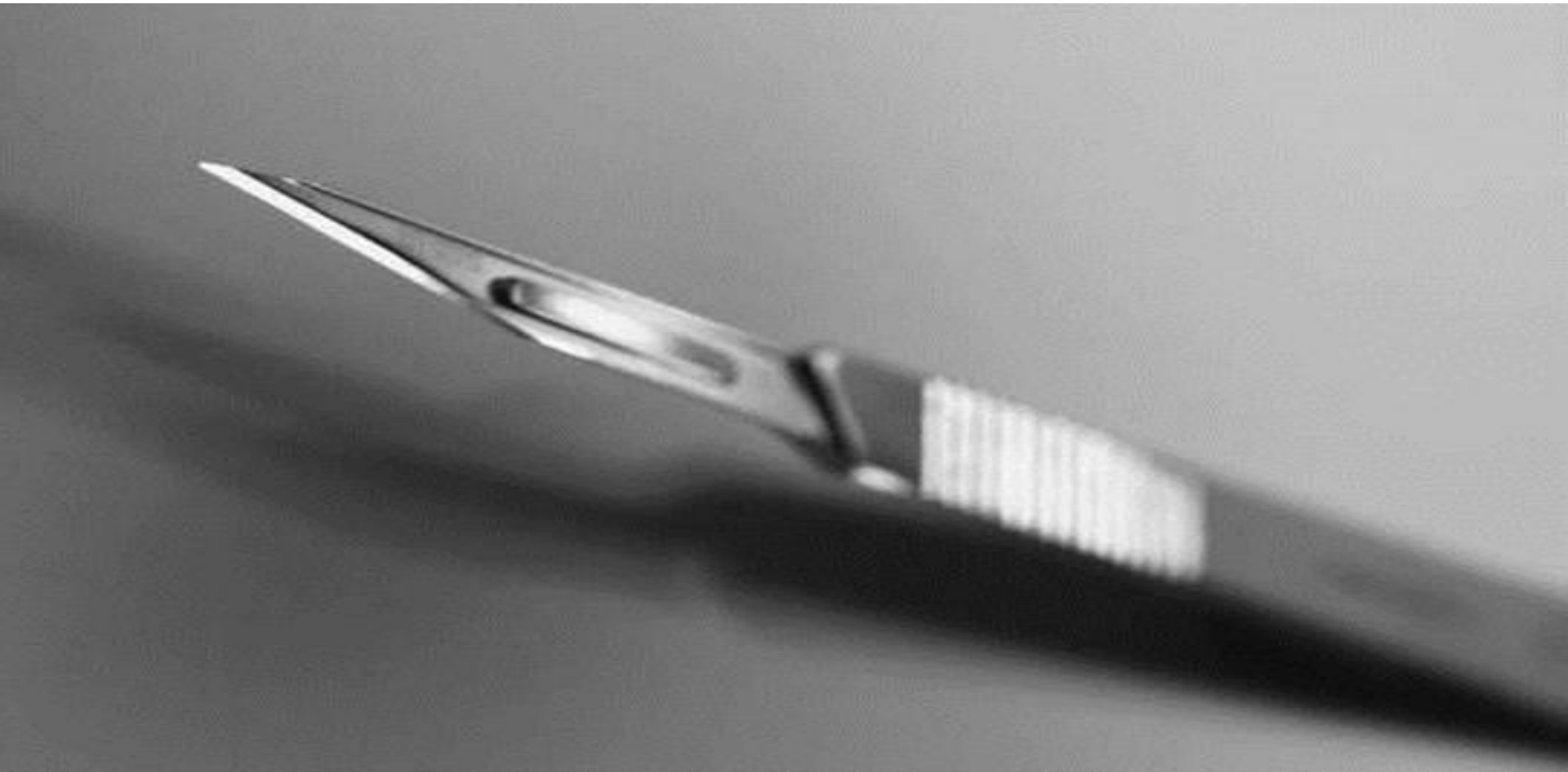


# Adverse Event Management / Prevention

ETS, Bern 2016, Vilborg Sigurdardottir



# Disclosure

PD Vilborg Sigurdardottir, MD  
University Clinic for Cardiology  
Centre for Heart Failure  
Inselspital, Berne

I have no financial relationships to disclose relevant to my presentation that create a conflict of interest.

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... from any institution

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... not related to  
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# SCORE: 3

