state of the art in
# ADVANCED HEART FAILURE
CLINICAL PRACTICE AND ORGANIZATIONAL MODELS

## SESION III: COMPLEX SURGERY AND SHORT-TERM MECHANICAL CIRCULATORY SUPPORT (MCS)

Cardiogenic shock in patient suitable for MCS or HT. Protocol in Galicia

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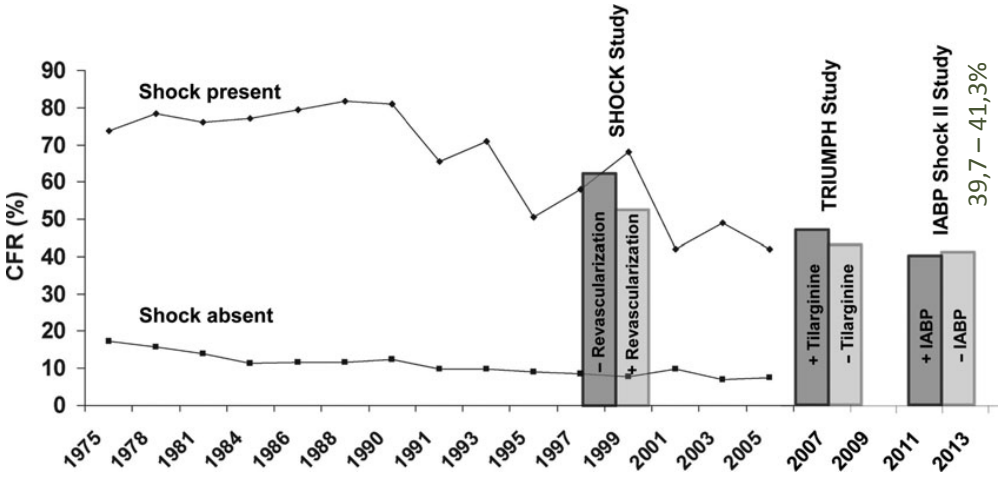
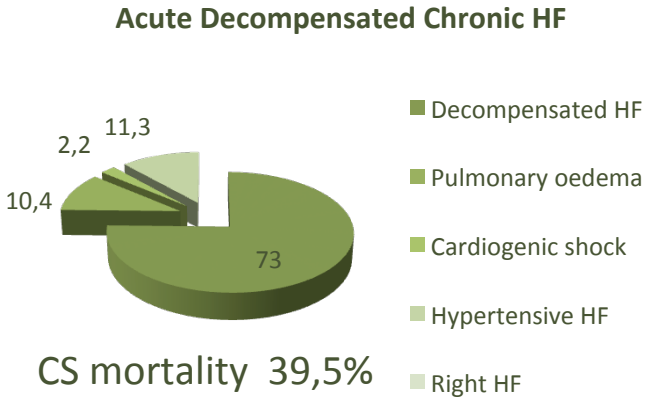
# Motivation:

## High mortality of Cardiogenic Shock: CS remains the most common cause of death in patients with AMI or ADHF




Trends in Mortality of CS in Acute Myocardial Infarction

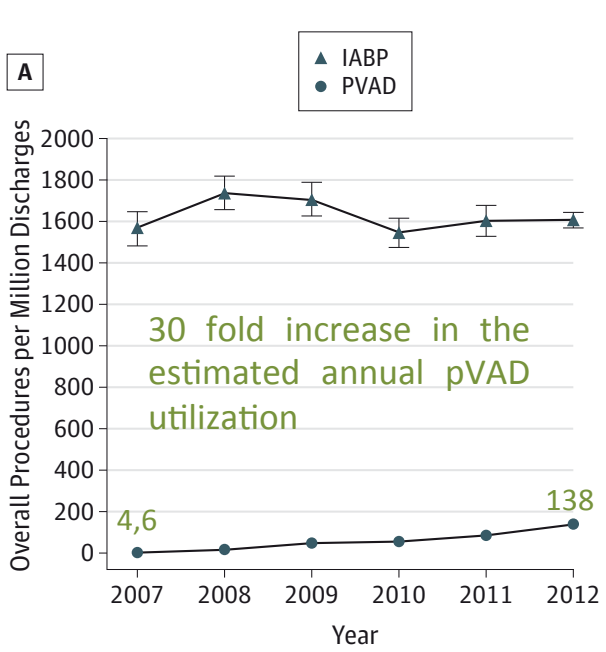


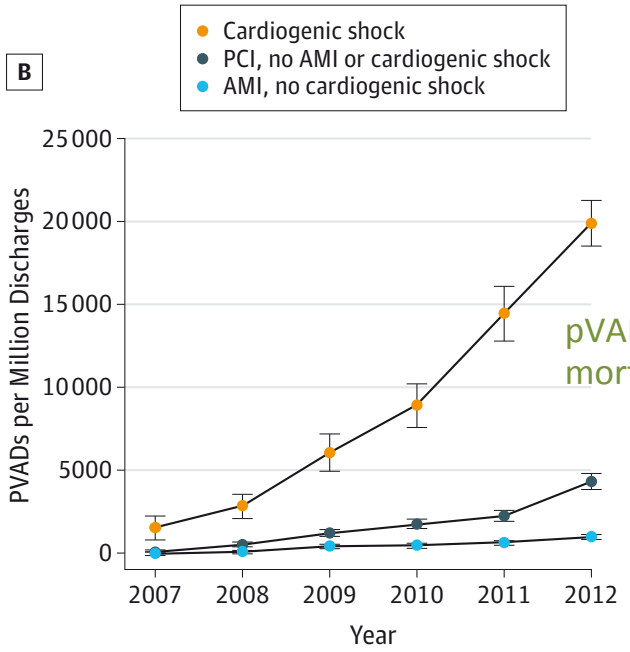

CS mortality 39,5%

Werdan et al. Eur Heart J. 2014;35:156-167
Nieminen et al. EurHeart J 2006;27:2725-2736

# Motivation:

**pVADs are increasingly used in patients with CS. Lack of clear guidelines on Indications, device selection and cost-efective care**



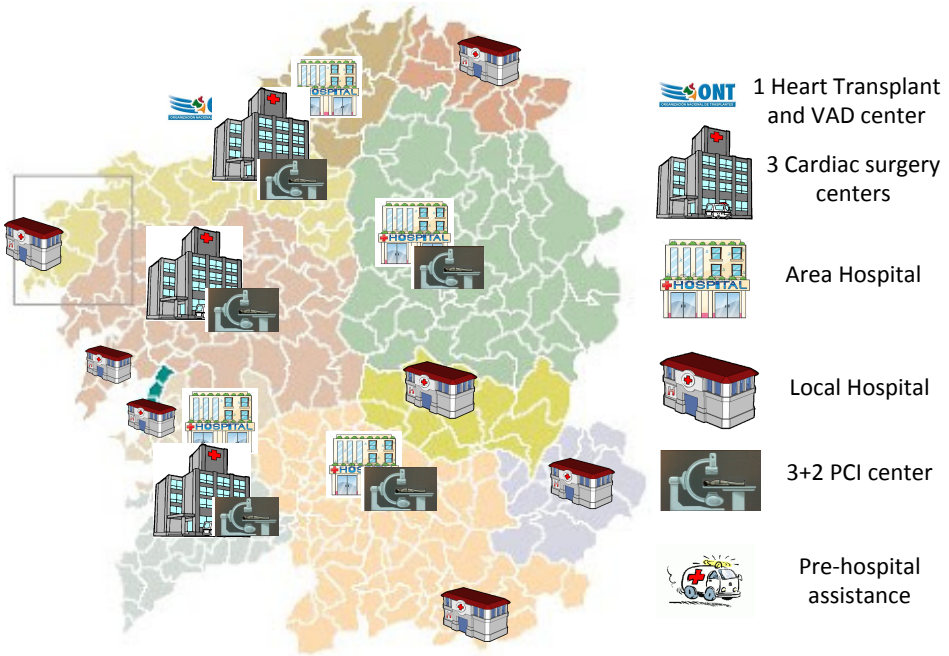




pVAD recipients with CS mortality 47,5%

Khera et al. JAMA Intern Med 2015;175(6):941-950

# Motivation:

## SERGAS Clinical Organizational Structure




## Heart Team:

**healthcare providers have to cooperate to improve survival of CS**

# Motivation:

**The goal of this document is to provide some recomendations on management of CS and ADHF for potential heart transplant or durable VADs recipients in Galician Region**

# Applicability:

**Patients in Cardiogenic Shock: "a state of critical end-organ hypoperfusion due to reduced cardiac output"**

**Systolic BP <90 mmHg for > 30 min or vasopressors required to achieve a BP ≥90 mmHg;**
**Pulmonary congestion or elevated left-ventricular filling pressures;**
**Signs of impaired organ perfusion :**
- **(a) altered mental status;**
- **(b) cold, clammy skin;**
- **(c) oliguria;**
- **(d) increased serum-lactate.**

**… after ruling a reversible cause of heart failure …**

# Applicability:

## … that meet the following criteria:

- Ventricular function is deemed unrecoverable or unlikely to recover without long-term device support.
- Deemed too ill to be weaned from temporary MCS devices or inotropic support.
- Capacity for meaningful recovery of end-organ function and quality of life.
- Without irreversible end-organ damage.

