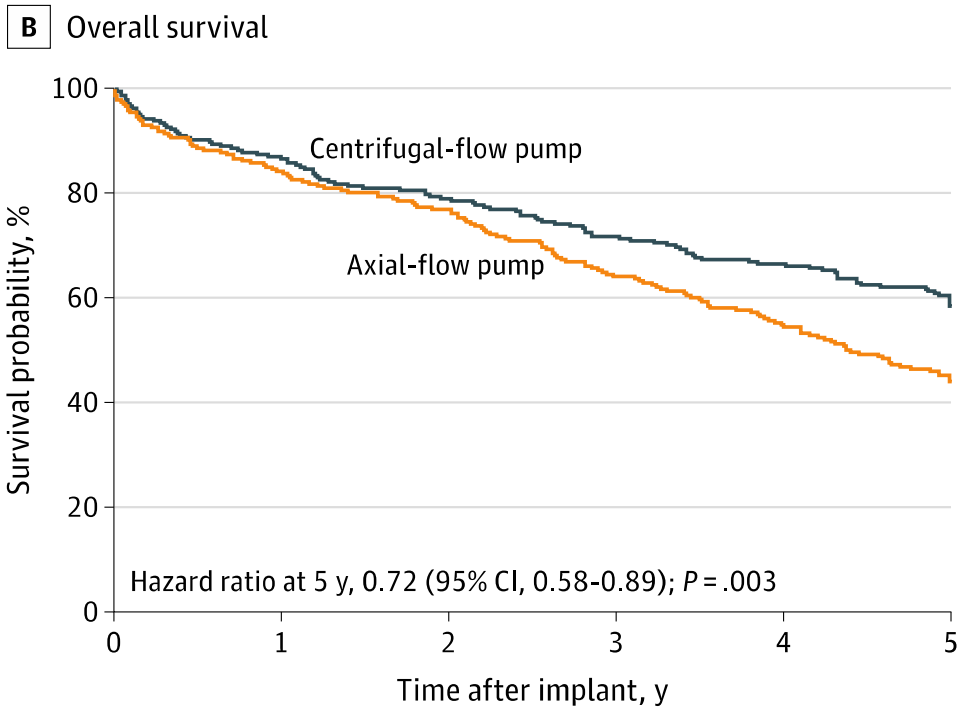


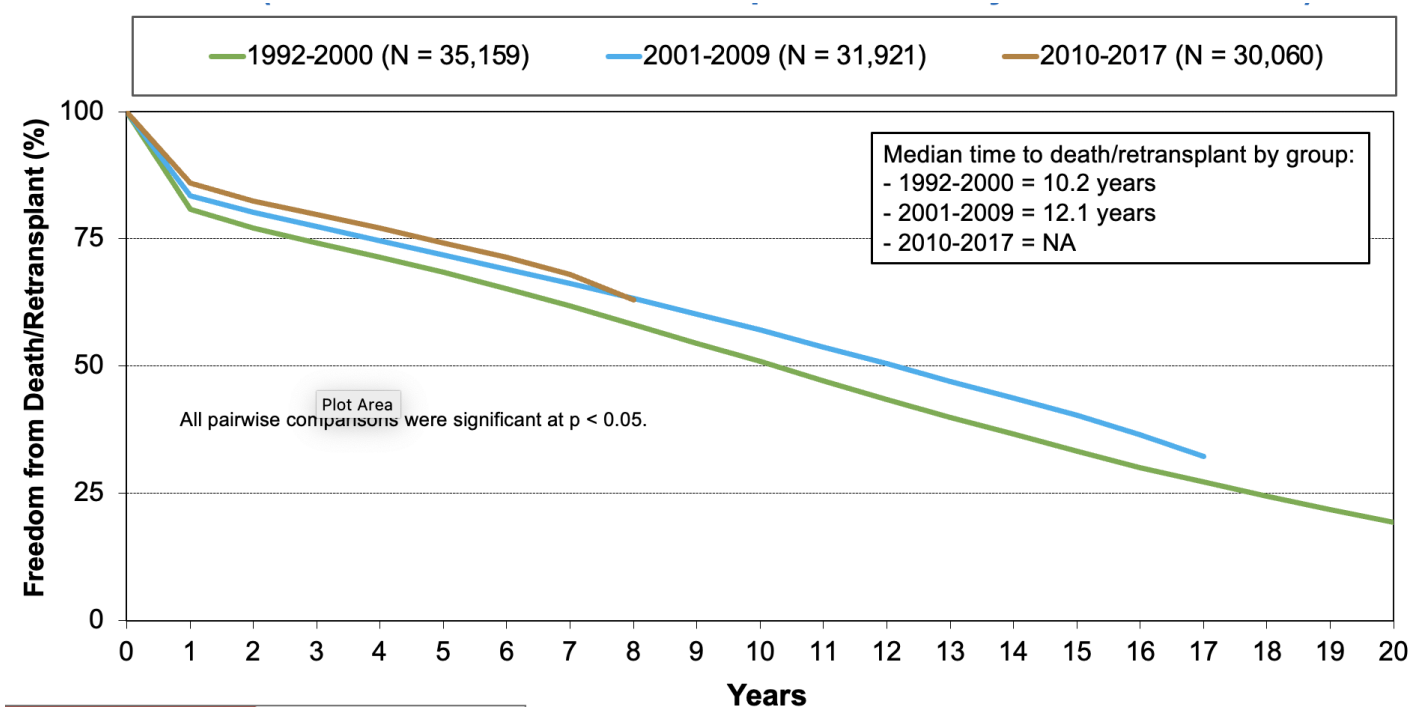


CENTRIFUGAL CONTINUOUS FLOW LVADS

	HeartMate 3	HVAD	EVAHEART 2	BrioVAD
Pump design	Cf-LVAD Centrifugal	Cf-LVAD Centrifugal	**Cf-LVAD Centrifugal**	**Cf-LVAD Centrifugal**
Impeller	MAG-Lev	Hydraulic (Blood)	**Hydraulic (Sterile water)**	MAG-Lev
Pump speed (clinical range)	4000 - 5500	1800 - 4000	**1600 – 2200 (Average: 1800)**	2800-3200
Inflow ID	19 mm	19 mm	**19 mm**	
Outflow graft ID	14 mm (polyester)	10 mm (polyester)	**14 mm (polyester)**	10 mm
Diameter	50 mm	47 mm	**51 mm**	47 mm
Pump pocket	Occasionally	No	**Required**	No