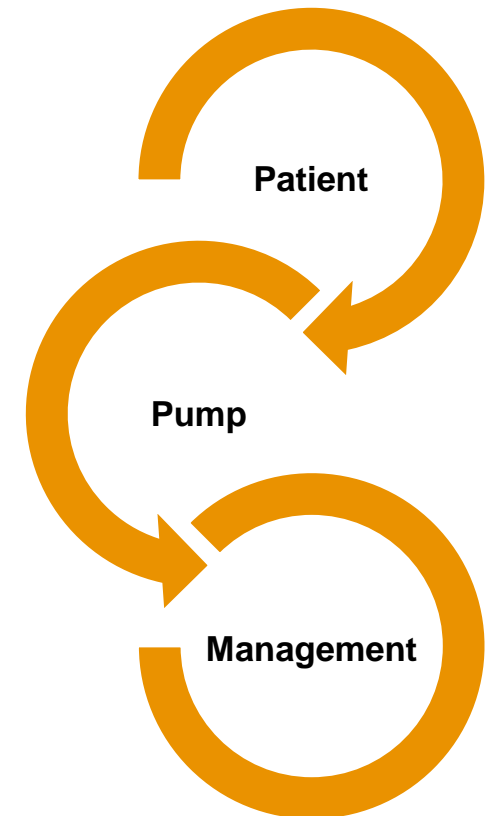
# Outlines – AE Management/ Prevention

Assessment of Disease Severity for Mechanical Circulatory Support

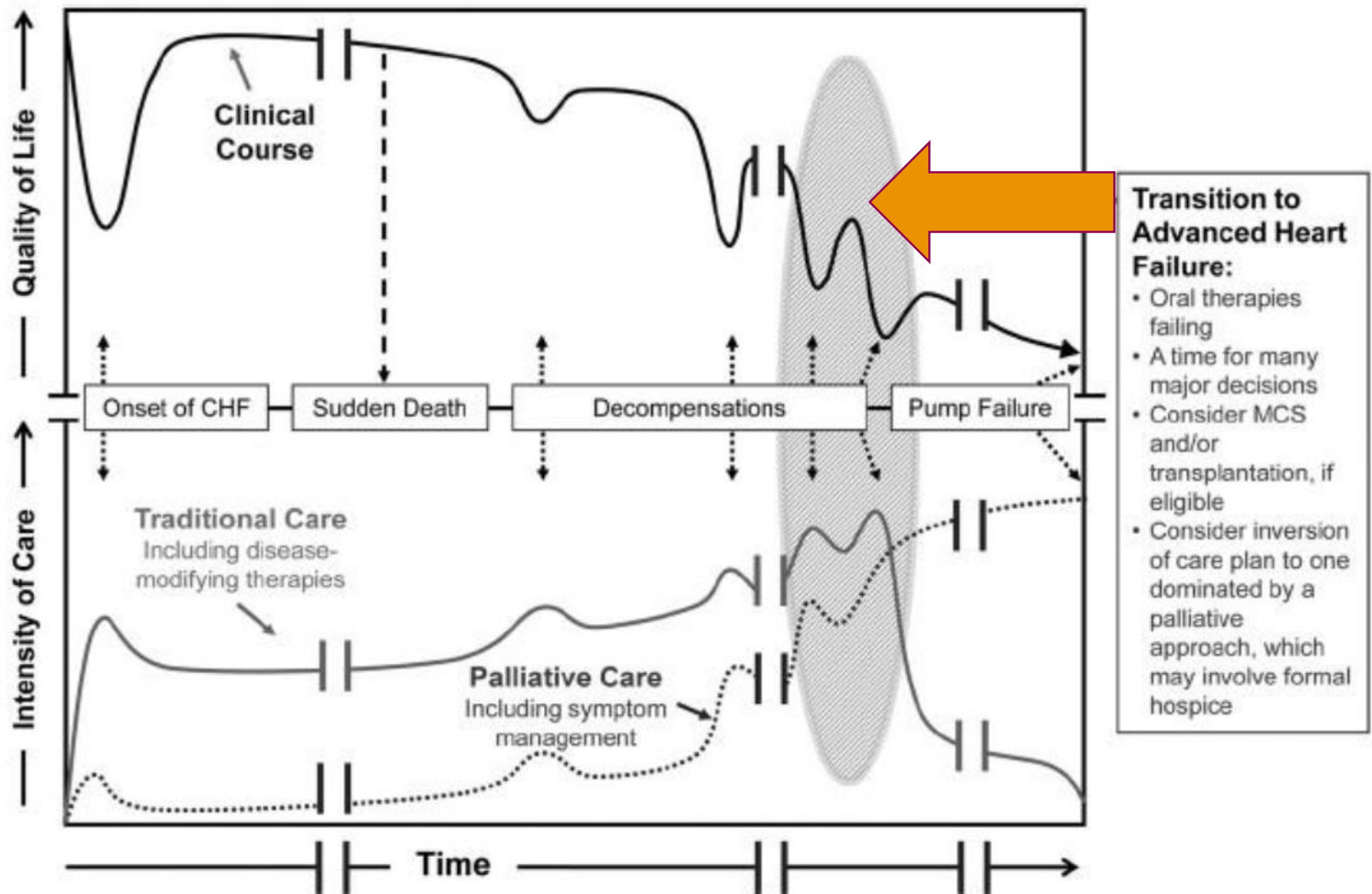
Assessment of Operative Risk

- Pre-op Optimization
- Peri - Postoperative AE

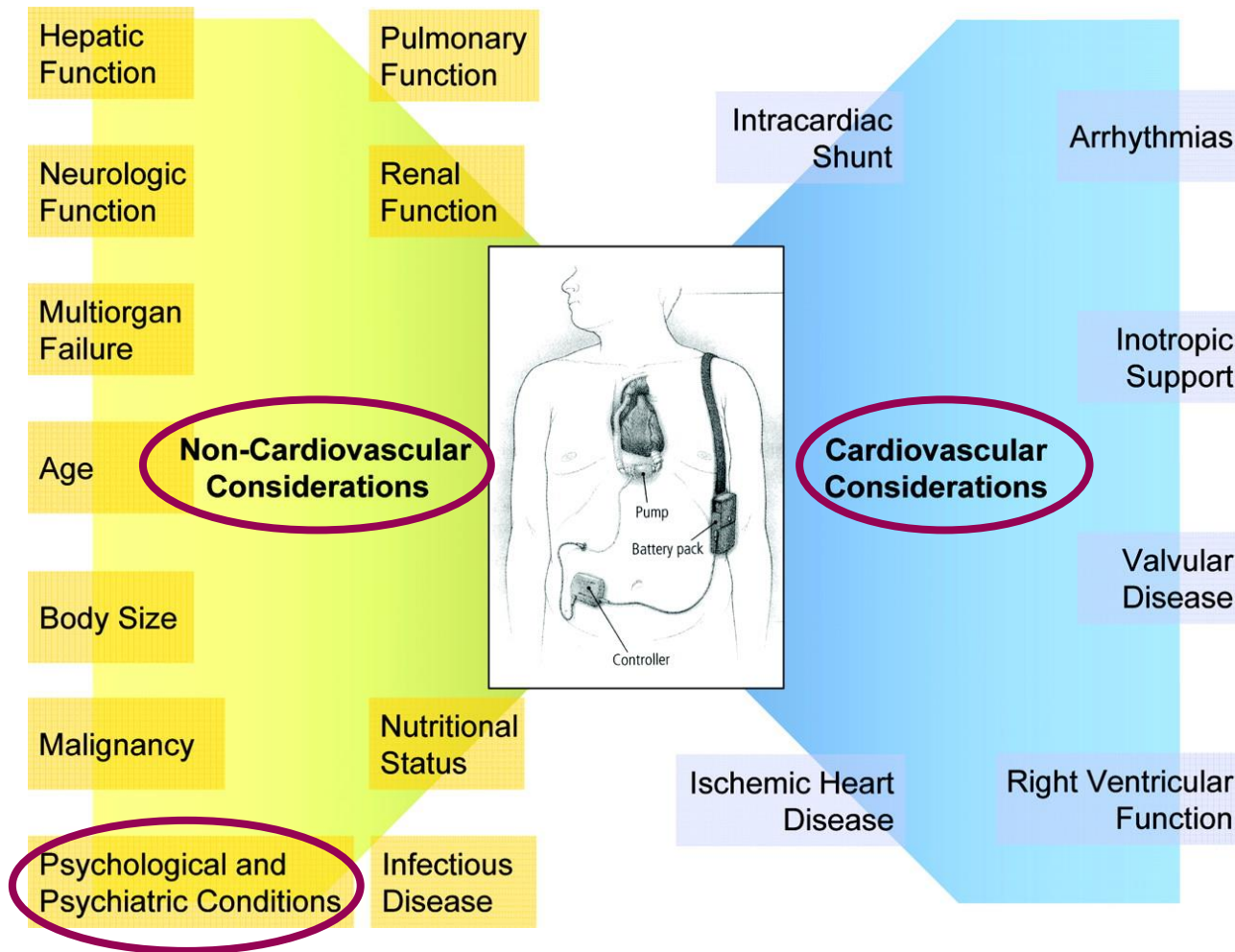
Institution related Aspects



# Clinical Course of Heart Failure



# Considerations for VAD Implant





# **2016 ESC Guidelines for the diagnosis and treatment of acute and chronic heart failure**

**The Task Force for the diagnosis and treatment of acute and chronic heart failure of the European Society of Cardiology (ESC)**

**Developed with the special contribution of the Heart Failure Association (HFA) of the ESC**

## **13. Mechanical circulatory support and heart transplantation**



# Timing for LVAD Implant

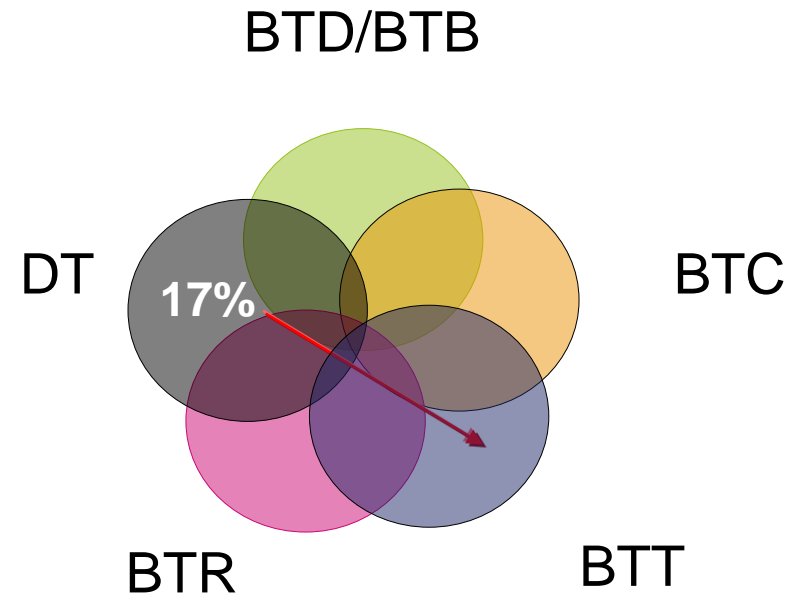
<b>Patients with &gt;2 months of severe symptoms despite optimal medical and device therapy and more than one of the following:</b>
LVEF <25% and, if measured, peak $\text{VO}_2$ <12 mL/kg/min.
$\geq 3$ HF hospitalizations in previous 12 months without an obvious precipitating cause.
Dependence on i.v. inotropic therapy.
Progressive end-organ dysfunction (worsening renal and/or hepatic function) due to reduced perfusion and not to inadequate ventricular filling pressure (PCWP $\geq 20$ mmHg and SBP $\leq 80$ –90 mmHg or CI $\leq 2$ L/min/m <sup>2</sup> ).
Absence of severe right ventricular dysfunction together with severe tricuspid regurgitation.

CI = cardiac index; HF = heart failure; i.v. = intravenous; LVEF = left ventricular ejection fraction; PCWP = pulmonary capillary wedge pressure; SBP = systolic blood pressure;  $\text{VO}_2$  = oxygen consumption.



# What is the Plan?

<b>Bridge to decision (BTD)/ Bridge to bridge (BTB)</b>	Use of short-term MCS (e.g. ECLS or ECMO) in patients with cardiogenic shock until haemodynamics and end-organ perfusion are stabilized, contra-indications for long-term MCS are excluded (brain damage after resuscitation) and additional therapeutic options including long-term VAD therapy or heart transplant can be evaluated.
<b>Bridge to candidacy (BTC)</b>	Use of MCS (usually LVAD) to improve end-organ function in order to make an ineligible patient eligible for heart transplantation.
<b>Bridge to transplantation (BTT)</b>	Use of MCS (LVAD or BiVAD) to keep patient alive who is otherwise at high risk of death before transplantation until a donor organ becomes available.
<b>Bridge to recovery (BTR)</b>	Use of MCS (typically LVAD) to keep patient alive until cardiac function recovers sufficiently to remove MCS.
<b>Destination therapy (DT)</b>	Long-term use of MCS (LVAD) as an alternative to transplantation in patients with end-stage HF ineligible for transplantation or long-term waiting for heart transplantation.