# Applicability:

## ... whithout contraindications:

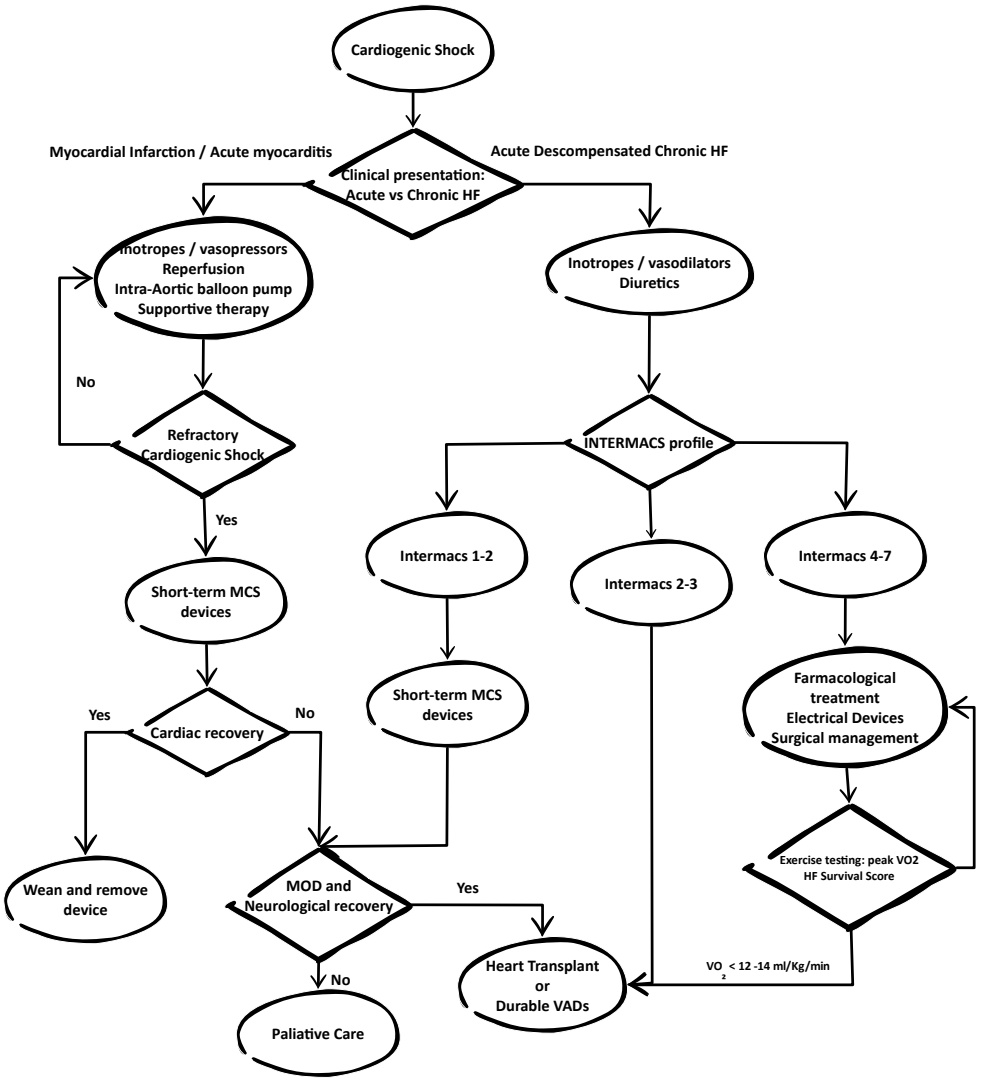
- Active infection
- Severe peripheral arterial or cerebrovascular disease
- Unhealed peptic ulcer
- Recent thrombo-embolism
- Significant renal failure (e.g. CCl < 50 mL/min)
- Systemic disease with multiorgan involvement (e.g. Diabetes Mellitus)
- Other serious co-morbidity with poor prognosis (e.g COPD)
- Treated cancer in previous 5 years
- High, fixed pulmonary vascular resistance ( >4-5 WU and mean TG > 15 mmHg)

# Structure:

## 1.- Early management

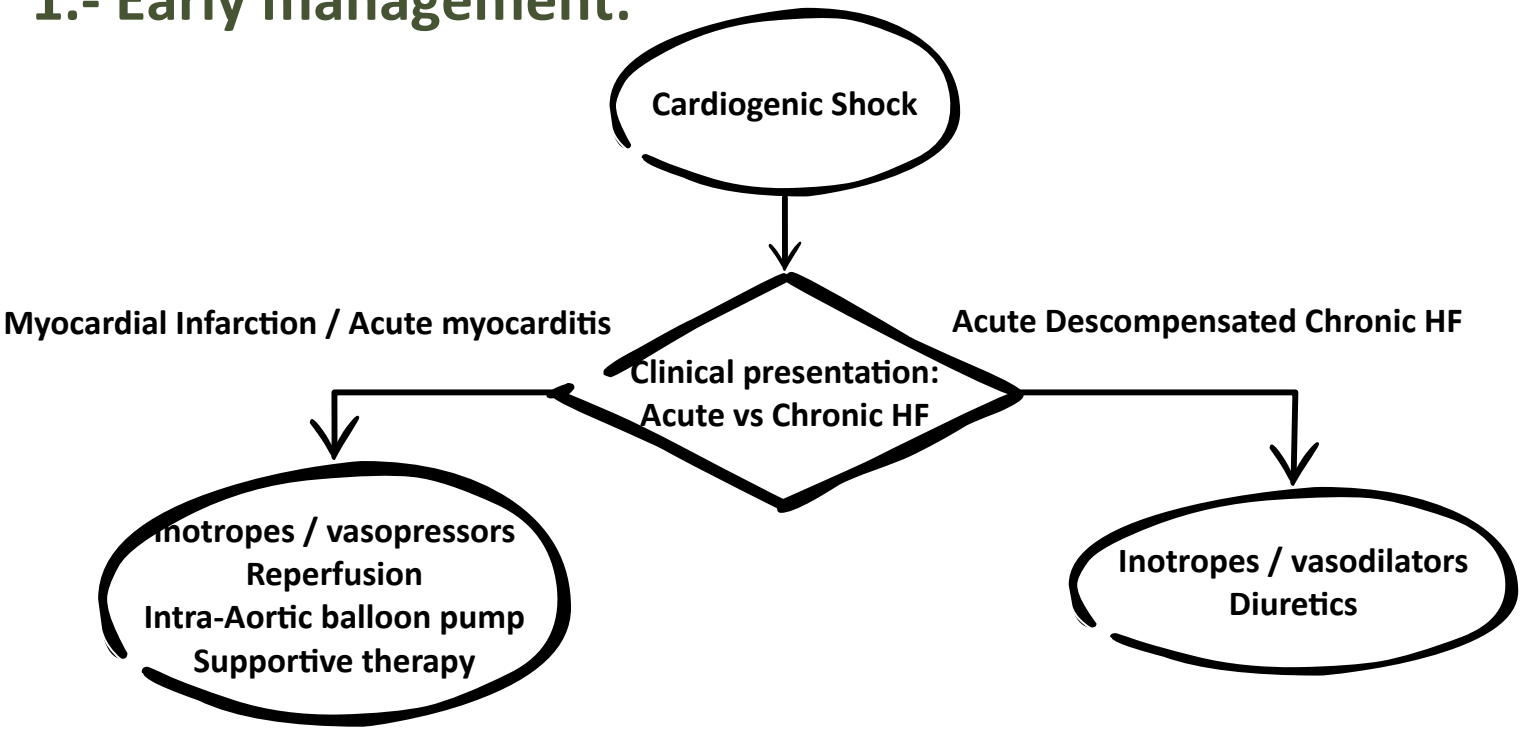
## 2.- Refractory CS management

## 3.- Outcome and Destination Therapy



# Structure:

## 1.- Early management:



# 1.- Early management: Clinical evaluation and diagnostic investigations

## Clinical presentation: AHF ("de novo") Vs ADCHF

- Age
- Underlying diseases
- Precipitating factors
- Hemodynamics profile

| Variable | De novo AHF | | *p* value |
|---|---|---|---|
| | Yes, *n* = 1,792 | No, *n* = 3,161 | |
| Median SBP (mmHg) (IQR) | 130 (95–160) | 130 (103–160) | <0.0001 |
| SBP < 100 (mmHg), no. (%) | 466 (26.3) | 549 (17.5) | <0.0001 |
| Median DBP (mmHg) (IQR) | 75 (60–90) | 80 (60–95) | <0.0001 |
| Heart rate, median (IQR) | 110 (90–122) | 107 (90–120) | 0.002 |
| Cardiogenic shock (%) | 19.1 | 7.5 | <0.0001 |
| Pulmonary edema (%) | 39.8 | 35.0 | 0.0008 |
| Cold extremities (%) | 29.3 | 24.3 | 0.0001 |
| Normal diuresis at baseline (%) | 55.2 | 52.6 | 0.093 |
| Median BNP (IQR)[a] | 908 (415–1,572) | 1,040 (376–2,212) | 0.020 |

| Characteristics | Total | De novo AHF | | *p* value de novo AHF, yes versus no |
|---|---|---|---|---|
| | | Yes | No[b] | |
| Patients, *n* (%) | 4,953 | 1,792 (36.2) | 3,161 (63.8) | |
| Age (years) | | | | <0.0001 |
| <50 | 9.5 | 15.4 | 6.2 | |
| 51–60 | 16.5 | 18.0 | 15.7 | |
| 61–70 | 29.3 | 28.4 | 29.8 | |
| 71–80 | 29.8 | 26.1 | 31.8 | |
| >80 | 14.9 | 12.1 | 16.5 | |
| Male gender (%) | 62.4 | 63.6 | 61.7 | 0.19 |
| Underlying diseases | | | | |
| Chronic systolic heart failure (%) | 36.4 | 2.6 | 55.4 | <0.0001 |
| Coronary artery disease (%) | 30.7 | 25.4 | 33.7 | <0.0001 |
| Hypertension (%)[a] | 70.2 | 66.3 | 72.4 | <0.0001 |
| Diabetes (%) | 45.3 | 38.8 | 49.0 | <0.0001 |
| Atrial fibrillation/flutter (%) | 24.4 | 13.4 | 30.6 | <0.0001 |
| Chronic renal disease (as reported) (%) | 21.4 | 11.0 | 27.1 | <0.0001 |
| Anaemia (%) | 14.4 | 8.9 | 17.4 | <0.0001 |
| COPD/asthma (%) | 24.8 | 15.8 | 29.7 | <0.0001 |
| Pacemaker (%) | 5.5 | 2.2 | 7.4 | <0.0001 |
| Cardiomyopathy (%) | 12.6 | 6.2 | 16.3 | <0.0001 |
| Precipitating factors (on admission) | | | | |
| Acute coronary syndrome (%) | 36.9 | 48.6 | 30.2 | <0.0001 |
| Arrhythmia (%) | 26.9 | 19.1 | 31.3 | <0.0001 |
| Infection (%) | 16.3 | 12.1 | 18.7 | <0.0001 |
| Poor compliance with medications (%) | 13.4 | 2.2 | 19.7 | <0.0001 |