5 YEAR SURVIVAL – LVAD VS HEART TRANSPLANT





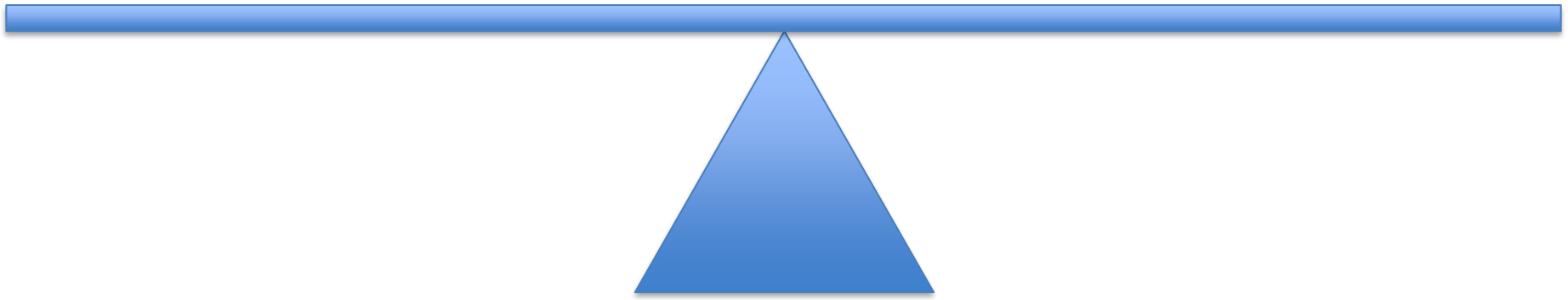
Hm3 - 5 year survival 58%

OHT - 5 year survival ~75%

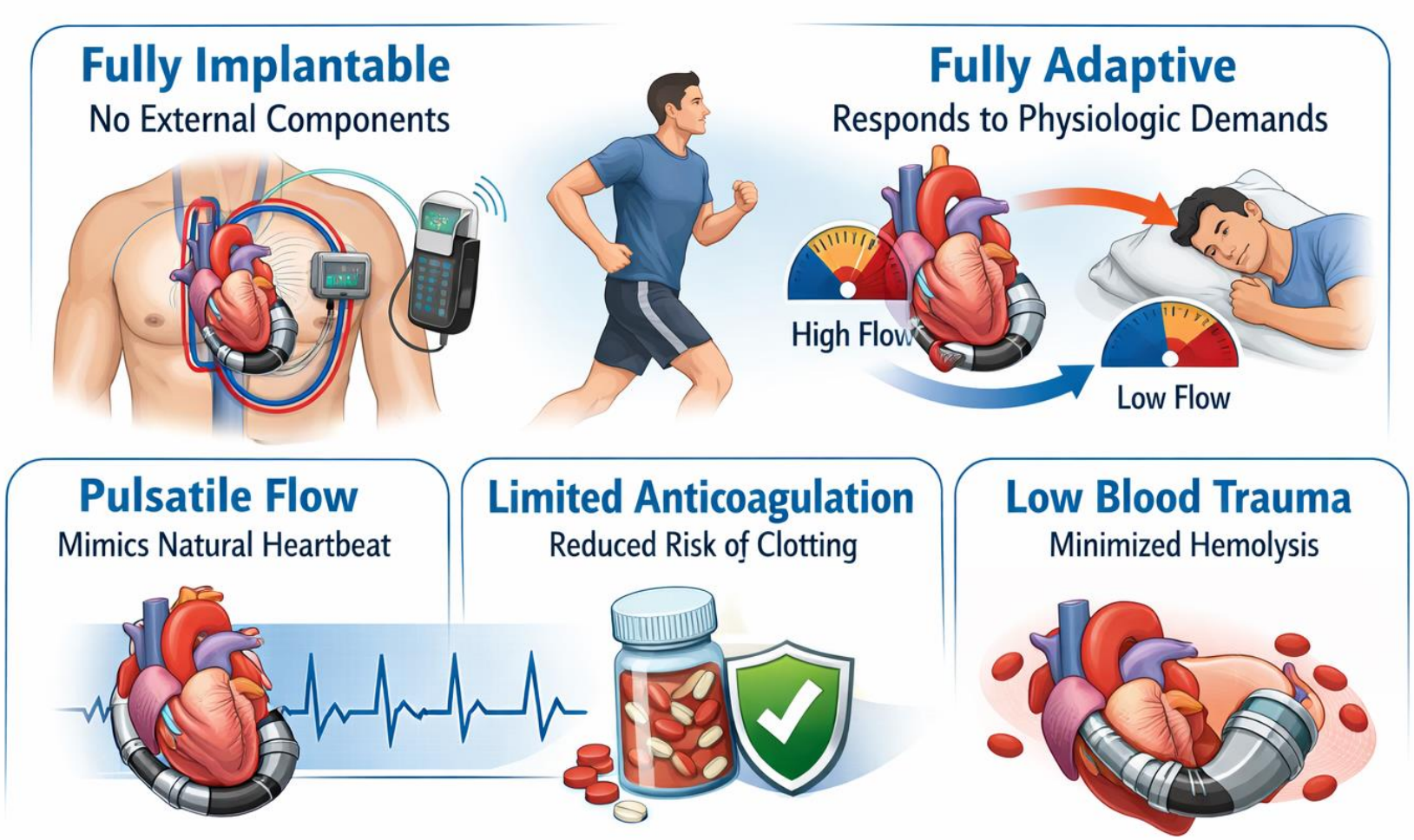
APPLICATION OF LVAD THERAPY

Improved Survival
Enhanced QOL
Symptom control

Device-related Infection
Stroke
Bleeding
Arrhythmias
Pump thrombosis



IDEAL PUMP FEATURES



Pumps to support

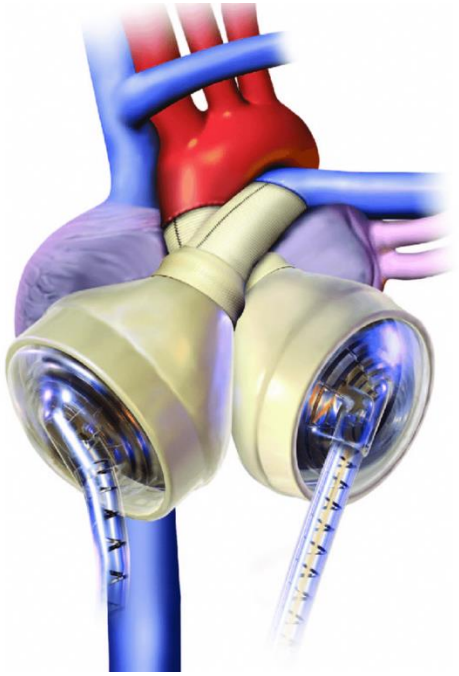
- LV
- RV
- Biventricular

TOTAL ARTIFICIAL HEART

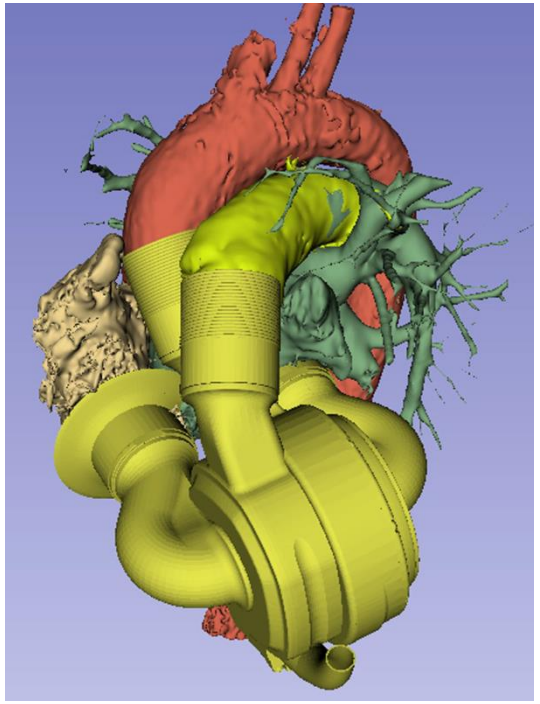
Serves as a Bridge to Transplant in patients with

- Severe biventricular heart failure
- Intractable Ventricular arrhythmias

Syncardia



Bivacor



TAH RESEARCH TRIAL

BiVACOR TOTAL ARTIFICIAL HEART
CLINICAL TRIAL
ABBREVIATED INCLUSION CRITERIA

1. 18 to 70 years of age
2. Severe, irreversible biventricular heart failure (HF) or has univentricular HF for which LVAD support is not recommended.

   ISHLT Guidelines for Biventricular Support

   A. Biventricular failure with ***at least 2*** of the following:

- RVEF ≤ 30%
- RVSWI ≤ 0.25
- TAPSE ≤ 14mm
- RV to LVEDD > 0.72
- CVP > 15
- PAPi <2
- Grade 4 TR
- CVP/PCWP > 0.63

   B. Refractory untreatable, recurrent & sustained VTACH or VFIB

   C. HF due to restrictive or constrictive physiology
3. Intermacs 2 or 3
4. NYHA IV
5. LVEF ≤ 25%
6. Inotrope dependent or has CI ≤ 2.2 without inotropes and meets ***one*** of the following criteria:

   A. Failure to respond to or not tolerating OMM

   B. HF for ≥ 14 days and is dependent on temporary MCS for ≥ 7 days

   C. HF due to restrictive or constrictive physiology
7. Patient is eligible for cardiac transplantation.

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(148) - Initial Clinical Experience with the BiVACOR Total Artificial Heart

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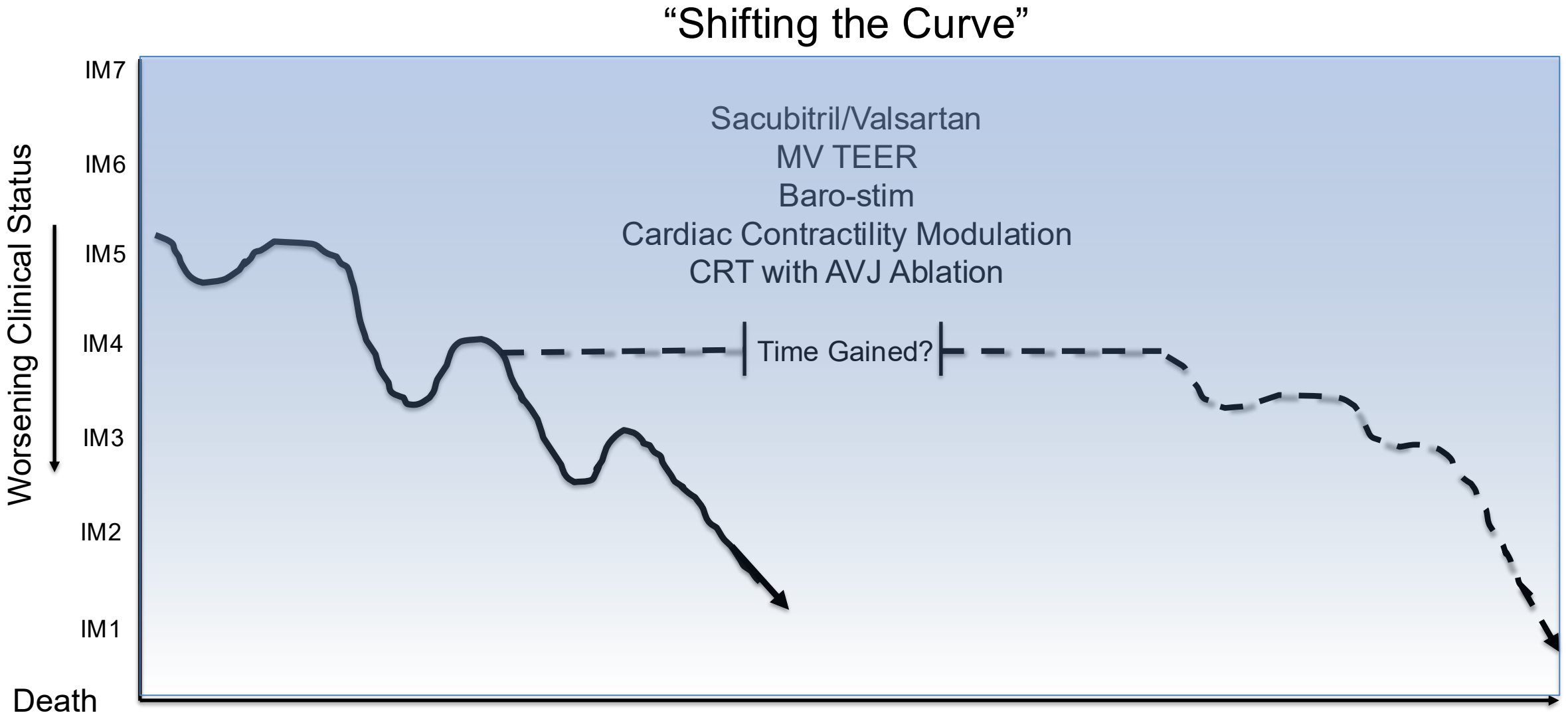
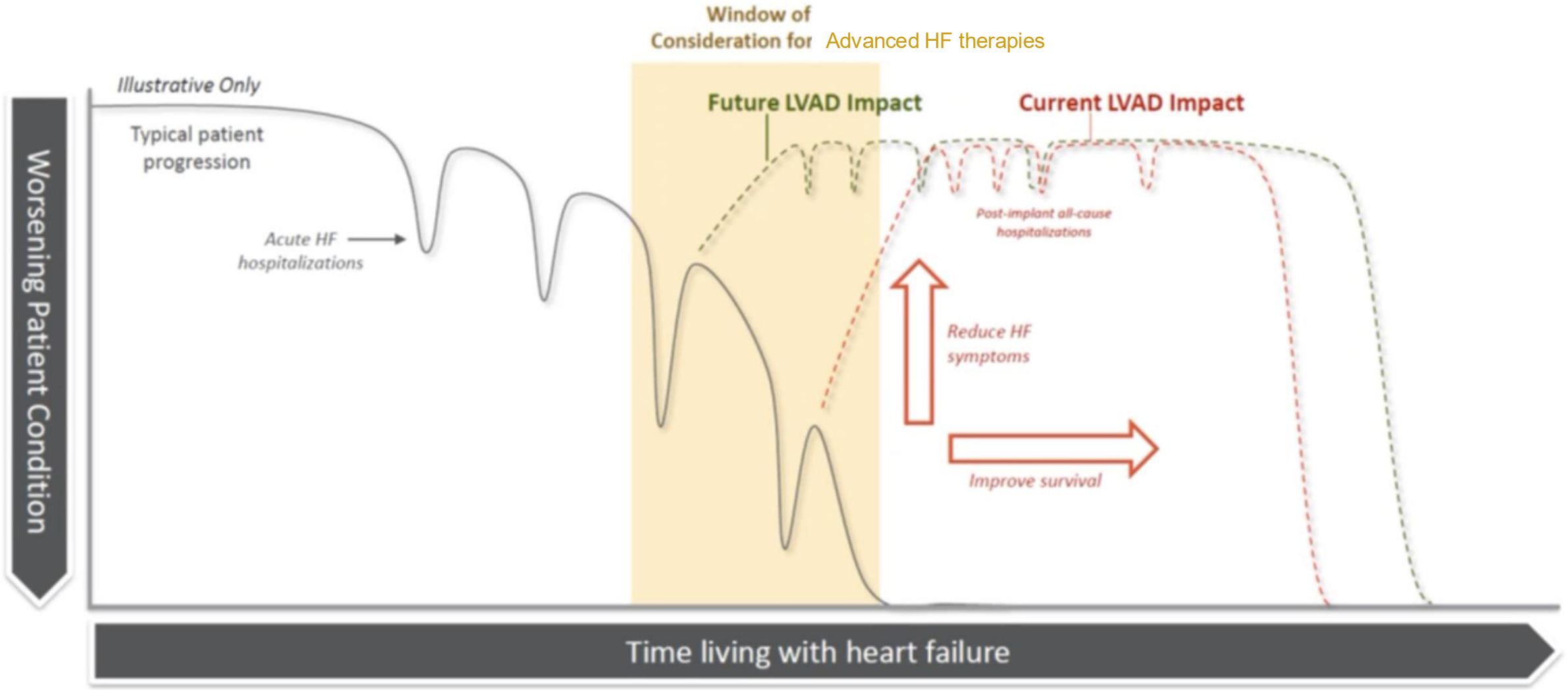
CAN WE CHANGE THE TRAJECTORY & FOR HOW LONG?