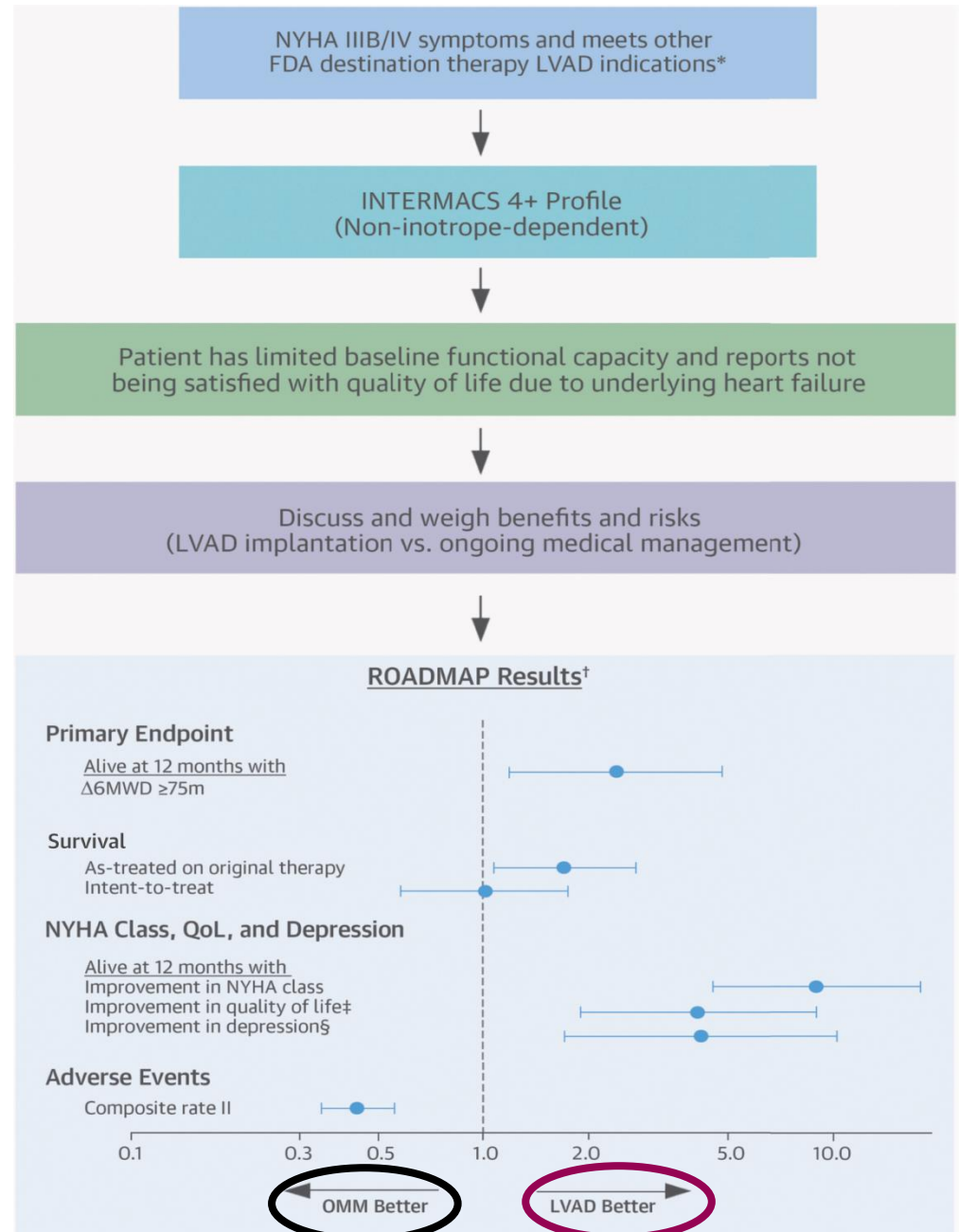


BiVAD = biventricular assist device; BTB = bridge to bridge; BTC = bridge to candidacy; BTD = bridge to decision; BTR = bridge to recovery; BTT = bridge to transplantation; DT = destination therapy; ECLS = extracorporeal life support; ECMO = extracorporeal membrane oxygenation; HF = heart failure; LVAD = left ventricular assist device; MCS = mechanical circulatory support; VAD = ventricular assist device.

# ROADMAP

## Optimal Medical Management vs LVAD Therapy

Inclusion criteria:  
≥1 hospitalization for HF in the  
last 12m and 6MWD <300 m



Estep, J.D. et al. J Am Coll Cardiol. 2015; 66(16):1747-61.

Estep JD et.al. JACC 2015;66;16 10

# Assessment of Operative Risk for VAD Implant

# Assessments of Risk

## Outpatient Setting

- Assessment of maximal oxygen consumption (Peak  $\text{VO}_2$ )
- Seattle Heart Failure Score
- Heart Failure Survival Score

## Inpatient Setting

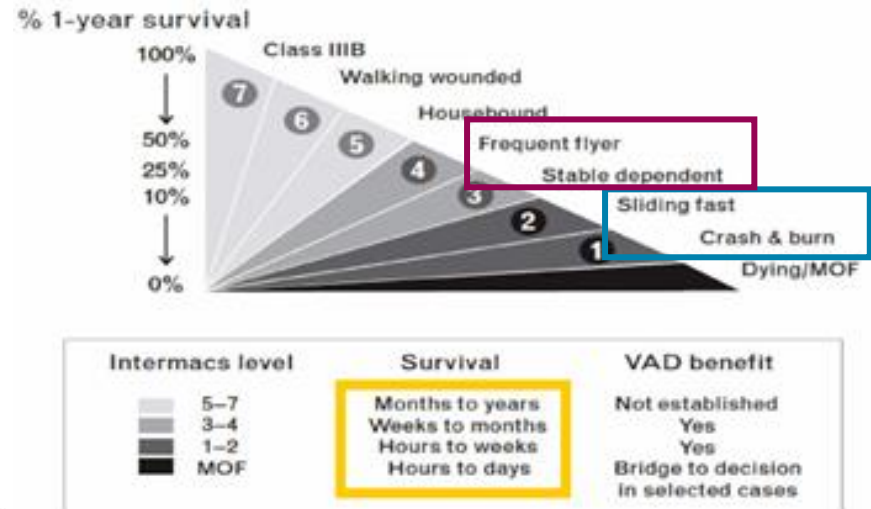
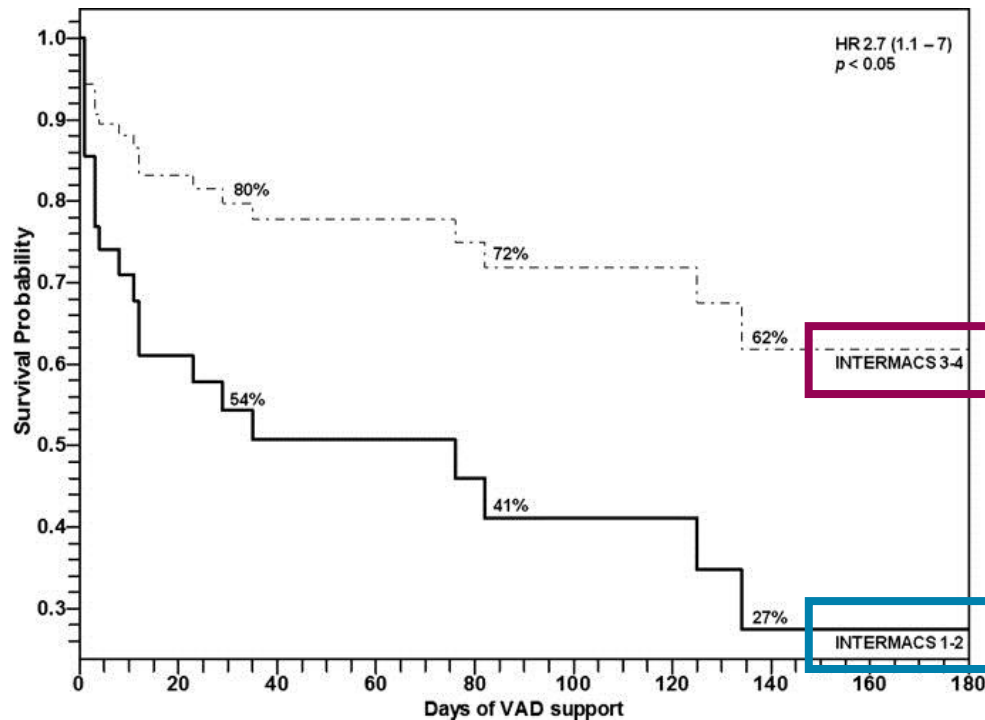
- ADHERE CART Analysis (BUN, SBP, Creatinine)
- SOFA - Complex
- INTERMACS Score
- SAVE

ISHLT GUIDELINES

# **The 2013 International Society for Heart and Lung Transplantation Guidelines for mechanical circulatory support: Executive summary**

*Co-chairs:* David Feldman, MD, PhD;\* Salpy V. Pamboukian, MD, MSPH;\*  
Jeffrey J. Teuteberg, MD;\*