Follath et al. Intensive Care Med 2011;37:619-626

# 1.- Early management: Clinical evaluation and diagnostic investigations

## Clinical profiles: CS forms a spectrum that ranges from mild hypo-perfusion to profound shock

### Refractory Cardiogenic Shock: Pharmacological criteria

### INTERMACS profiles

| | | |
|---|---|---|
| 1 | Critical cardiogenic shock ("Crash and burn") | Life-threatening hypotension and rapidly escalating inotropic/pressor support, with critical organ hypoperfusion often confirmed by worsening acidosis and lactate levels. |
| 2 | Progressive decline ("Sliding fast" on inotropes) | "Dependent" on inotropic support but nonetheless shows signs of continuing deterioration in nutrition, renal function, fluid retention, or other major status indicator. Can also apply to a patient with refractory volume overload, perhaps with evidence of impaired perfusion, in whom inotropic infusions *cannot be maintained* due to tachyarrhythmias, clinical ischemia, or other intolerance. |
| 3 | Stable but inotrope dependent | Clinically stable on mild-moderate doses of intravenous inotropes (or has a temporary circulatory support device) after repeated documentation of failure to wean without symptomatic hypotension, worsening symptoms, or progressive organ dysfunction (usually renal). |
| 4 | Resting symptoms on oral therapy at home | Patient who is at home on oral therapy but frequently has symptoms of congestion at rest or with activities of daily living (dressing or bathing). He or she may have orthopnea, shortness of breath during dressing or bathing, gastrointestinal symptoms (abdominal discomfort, nausea, poor appetite), disabling ascites, or severe lower-extremity edema. |
| 5 | Exertion intolerant ("housebound") | Patient who is comfortable at rest but unable to engage in any activity, living predominantly within the house or housebound. |
| 6 | Exertion limited ("walking wounded") | Patient who is comfortable at rest without evidence of fluid overload but who is able to do some mild activity. Activities of daily living are comfortable and minor activities outside the home such as visiting friends or going to a restaurant can be performed, but fatigue results within a few minutes or with any meaningful physical exertion. |
| 7 | Advanced NYHA class III | Patient who is clinically stable with a reasonable level of comfortable activity, despite a history of previous decompensation that is not recent. This patient is usually able to walk more than a block. Any decompensation requiring intravenous diuretics or hospitalization within the previous month should make this person a Patient Profile 6 or lower. |

Samuels et al. J Card Surg 1999;14:288-293
Beurtheret S et al. Eur Heart J 2013;34:112-120

# 1.- Early management: Clinical evaluation and diagnostic investigations

## Clinical profiles: INTERMACS

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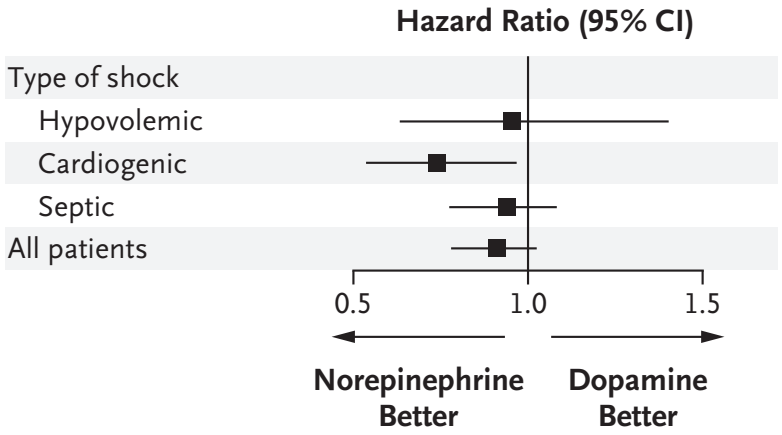
| 7 | Advanced NYHA class III | Patient who is clinically stable with a reasonable level of comfortable activity, despite a history of previous decompensation that is not recent. This patient is usually able to walk more than a block. Any decompensation requiring intravenous diuretics or hospitalization within the previous month should make this person a Patient Profile 6 or lower. |

# 1.- Early management: Initial stabilization:

## Fluids to obtain euvolaemia (pathophysiological considerations)

## Vasopressors: Norepinephrine first choice vasopressor

### Dopamine vs Norepinephrine: SOAP II study




Dopamine is associated with more arrhythmic events and 28-d mortality in patients with cardiogenic shock.

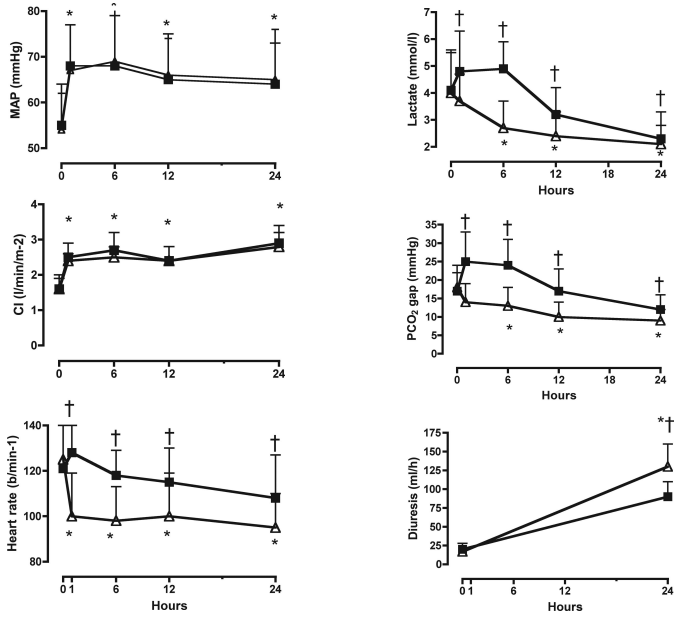
De Backer D et al. N Engl J Med 2010;362:779-89

# 1.- Early management: Initial stabilization:

## Inotropes:

### Norepinephrine-dobutamine vs epinephrine

Systemic and regional hemodynamics in CS




Epinephrine is associated with:

- transient lactic acidosis,
- elevated HR,
- more arrhythmia,
- inadequacy of gastric mucosa perfusion

No difference 28 d mortality

Levy B et al. Crit Care Med 2011;39:450-455

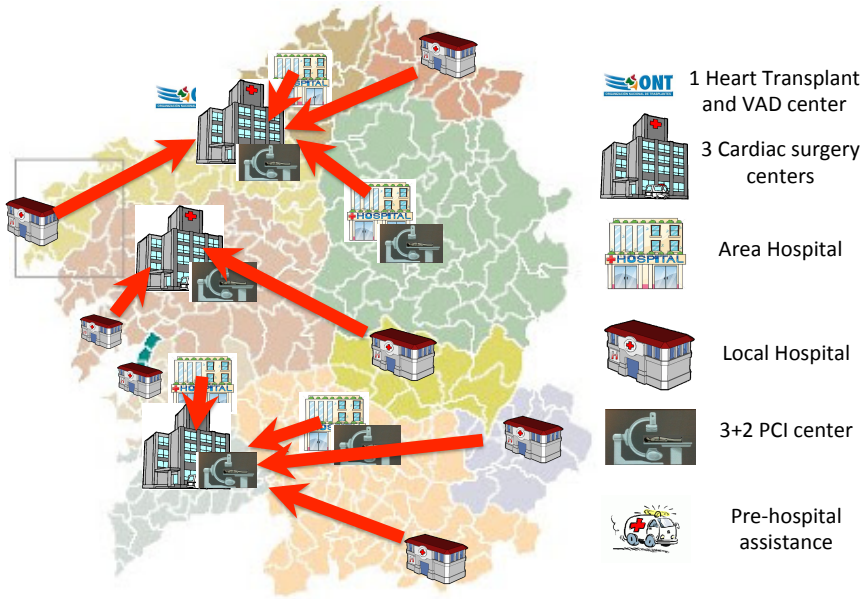
# 1.- Early management: Initial stabilization:

## Inotropes:

### Levosimendan

| Study | Patients | Levosimendan dosage | Comparator | Aim | Outcomes |
|---|---|---|---|---|---|
| **HF** | | | | | |
| REVIVE Trial[51,52] | 700 with HF and symptoms at rest | 0.1–0.2 μg/kg/min (I) | Placebo | Effects on composite clinical endpoints | Levosimendan produced an early greater symptom response and decreased creatinine and BNP levels |
| SURVIVE Trial[54] | 1327 with decompensated HF requiring inotropes | 12μg/kg + 0.1–0.2 μg/kg/min | Dobutamine (5–40 μg/kg/min) | Effects on mortality at 180 days | No differences in terms of mortality between levosimendan and dobutamine |
| **CS** | | | | | |
| Lilleberg *et al.*[55] | 23 after CABG | 8 or 24 μg/kg (B) | Placebo | Effects on systemic and coronary haemodynamics and myocardial substrate utilization | Levosimendan improved systemic and coronary blood flow and did not increase myocardial oxygen consumption or change substrate utilization |
| Labriola *et al.*[57] | 11 with severe LV dysfunction after CS | 12 μg/kg + 0.1 μg/kg/min | – | Efficacy in low-output syndrome following CS | In eight patients, cardiac index was increased by >30% and PCWP reduced to <18 mmHg within 3 h |
| Nijhawan *et al.*[58] | 18 after CABG | 0.2–0.3 μg/kg/min (I) | Placebo | Efficacy after cardio-pulmonary bypass | Increased cardiac output and reduced systemic vascular resistance |
| Barisin *et al.*[59] | 31 after CS | 12–24 μg/kg (B) | Placebo | Effects on ischaemic myocardial impairment during and after off-pump CABG | Increase in cardiac output, EF, and decrease in systemic vascular resistances |
| Plochl and Rajek[56] | 10 after CS | 0.1–0.2 μg/kg/min (I) as adjunctive therapy | – | Effects on haemodynamics in critically ill post-operative patients | Levosimendan increased cardiac output and stroke volume with decreases in systemic vascular resistance |
| **Shock** | | | | | |
| Delle Karth *et al.*[80] | 10 with cardiogenic shock | 0.1 μg/kg/min (I) | – | Efficacy in cardiogenic shock following acute ischaemia or cardiac surgery | Levosimendan treatment resulted in a significant increase in cardiac output together with a decrease in systemic vascular resistance |
| Lehmann *et al.*[81] | 10 with cardiogenic shock undergoing emergency surgery | 6 μg/kg + 0.2 μg/kg/min | – | Efficacy in high risk patients, with cardiogenic shock and acute ischaemia | 8 patients survived without any multiorgan failure |
| Morelli *et al.*[88] | 28 with septic shock | 0.2 μg/kg/min (I) | Dobutamine (5 μg/kg/min) | Efficacy in sepsis-induced dysfunction | Levosimendan improvef systemic haemodynamics and regional perfusion |

# 1.- Early management: Treatment precipitating factors




**Patients who present to hospitals without PCI capability are usually emergently transported to a PCI center, because mortality without transfer is markedly elevated.**


2011 ACCF/AHA/SCAI Guideline for Percutaneous Coronary Intervention. Circulation 2011;124:574-651

# 1.- Early management: Treatment precipitating factors

## Revascularization: Class I (B) recomendation (AHA/ESC)

SHOCK Trial and Shock Registry: 13% reduction 6m and 1y mortality

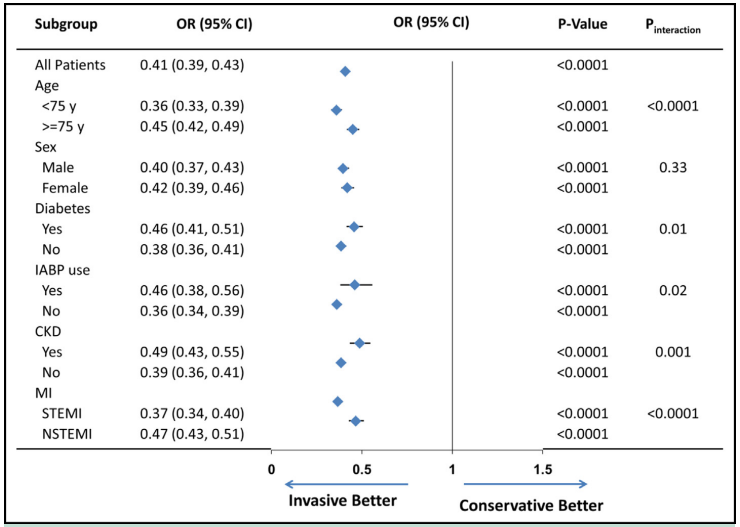



**Figure 3** In-hospital mortality among patients with cardiogenic shock managed invasively vs conservatively in the propensity score-matched cohort.

Real world practice: lower in-hospital mortality in patients managed invasively
(National Inpatient Sample. US hospitals. Propensity score matching)

Hochman J et al. N Engl J Med 1999;341:625-634

Bangalore et al. The American Journal of Medicine. 2015:128(6):601-608

# 1.- Early management: Treatment precipitating factors

## Revascularization: Class I (B) recomendation (AHA/ESC)

- SHOCK Trial and Shock Registry: 13% reduction 6m and 1y mortality

## Surgical management:

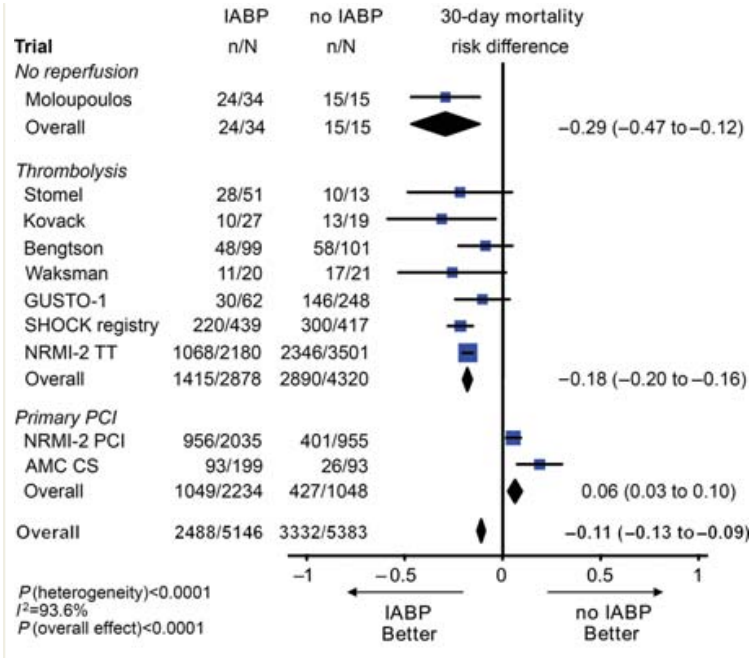
- Prompt repair (with or without CABG) myocardial infarction mechanical complications
- Valvular replacement (balloon dilation)

## Arrhythmias threatment

# 1.- Early management: Intra-aortic balloon pump

## Systematic review and meta-analysis

Thrombolysis studies Vs Primary PCI studies




**Decrease in 30 day mortality of 18%**
**(95% CI, 16–20%; P , 0.0001)**

**Increase in 30 day mortality of 6%**
**(95% CI, 3–10%; P = 0.0008)**

Sjauw et al. Eur Heart J 2009;30:459-468

# 1.- Early management: Intra-aortic balloon pump

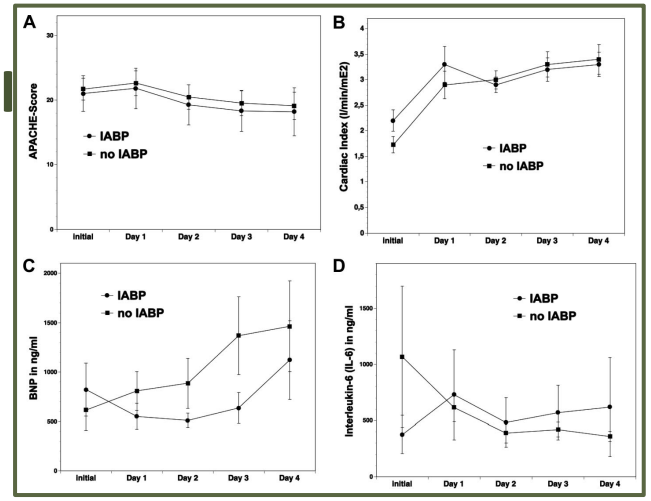
## Systematic review and meta-analysis

Thrombolysis studies Vs Primary PCI studies

Sjauw et al. Eur Heart J 2009;30:459-468

## IABP SHOCK Trial

No significant reduction in MODS and SIRS. Significant LV unloading




n = 45
(IABP group 23)