SHOULD PATIENTS RECEIVE LVADS BEFORE DETERIORATION?



TEAM HF TRIAL

Inclusion Criteria

Patients must have **ambulatory advanced HFrEF but not yet inotrope-dependent**.

Core physiologic criteria

- NYHA class **IIIB or IV** heart failure Abbott
- **LVEF ≤30%** Abbott
- **Cardiac index ≤2.5 L/min/m²** Abbott

Evidence of functional limitation

- **6-minute walk ≤350 m** OR
- **Peak VO_2 ≤14 mL/kg/min (or <50% predicted)** Abbott +1

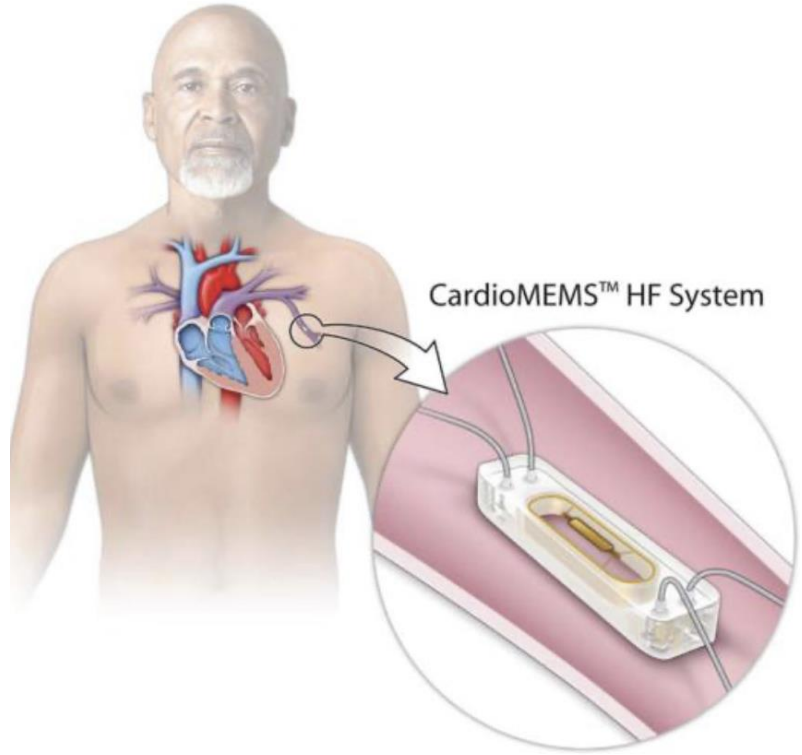
INTERMACS 4-7

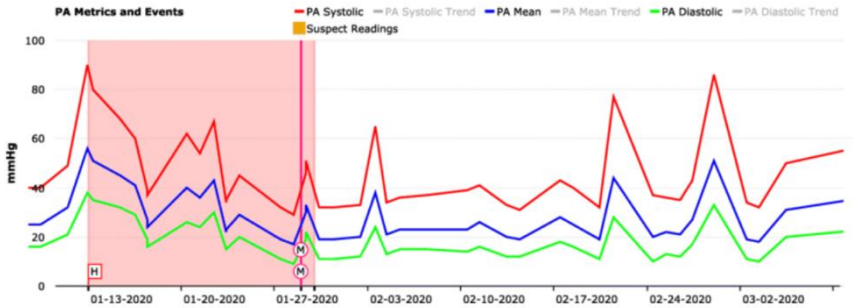
Clinical severity

- ≥1 **HF hospitalization within the past 12 months** Abbott

Hemodynamic monitoring

- Implanted **CardioMEMS PA sensor** (existing or implanted during study) Abbott +1





The Christ Hospital™ Health Network

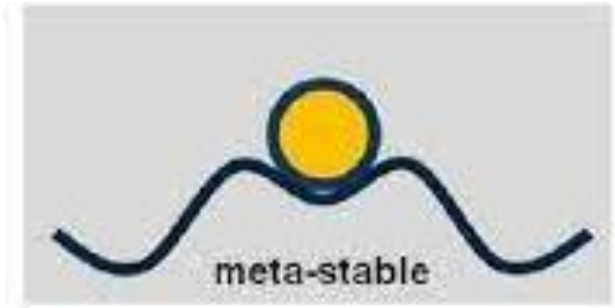
CLASS IV HEART FAILURE – A META-STABLE STATE

INTERMACS 4-7

Refer to Advanced HF Clinic

Routine CPET
RHC
ProBNP

If required inotropes or MCS to rescue how stable for how long?



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THANK YOU FOR YOUR ATTENTION