# INTERMACS Scale to Predict Outcome after VAD implantation



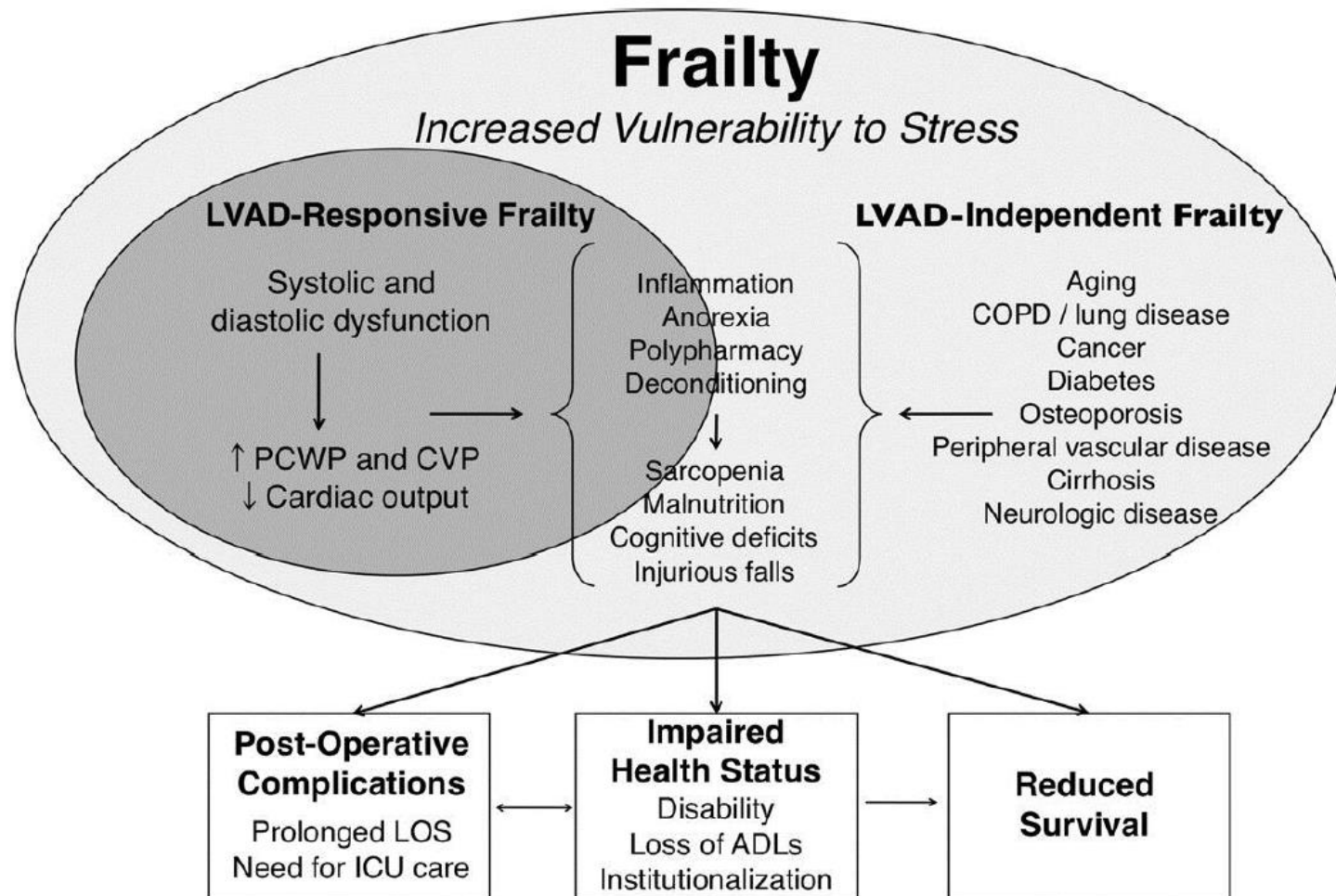
Alba AC et.al. JHLT 2009:288;8

# Frailty and the Selection of Patients for Destination Therapy Left Ventricular Assist Device

*Circ Heart Failure* 2012; 5:286

Kelsey M. Flint, MD; Daniel D. Matlock, MD, MPH; JoAnn Lindenfeld, MD; Larry A. Allen, MD, MHS

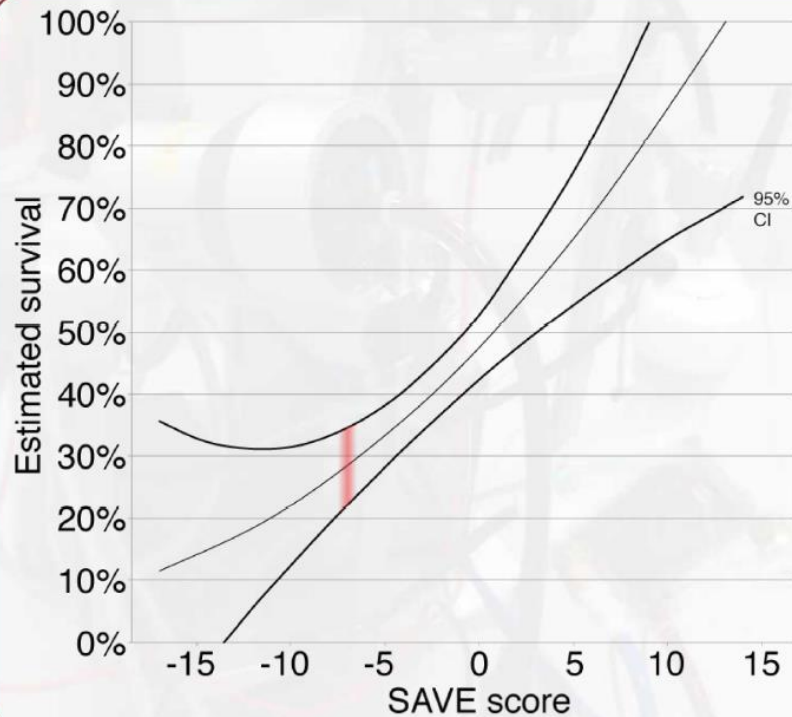
A





# SAVE

Survival After Veno-arterial ECMO



## Diagnosis:

Myocarditis  
Refractory VT/VF  
Post heart or lung transplantation  
Congenital heart disease  
Other diagnoses

☐ NO  
☐ NO  
☐ NO  
☐ NO  
☒ YES

## Age (years):

18-38 ☐  
39-52 ☐  
53-62 ☒  
≥63 ☐

## Weight (kg):

<65 ☒  
65-89 ☐  
≥90 ☐

## Cardiac:

Pulse pressure pre ECMO ≤20 mmHg

☒ YES

Diastolic BP pre ECMO ≥40 mmHg

☐ NO

Pre-ECMO cardiac arrest

☐ NO

## Respiratory:

Peak inspiratory pressure ≤20 cmH<sub>2</sub>O

☒ YES

Intubation duration pre ECMO (hrs)