Prondzinsky et al. Crit Care Med 2010;38:152-160

# 1.- Early management: Intra-aortic balloon pump

## Systematic review and meta-analysis

Thrombolysis studies Vs Primary PCI studies

Sjauw et al. Eur Heart J 2009;30:459-468

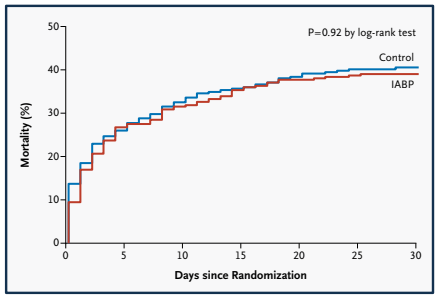
## IABP SHOCK Trial

No significant reduction in MODS and SIRS. Significant LV unloading

Prondzinsky et al. Crit Care Med 2010;38:152-160

## IABP SHOCK Trial II

| Outcome | IABP (N=300) | Control (N=298) | P Value | Relative Risk with IABP (95% CI) |
|---|---|---|---|---|
| | *number (percent)* | | | |
| Primary end point: all-cause mortality at 30 days | 119 (39.7) | 123 (41.3) | 0.69 | 0.96 (0.79–1.17) |
| Reinfarction in hospital | 9 (3.0) | 4 (1.3) | 0.16 | 2.24 (0.70–7.18) |
| Stent thrombosis in hospital | 4 (1.3) | 3 (1.0) | 0.71 | 1.32 (0.30–5.87) |
| Stroke in hospital | 2 (0.7) | 5 (1.7) | 0.28 | 0.40 (0.08–2.03) |
| Ischemic | 2 (0.7) | 4 (1.3) | 0.45 | 0.49 (0.09–2.71) |
| Hemorrhagic | 0 | 1 (0.3) | 0.50 | — |
| Peripheral ischemic complications requiring intervention in hospital | 13 (4.3) | 10 (3.4) | 0.53 | 1.29 (0.58–2.90) |
| Bleeding in hospital* | | | | |
| Life-threatening or severe | 10 (3.3) | 13 (4.4) | 0.51 | 0.76 (0.34–1.72) |
| Moderate | 52 (17.3) | 49 (16.4) | 0.77 | 1.05 (0.74–1.50) |
| Sepsis in hospital | 47 (15.7) | 61 (20.5) | 0.15 | 0.77 (0.54–1.08) |




Thiele et al. N Engl J Med 2012;367(14):1287-96

# 1.- Early management: Intra-aortic balloon pump. Recommendation for use:

1.- **CS after STEMI** who do not quickly stabilize with pharmacological therapy (Class IIa/IIb B). Routine use of IABP in patients with CS is not recommended (Class III A)

2.- IABP insertion should be considered in patients with haemodynamic instability/cardiogenic shock due to **mechanical complications** (Class IIa C)

3.- Acute **ICP failure**: … When severe haemodynamic instability is present, IABP or mechanical circulatory assistance may be desirable **before emergency surgery**.

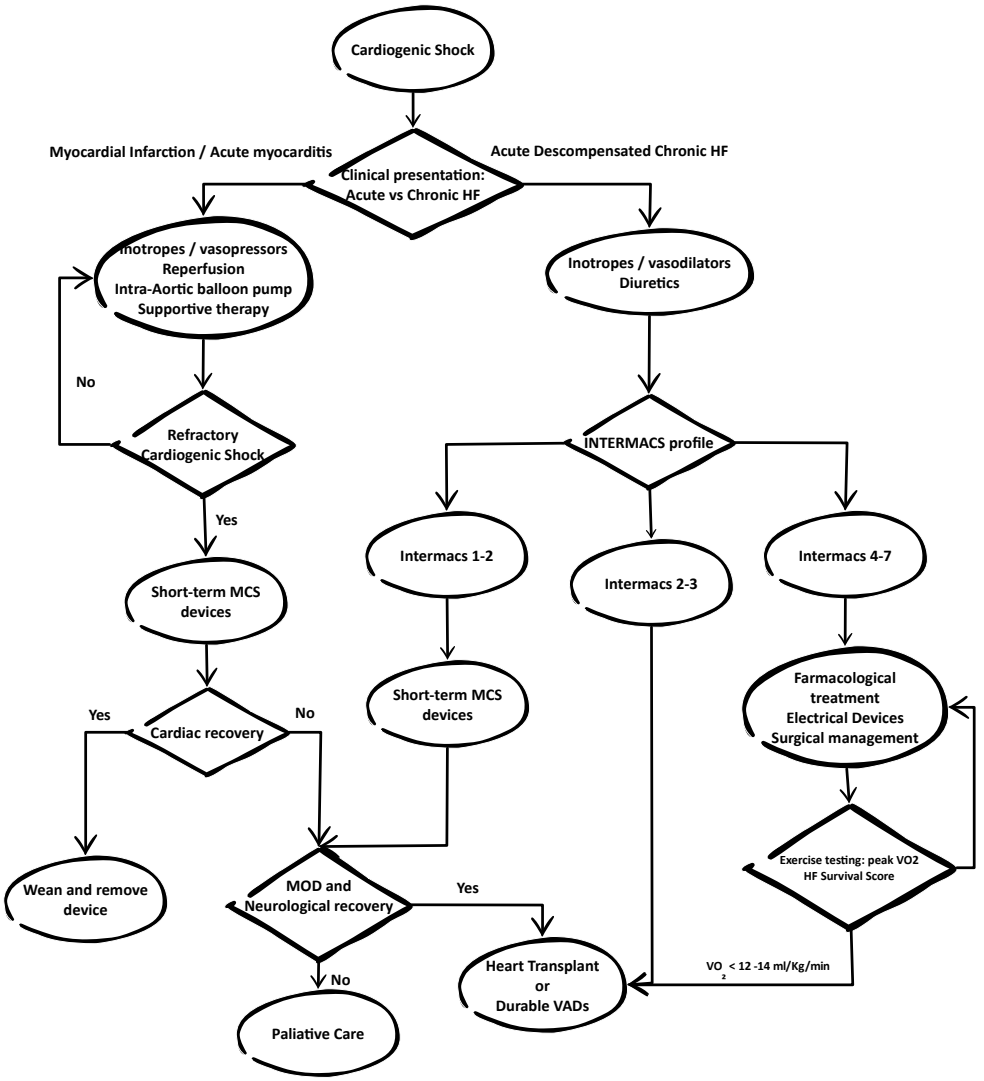
4.- Hospitals Without On-Site Cardiac Surgery: **Transfer** emergently for coronary bypass surgery patients with High-grade left main or 3-vessel coronary disease with clinical or hemodynamic instability, failed or unstable PCI result and ongoing ischemia; preferably with IABP support

# Structure:

## 1.- Early management

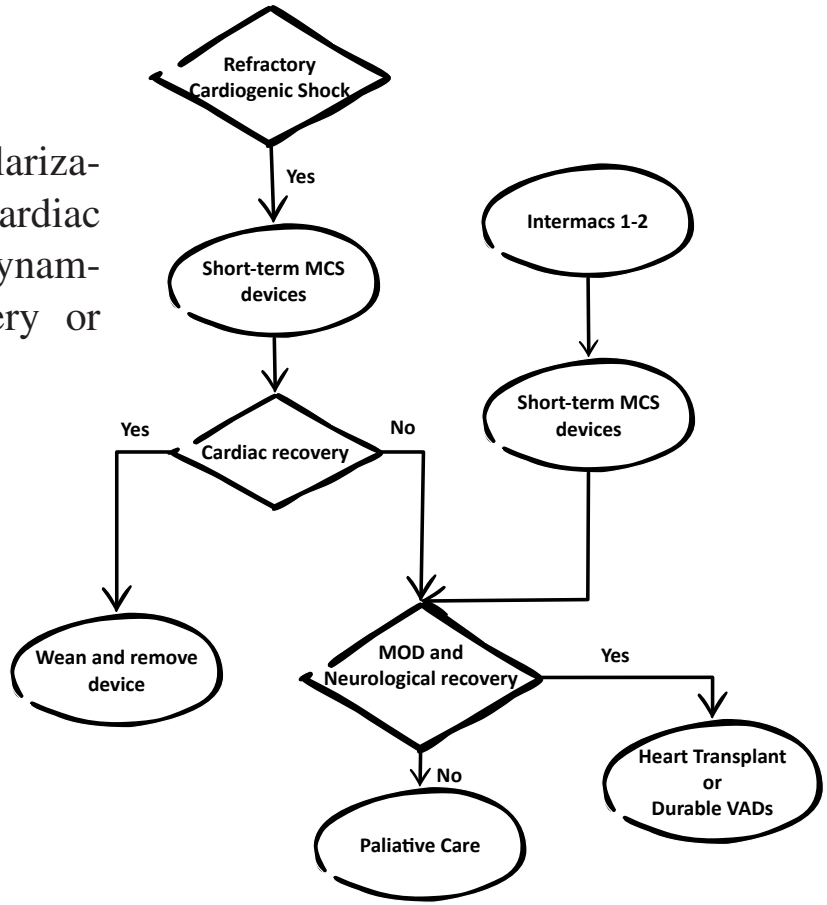
## 2.- Refractory CS management

## 3.- Outcome and Destination Therapy



## 2.- Refractory CS management:

Refractory cardiogenic shock unresponsive to revascularization may necessitate institution of more intensive cardiac support with a ventricular assist device or other hemodynamic support devices to allow for myocardial recovery or subsequent cardiac transplantation in suitable patients.