≤10 ☒  
11-29 ☐  
≥30 ☐

## Renal:

Acute renal failure

☒ YES

Chronic renal failure

☐ NO

HCO<sub>3</sub> pre ECMO ≤15 mmol/L

☐ NO

## Other organ failures pre ECMO:

Central nervous system dysfunction

☐ NO

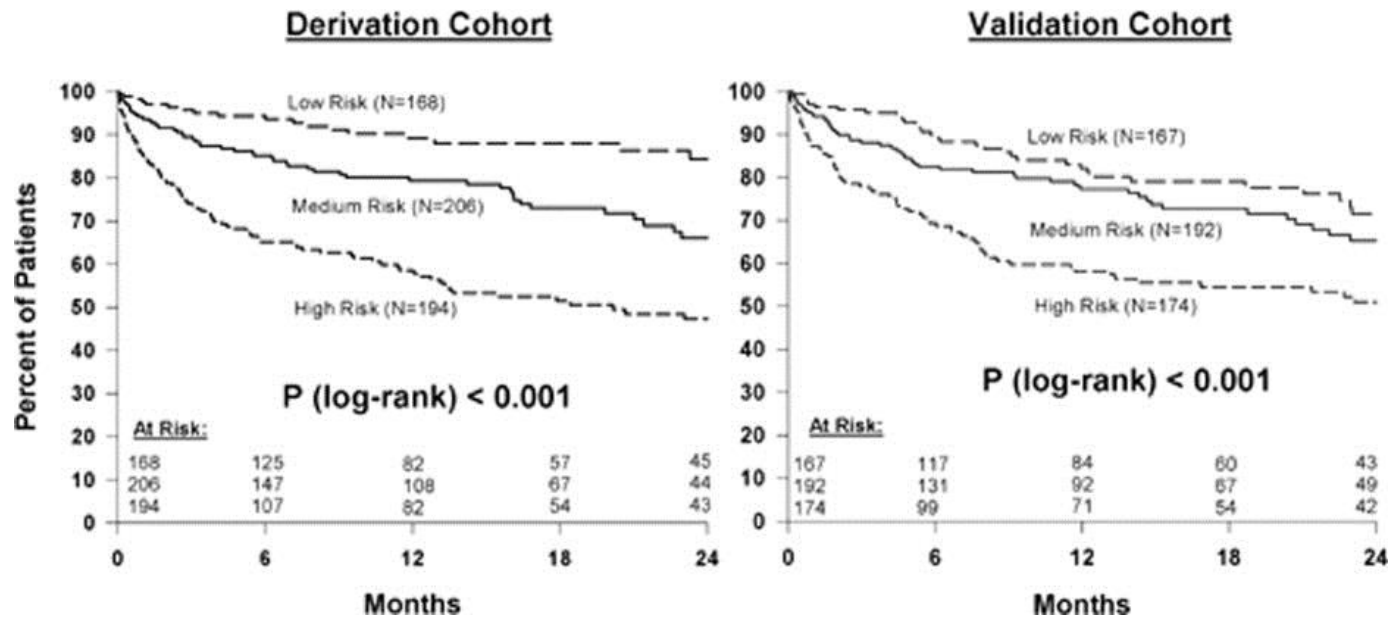
Liver failure

☒ YES

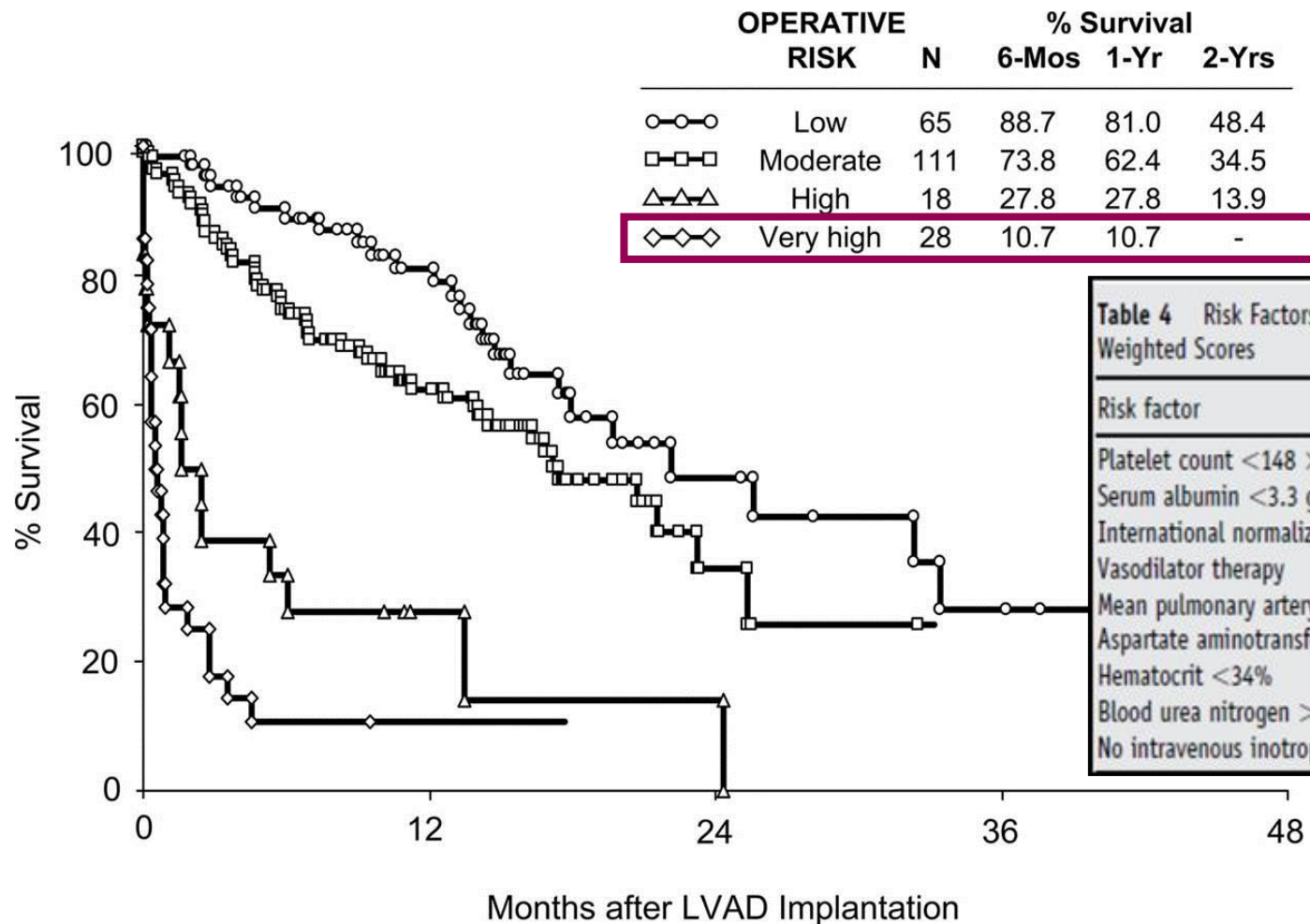
# HeartMate II Risk Score

Preoperative predictors of mortality in candidates for LVAD

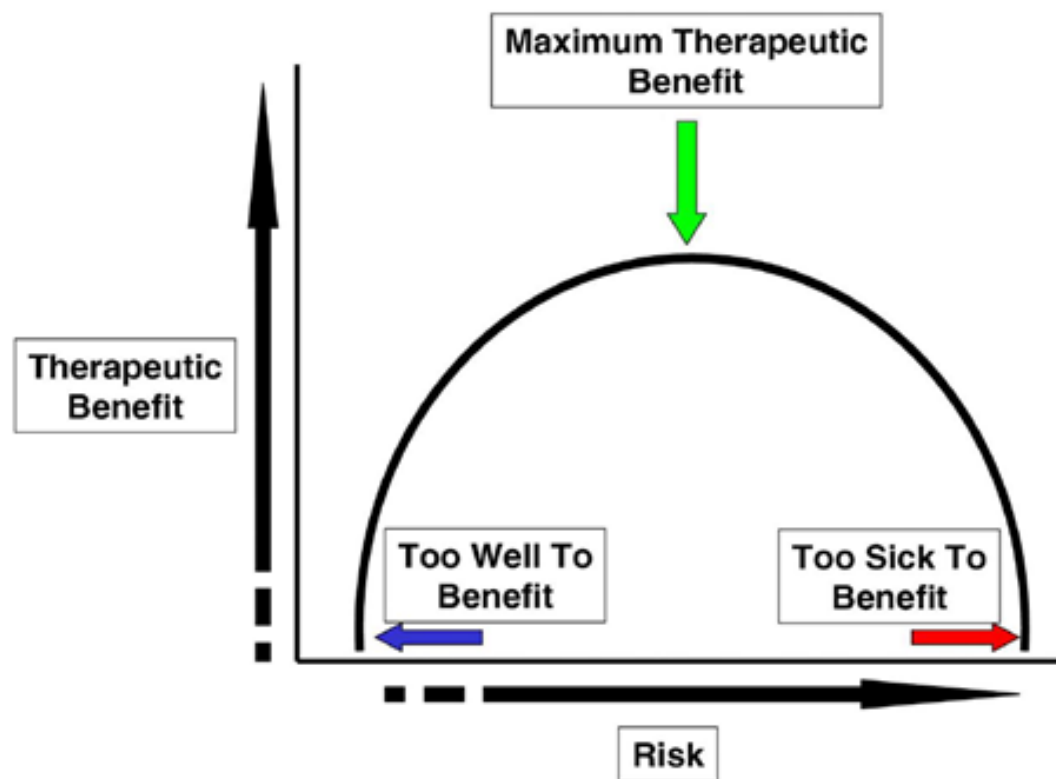
- Age, albumin, se-creatinine, INR, implant after 2007 and implant center experience  $\geq 15$



# HeartMate XVE, DT Risk Score: It might be Too Late!

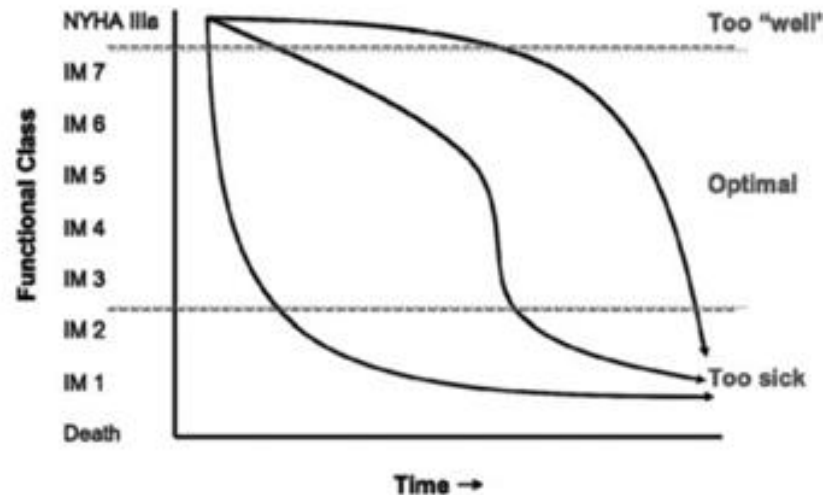


# Principle of Risk Assessment: the Ideal



# Risk Assessment in Reality

- Even small changes in patient condition can affect the balance
- Re-assess your strategy!



# Peri - Postoperative AE

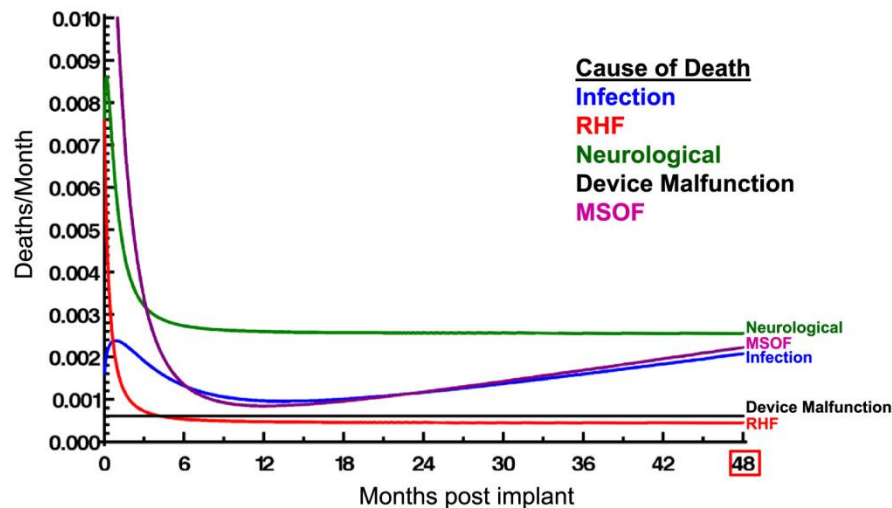
# Adverse Events after VAD - Implantation

**Early:** RHF, neurological, MSOF  
**Late:** Infection, Neurological, MSOF

**SAE:** Infection, Bleeding, Stroke

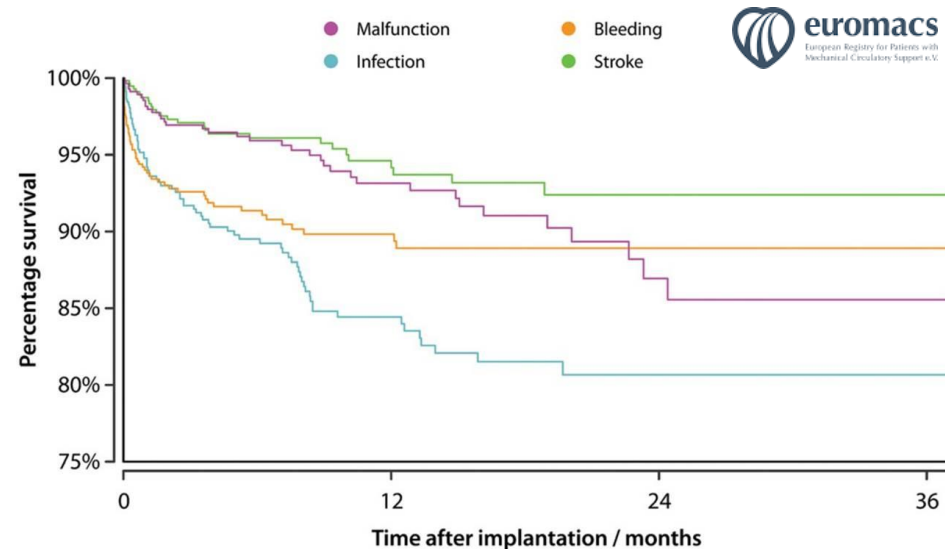
Intermacs Continuous Flow LVAD/BiVAD Implants: 2008 – 2014, n=12030

Instantaneous Death Rate (Hazard) for selected causes



MSOF, multisystem organ failure.

Continuous flow primary LVAD and BiVAD implantations for adults:  
 Freedom from major adverse events with 95% confidence intervals;  
 (n=525 LVADs and n=64 BiVADs)



euromacs  
 European Registry for Patients with  
 Mechanical Circulatory Support s.r.l.

Kirklin JHLT 2015;34

De By; EJCTS 2015;47



# Pre-operative Optimization

## Invasive Hemodynamic Monitoring

- INTERMACS 1-3, for 4-7 selective

## Aim

- Hepatic Decongestion/ Reduction in CVP
- Optimize organ perfusion, inotropes, vasodilator therapy tailored to reduce PVR, increase CO

## If unresponsive

- Possible IABP
- Possible Temporary ECMO (VAD)

# Peri-operative Management

## Intraoperative

- Multidisciplinary Management
- Individual Patient situation

## Early Post-Operative Management

- Clear strategy for this particular patient
- Who is in charge?

# Patient Education !

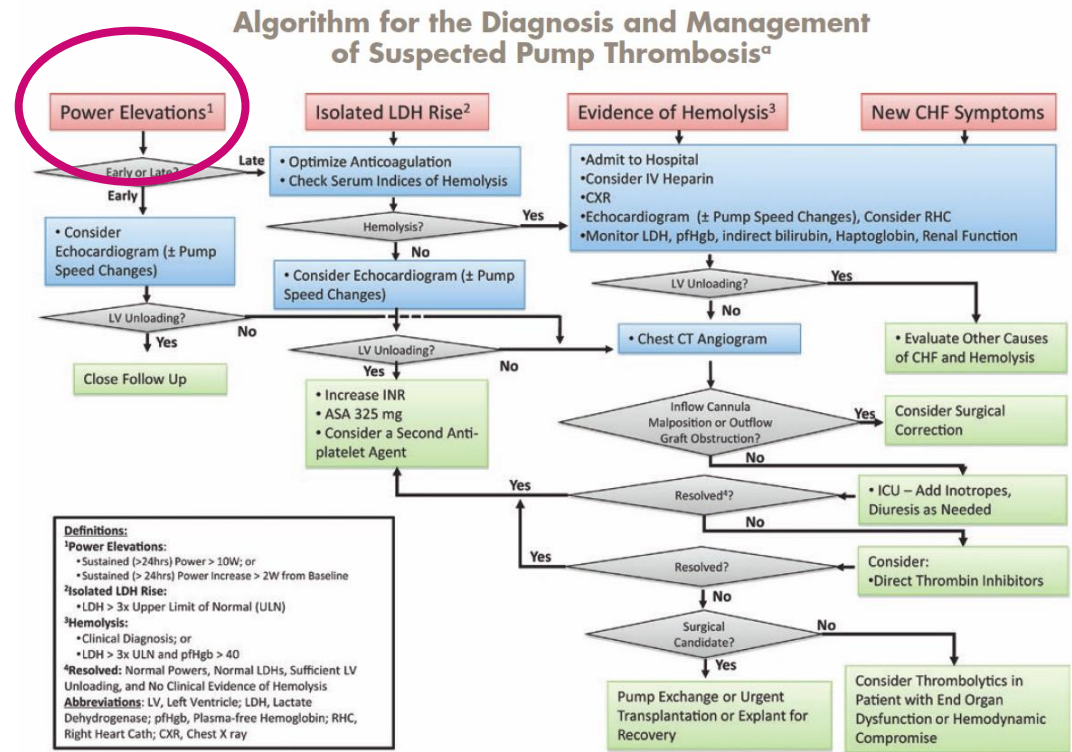
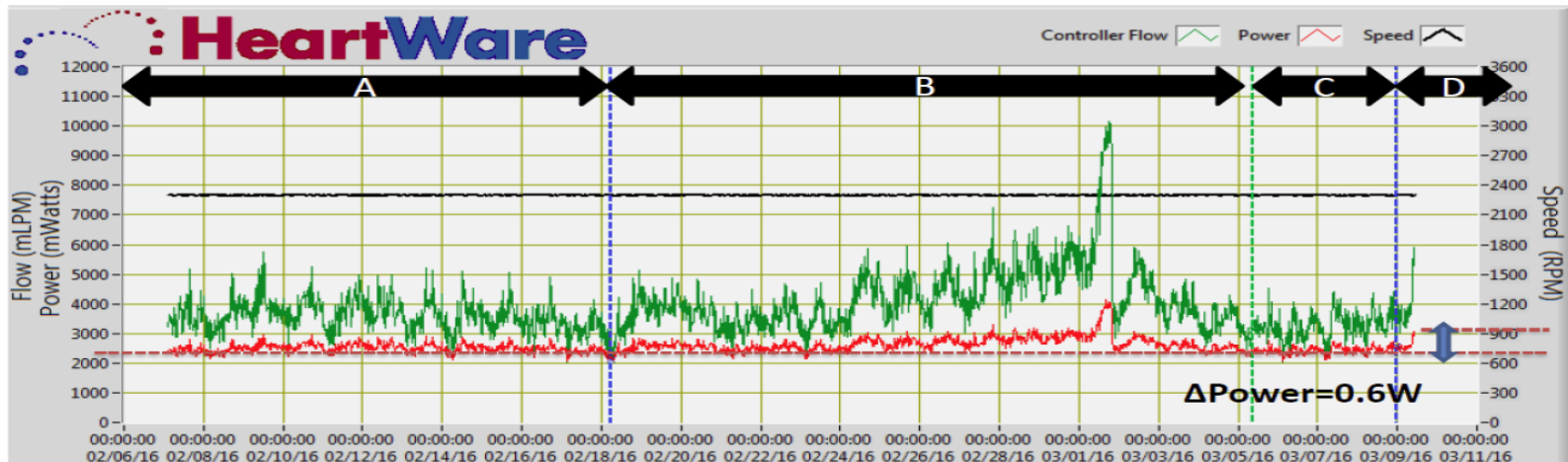


Figure 1: LVAD Trend over the last 31 days



# Institution related Aspects

# Safe?



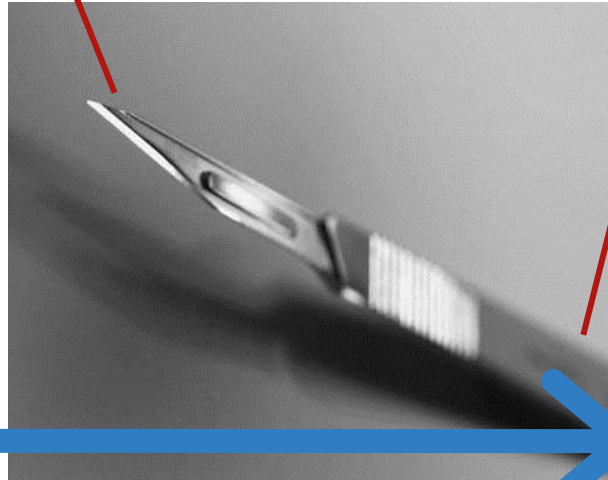
Ok, we give up! Where did you hide the patient?

# Patient safety - System Errors and Weaknesses

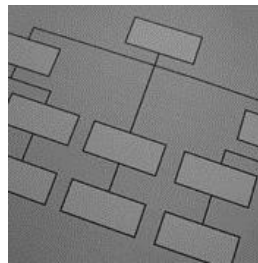
Individual



Adverse Event



Communication  
Information  
Education  
Environment  
Equipment  
Routines  
Guidelines/SOP  
Barriers  
etc.