2011 ACCF/AHA/SCAI Guideline for Percutaneous Coronary Intervention. Circulation 2011;124:574-651

## 2.- Refractory CS management: Short-Term MCS.

**Ideal MCS:** Reduction wall stress and oxygen consumption (Myocardial recovery), normalization of hemodynamics (MODS prevention/Therapy) and low adverse effects

**Effects of pVADs:**

- Rapid reversed hemodynamic compromise
- Reduce LV wall stress and Neurohormonal axis activation, but increased systemic inflammation
- LV unloading may result in infarct size reduction and increased LV recovery

Biswaijit Kar et al. J Am Coll Cardiol 2011;57:688-696
Shah NR et al. J Am Coll Cardiol HF 2013;1:200-206
Meyns et al. J Am Coll Cardiol 2003;41:1087-95

# 2.- Refractory CS management: Short-Term MCS.

## Key Articles on MCS for Refractory Cardiogenic Shock:

| | IABP-SHOCK II[14] | Thiele *et al.*[15] | Burkoff *et al.*[16] | Seyfarth *et al.*[17] | O'Neill *et al.*[18] | Lauten *et al.*[19] | Lemaire *et al.*[7] | Lamarche *et al.*[8] | Combes *et al.*[20] | Bermudez *et al.*[21] |
|---|---|---|---|---|---|---|---|---|---|---|
| **Year of publication** | 2012 | 2005 | 2006 | 2008 | 2013 | 2012 | 2014 | 2011 | 2008 | 2011 |
| **Study design** | Randomized, prospective, multicenter | Randomized, prospective, single center | Randomized, prospective, multicenter | Randomized, prospective, 2-center | Observational, retrospective, registry data | Observational, retrospective, registry data | Record review, retrospective, single center | Record review, retrospective, single center | Record review, retrospective, single center | Record review, retrospective, single center |
| **Number of patients** | 600 | 41 | 42 | 26 | 154 | 120 | 47 | 29 | 81 | 33 |
| **Type of MCS** | IABP | TandemHeart | TandemHeart | Impella 2.5 | Impella 2.5 | Impella 2.5 | Impella 2.5 & 5.0 | Impella 5.0 | ECMO | ECMO |
| **Control** | Medical therapy | IABP | IABP | IABP | N/A | N/A | N/A | ECMO | N/A | N/A |
| **Hemodynamic effect** | N/A | Significant improvement | Significant improvement | Significant improvement | Significant improvement | N/A | N/A | N/A | N/A | N/A |
| **Clinical outcomes** | 30-day mortality, 39% (vs. 41%; p = ns) | 30-day mortality, 43% (vs. 45%; p = ns) | 30-day mortality, 53% (vs. 64%; p = ns) | 30-day mortality, 46% (vs. 46%; p = ns) | Survival to discharge, 50.7% | 30-day mortality, 64.2% | 30-day mortality, 25% | 30-day mortality, 38% (vs. 44%) | Survival to discharge, 42% | 30-day mortality, 36% |

IABP = intra-aortic balloon pump; MCS = mechanical circulatory support; ECMO = extracorporeal membrane oxygenation.

# 2.- Refractory CS management: Short-Term MCS.

## Recommendation for short-term MCS

LV assist devices for circulatory support may be considered in patients with **refractory cardiogenic shock**. (Class IIb C)[1]

Non-durable MCS (pVADs and extracorporeal VADs), is reasonable as a **"bridge to recovery"** or **"bridge to decision"** for selected patients with HFrEF with acute, profound hemodynamic compromise. (Class IIa B)[2]

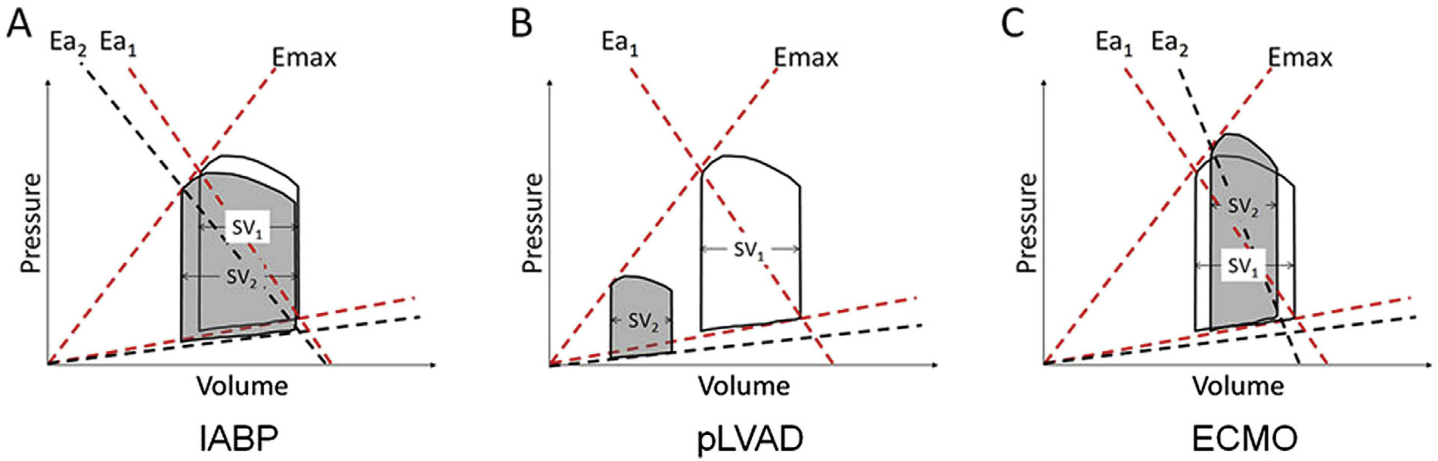
The use of temporary MCS should be strongly considered in patients with MOF, sepsis, or on mechanical ventilation to allow successful **optimization** of clinical status and neurologic assessment **prior to placement of a long term MCSD**. (Class I C)[3]

[1]AHA and ESC Guidelines for the Management of STEMI
[2]2013 ACCF/AHA Guideline for the Management of Heart Failure
[3]2013 ISHLT MCS Guidelines. Feldman et al. J Heart Lung Transplant 2013:32:157-187

# 2.- Refractory CS management: Short-Term MCS.

## Device selection:

### Cardiac effects of Mechanical Support



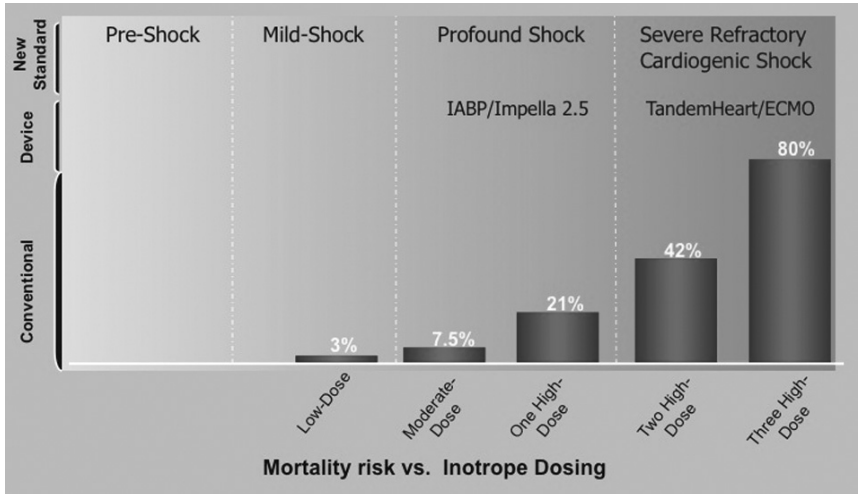

Rihal et al. J Am Coll Cardiol 2015;65(19:7-26

# 2.- Refractory CS management: Short-Term MCS.

## Device selection:

### Cardiac effects of Mechanical Support

### Hemodynamic condition of the patient and Device support




Kar et al. Circulation 2012;125:1809-1817

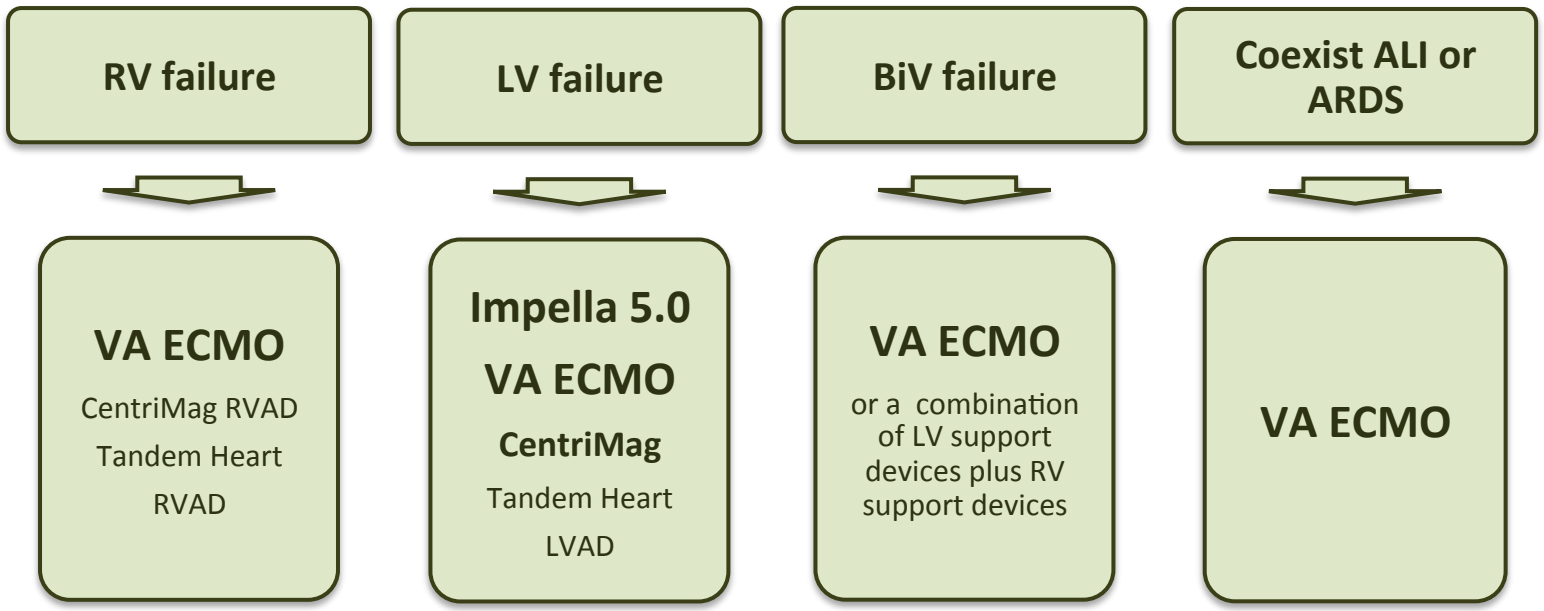
## 2.- Refractory CS management: Short-Term MCS.