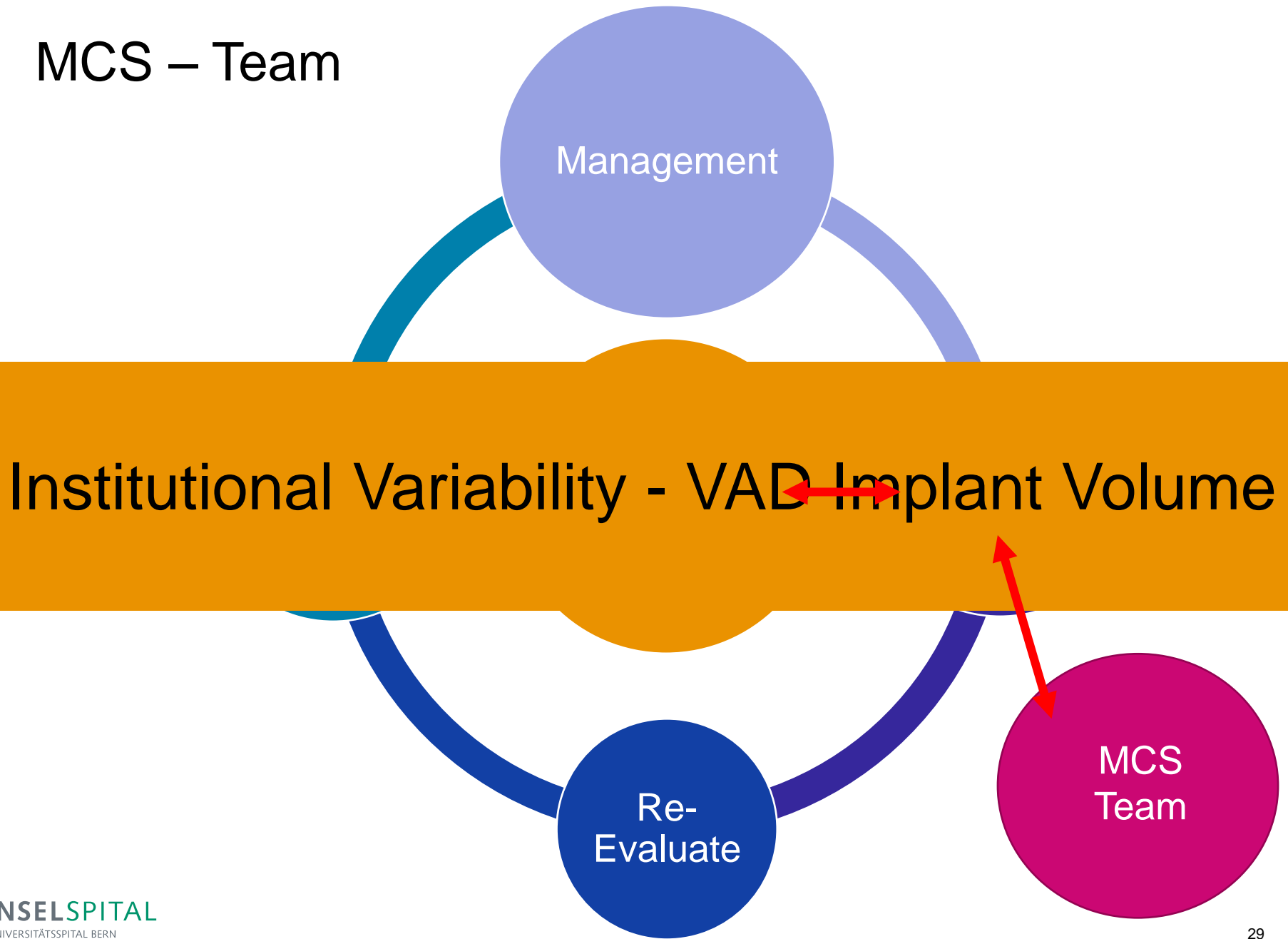
## Systemperspective

Open culture for discussions about failures

Technique

Organisation

MCS – Team



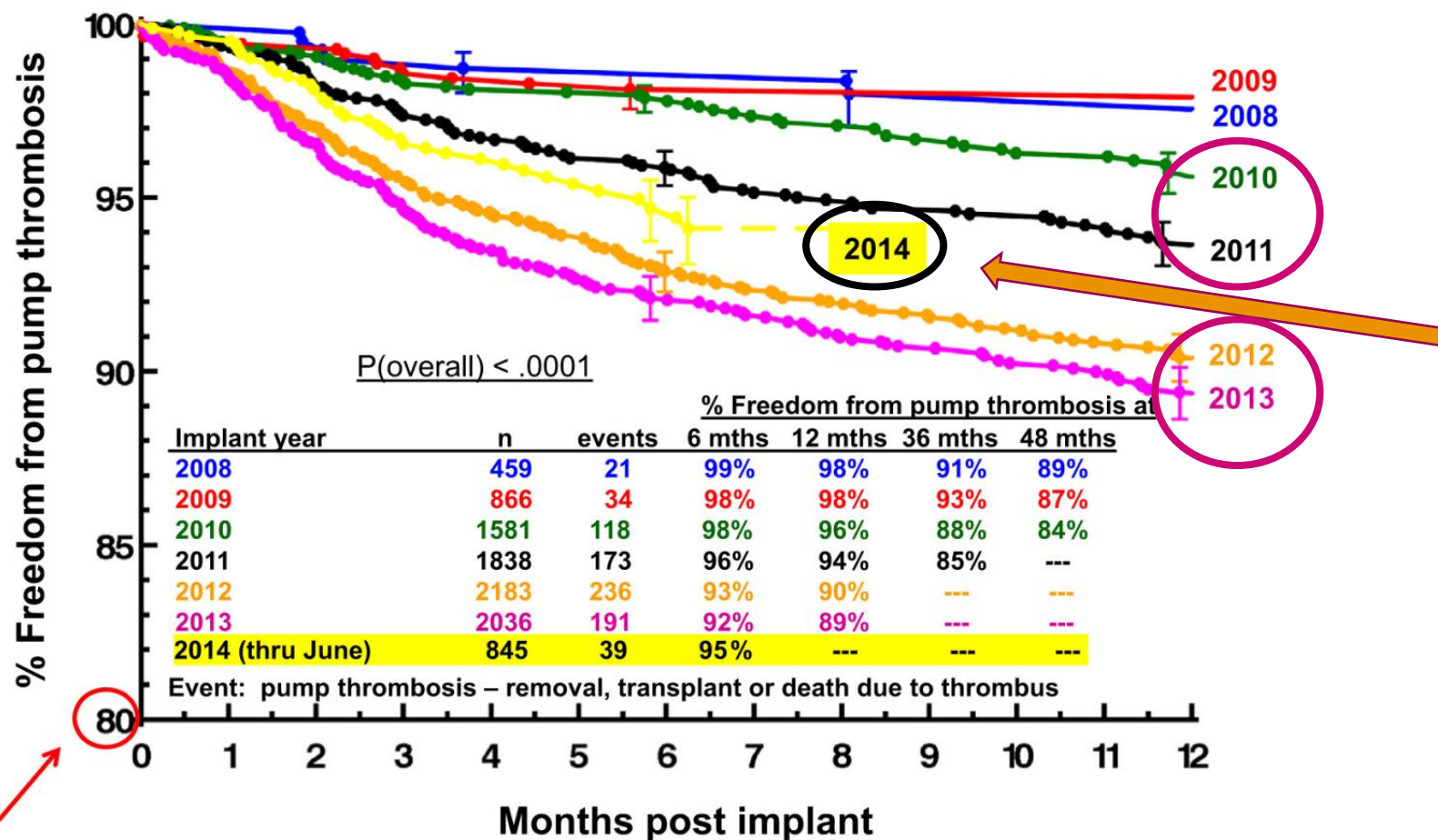


Implants: April 2008 – June 2014, n=9808

Follow-up: Thru September 2014

“Expanded Scale”