## Device selection:

- Cardiac effects of Mechanical Support
- Hemodynamic condition of the patient and Device support
- Technical considerations (ease and rapidity of insertion)
- Cost Effectiveness

## 2.- Refractory CS management: Short-Term MCS.

## Device selection:

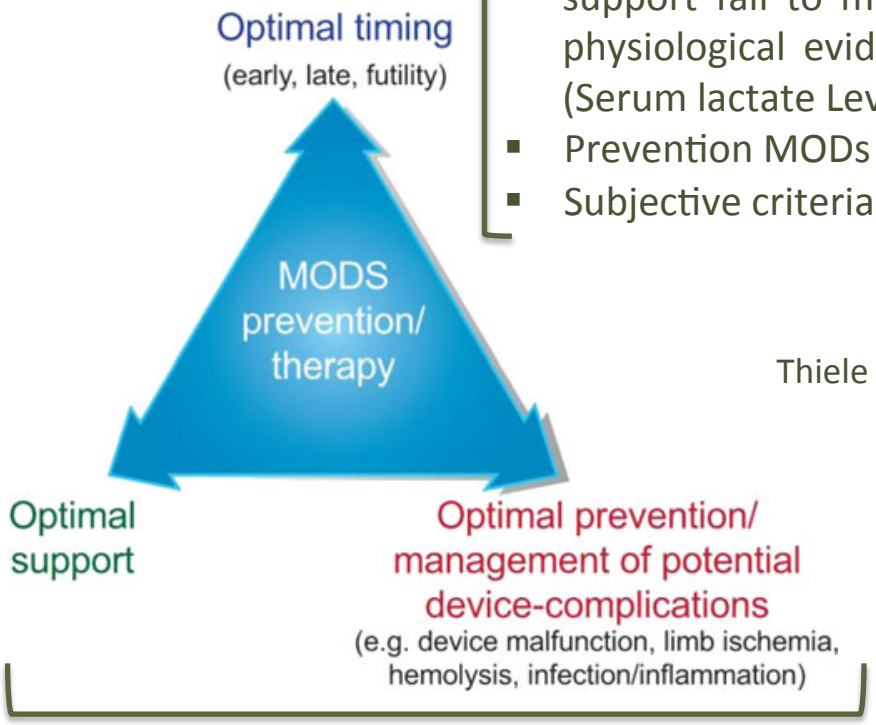



Lamarche et al. J Thorac Cardiovasc Surg 2011;142:60-5
Sayer et al. Curr Opin Crit Care 2012;18:409-416

# 2.- Refractory CS management: Short-Term MCS.

## Optimal management:

- Early when fluid resuscitation and pharmacologic support fail to maintain a SBP > 90 mmHg and physiological evidence of visceral hypoperfusion (Serum lactate Level: risk factor for poor survival)
- Prevention MODs
- Subjective criteria.




Thiele et al. Eur Heart J 2015;36:1223-1230

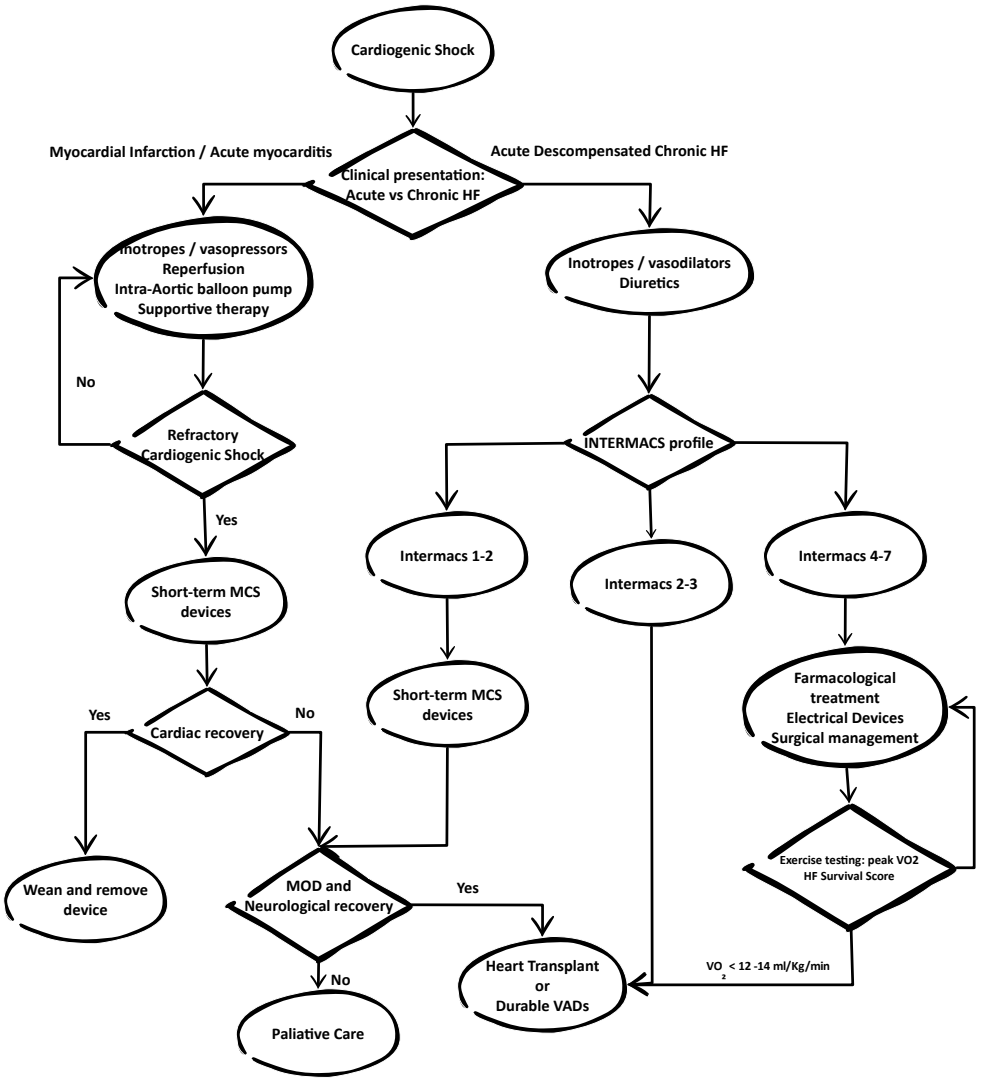
Device-efficacy Vs Device-related complications