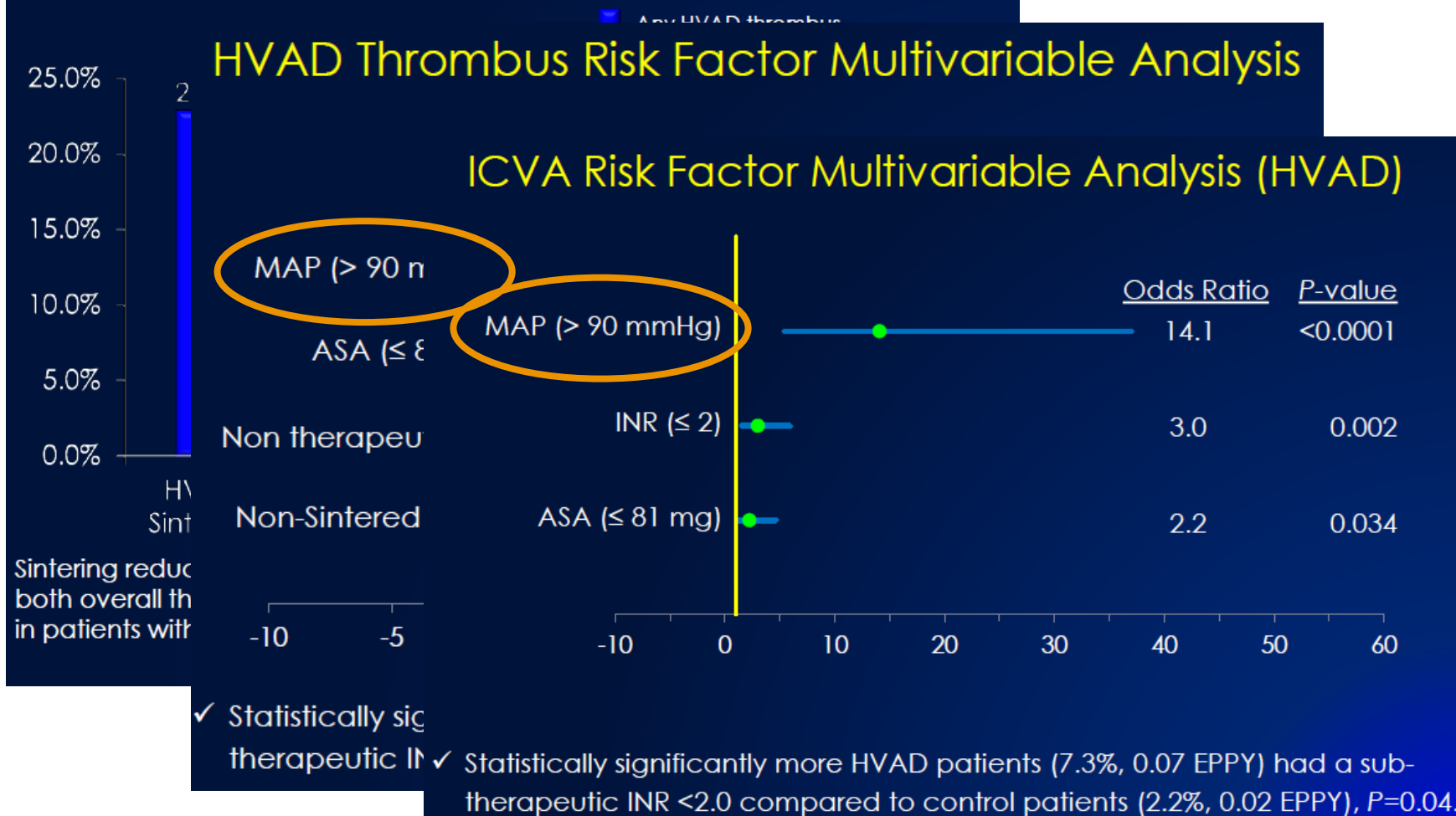
By Implant year



In 2014, freedom from pump thrombosis improved to a level approaching that in 2011

# ENDURANCE Trial

## Pump Thrombosis (2 years)



# Prevention of AE - Summary

Carefully assess Frailty in the VAD candidates

- Chronic disease with limited survival

Scores as a Forum for discussion

Emergency situations, be careful – INTERMACS 1-2 vs 3-4?

Strategy – Re-evaluation – Feedback to the MCS Team

LVAD Implantation should never be an emergency



Thank you for your attention!

Adverse Event Management / Prevention

ETS, Bern 2016, Vilborg Sigurdardottir



# Adverse Event Management / Prevention

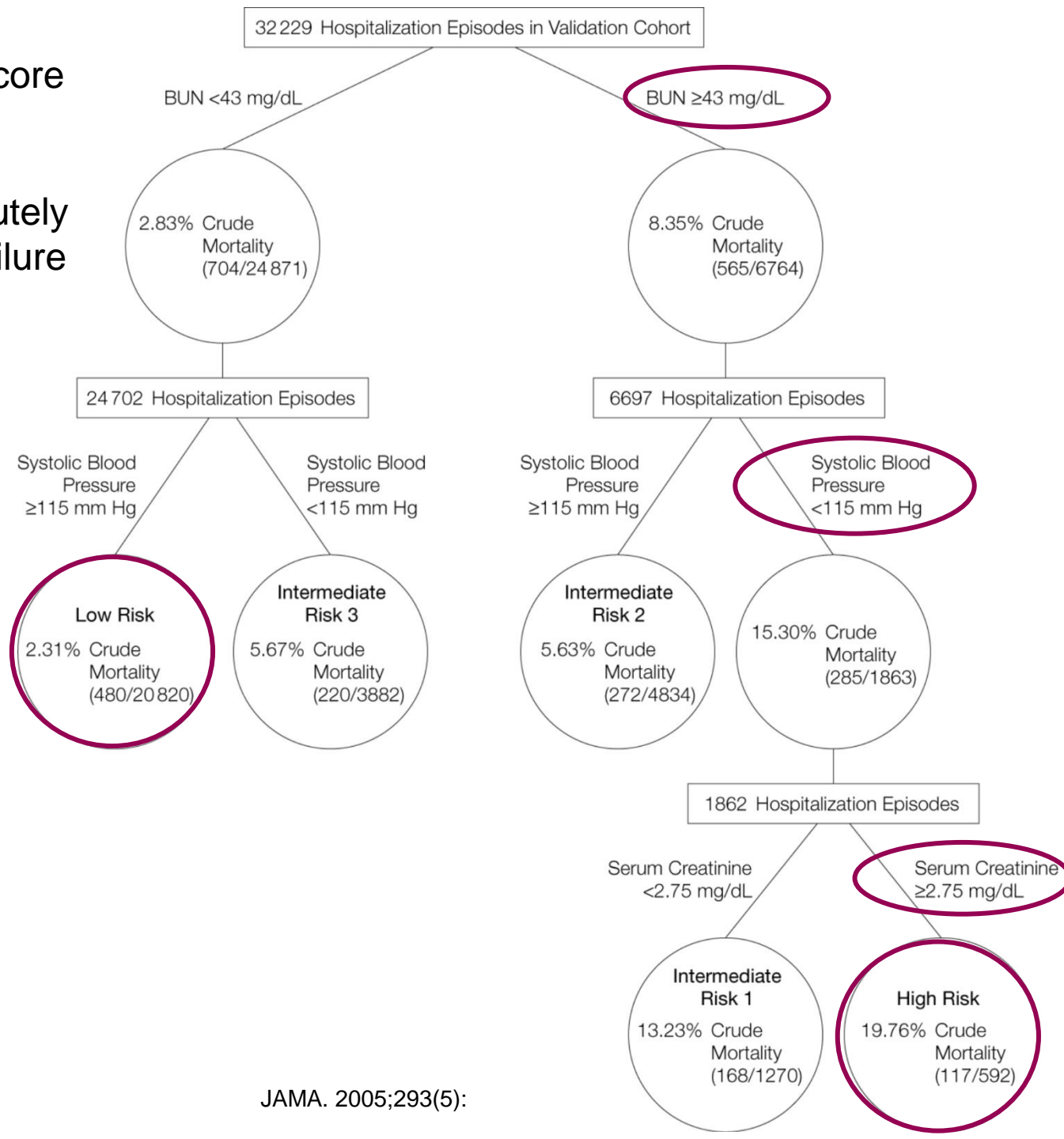
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Thank you for your attention!



# ADHERE Inhospital risk score

## Risk Stratification for In-Hospital Mortality in Acutely Decompensated Heart Failure



JAMA. 2005;293(5):

INTERMACS level	NYHA Class	Description	Device	1y survival with LVAD therapy
1. Cardiogenic shock "Crash and burn"	IV	Haemodynamic instability in spite of increasing doses of catecholamines and/or mechanical circulatory support with critical hypoperfusion of target organs (severe cardiogenic shock).	ECLS, ECMO, percutaneous support devices	52.6±5.6%
2. Progressive decline despite inotropic support "Sliding on inotropes"	IV	Intravenous inotropic support with acceptable blood pressure but rapid deterioration of renal function, nutritional state, or signs of congestion.	ECLS, ECMO, LVAD	63.1±3.1%
3. Stable but inotrope dependent "Dependent stability"	IV	Haemodynamic stability with low or intermediate doses of inotropics, but necessary due to hypotension, worsening of symptoms, or progressive renal failure.	LVAD	78.4±2.5%
4. Resting symptoms "Frequent flyer"	IV ambulatory	Temporary cessation of inotropic treatment is possible, but patient presents with frequent symptom recurrences and typically with fluid overload.	LVAD	78.7±3.0%
5. Exertion intolerant "Housebound"	IV ambulatory	Complete cessation of physical activity, stable at rest, but frequently with moderate fluid retention and some level of renal dysfunction.	LVAD	93.0±3.9% <sup>a</sup>
6. Exertion limited "Walking wounded"	III	Minor limitation on physical activity and absence of congestion while at rest. Easily fatigued by light activity.	LVAD / Discuss LVAD as option	-
7. "Placeholder"	III	Patient in NYHA Class III with no current or recent unstable fluid balance.	Discuss LVAD as option	-

ECLS = extracorporeal life support; ECMO = extracorporeal membrane oxygenation; INTERMACS = Interagency Registry for Mechanically Assisted Circulatory Support; LVAD = left ventricular assist device; NYHA = New York Heart Association.

<sup>a</sup>Kaplan-Meier estimates with standard error of the mean for 1 year survival with LVAD therapy. Patients were censored at time of last contact, recovery or heart transplantation. Due to small numbers outcomes for INTERMACS levels 5, 6, 7 were combined<sup>610</sup>.

Patients with active infection, severe renal, pulmonary or hepatic dysfunction or uncertain neurological status after cardiac arrest or due to cardiogenic shock are not usually candidates for BTT or DT but may be candidates for BTC



# Heart Failure Survival Score (HFSS)

Event free survival rates at 1 year

- Peak  $\text{VO}_2$
- LVEF%
- Se-sodium
- QRS interval  $\geq 120$  msec
- Coronary artery disease
- MAP
- Heart rate