# Structure:

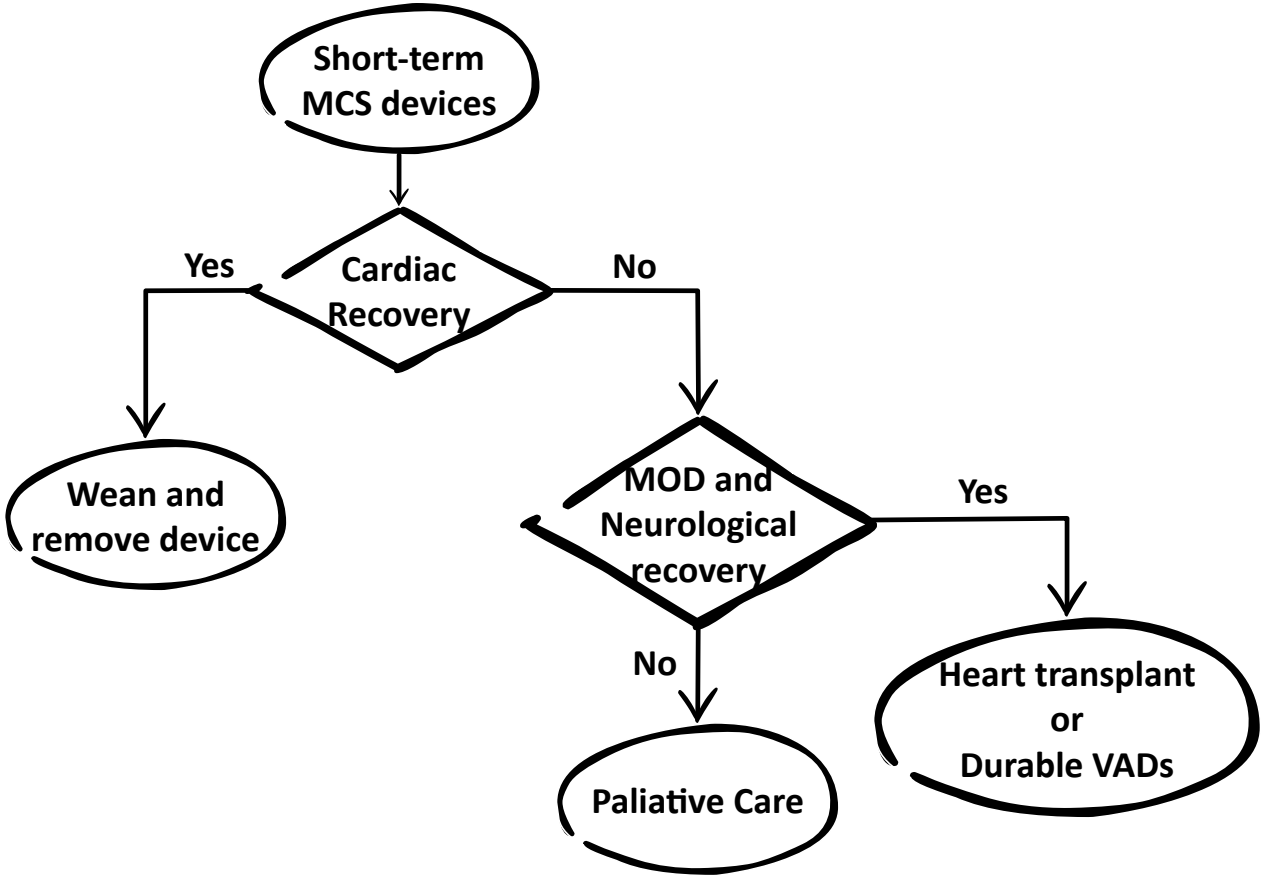
## 1.- Early management

## 2.- Refractory CS management

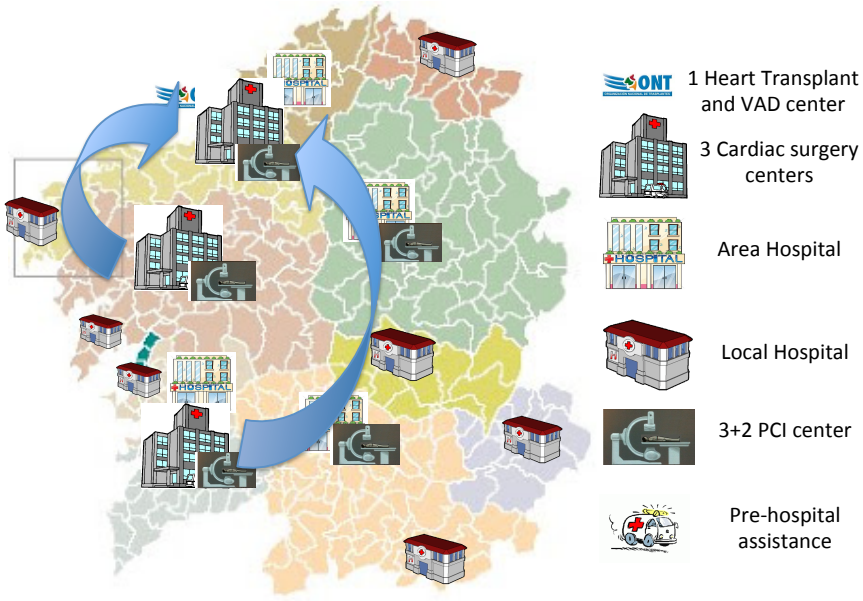
## 3.- Outcome and Destination Therapy



## 3.- Outcome and Destination Therapy:



# 3.- Outcome and Destination Therapy:




**Patients stable on Short-Term MCS and whithout cardiac recovery should be transfer to Heart-transplant /Durable VAD center.**

SERVIZO GALEGO de SAÚDE | Dirección de Asistencia Sanitaria

OCT

Urxencias Sanitarias 061

PROTOCOLO AUTONÓMICO

DE TRANSPORTE INTERHOSPITALARIO DEL PACIENTE EN SHOCK CARDIOGÉNICO REFRACTARIO Y CANDIDATO A TRASPLANTE CARDÍACO

# 3.- Outcome and Destination Therapy:

## MODS and neurology disfunction : Risk factors for mortality

**Table 5** Risk Factors for Mortality for Adult Heart Transplants

| Model | Variable | No. | HR | 95% CI | *p*-value |
|---|---|---|---|---|---|
| 1 year mortality, $n = 10{,}739$ (Jan 2007–June 2012)[a] | RVAD | 22 | 3.26 | 1.60–6.65 | 0.0012 |
| | Temporary circulatory support[b] * | 173 | 2.31 | 1.70–3.15 | <.0001 |
| | Ventilator * | 322 | 2.03 | 1.59–2.61 | <.0001 |
| | Chronic pulsatile flow BiVAD | 254 | 1.99 | 1.45–2.73 | <.0001 |
| | Recipient history of dialysis * | 278 | 1.90 | 1.49–2.44 | <.0001 |
| | Total artificial heart | 113 | 1.77 | 1.14–2.74 | 0.0104 |
| | Diagnosis: congenital vs CM | 276 | 1.66 | 1.18–2.32 | 0.0034 |
| | Previous transplant | 336 | 1.57 | 1.19–2.08 | 0.0016 |
| | Chronic continuous-flow LVAD | 2,351 | 1.44 | 1.21–1.73 | <.0001 |
| | Transplant year: 2007 vs 2011/2012 | 1,911 | 1.28 | 1.07–1.53 | 0.0081 |
| | Previous transfusion | 2,476 | 1.27 | 1.10–1.47 | 0.0010 |
| | Male recipient/female donor vs male recipient/male donor | 1,598 | 1.27 | 1.08–1.50 | 0.0039 |
| | Transplant year: 2008 vs 2011/2012 | 1,829 | 1.26 | 1.05–1.51 | 0.0136 |
| | IV drug therapy for recipient infection | 1,093 | 1.24 | 1.04–1.47 | 0.0162 |
| | Diagnosis: CAD vs CM | 4,206 | 1.17 | 1.02–1.34 | 0.0278 |
| | Not hospitalized just before transplant | 5,914 | 0.80 | 0.70–0.91 | 0.0010 |

*Spanish Heart Transplantation Registry

2014 ISHLT Adult Heart Transplantation Report. J Heart Lung Transplant 2014;33(10):996-1008

# 3.- Outcome and Destination Therapy:

## MODS and neurology disfunction : Risk factors for mortality

**Table 6** Adult Primary Continuous-flow LVAD and BiVAD Implants: June 2006 to December 2013 ($N = 9,372$)

| | Early hazard | | Late hazard | |
|---|---|---|---|---|
| Risk factors for death | Hazard ratio | *p*-value | Hazard ratio | *p*-value |
| ***Demographics*** | | | | |
| Age (older) | 1.36 | <0.0001 | | |
| Female | 1.20 | 0.007 | | |
| BMI (higher) | 1.13 | <0.0001 | | |
| ***Clinical status*** | | | | |
| History of stroke | 1.30 | 0.03 | | |
| INTERMACS Level 1 | 1.69 | <0.0001 | | |
| INTERMACS Level 2 | 1.44 | <0.0001 | | |
| Destination therapy | 1.24 | 0.0005 | | |
| ***Non-cardiac systems*** | | | | |
| Albumin (lower) | 0.90 | 0.02 | | |
| Creatinine (higher) | | | 1.05 | 0.0003 |
| Dialysis | 2.37 | <0.0001 | | |
| BUN (higher) | 1.06 | <0.0001 | 1.06 | 0.01 |
| ***Right heart dysfunction*** | | | | |
| Right atrial pressure (higher) | 1.11 | 0.02 | | |
| RVAD in same operation | 2.45 | <0.0001 | | |
| Bilirubin (higher) | 1.21 | <0.0001 | | |
| Ascites | 1.27 | 0.01 | | |
| ***Surgical complexities*** | | | | |
| History of cardiac surgery | 1.43 | <0.0001 | | |
| Concomitant cardiac surgery | | | 1.21 | 0.0008 |

Sixth INTERMACS annual report. J Heart Lung Transplant 2014;33:555-564

# 3.- Outcome and Destination Therapy:

## MODS and neurology disfunction : Risk factors for mortality

## End-organ recovery is key to success for ECMO as a bridge to Heart transplantation or implantable LVAD

| | Before ECLS | Before VAD | *P*-value |
|---|---|---|---|
| Creatinine (mg/dl) | 1.86 ± 0.91 | 1.32 ± 0.52 | 0.02 |
| MDRD-GFR (ml/min/1.78 $m^2$) | 48.73 ± 26.64 | 66.26 ± 28.33 | 0.01 |
| Bilirubin (mg/dl) | 2.03 ± 1.30 | 3.08 ± 2.13 | 0.05 |
| Aspartate aminotransferase (U/l) | 1426 ± 2176 | 277 ± 259 | 0.04 |
| Alanine aminotransferase (U/l) | 982 ± 1466 | 357 ± 447 | 0.04 |
| MELD-XI score (pts) | 18.43 ± 7.72 | 16.08 ± 8.59 | 0.05 |
| $FiO_2$ (%) | 52 ± 18 | 26 ± 23 | <0.01 |
| Positive end-expiratory pressure (mbar) | 7 ± 3 | 5 ± 4 | 0.02 |
| Peak inspired pressure (mbar) | 21 ± 4 | 17 ± 4 | 0.01 |
| Noradrenaline (µg/kg/min) | 0.408 ± 0.355 | 0.056 ± 0.097 | <0.01 |
| Levosimendan (µg/kg/min) | 0.056 ± 0.085 | 0.010 ± 0.032 | 0.06 |
| Dobutamine (µg/kg/min) | 4.362 ± 5.268 | 0.056 ± 0.097 | 0.06 |
| Haemoglobin (mg/dl) | 11.1 ± 2.0 | 9.6 ± 0.9 | <0.01 |
| Platelets ($\times 10^9$) | 166 ± 111 | 69 ± 47 | <0.01 |
| C-reactive protein (mg/dl) | 11.29 ± 9.45 | 13.21 ± 6.80 | 0.80 |
| Leucocytes ($\times 10^9$) | 14.0 ± 7.9 | 11.1 ± 3.5 | 0.21 |

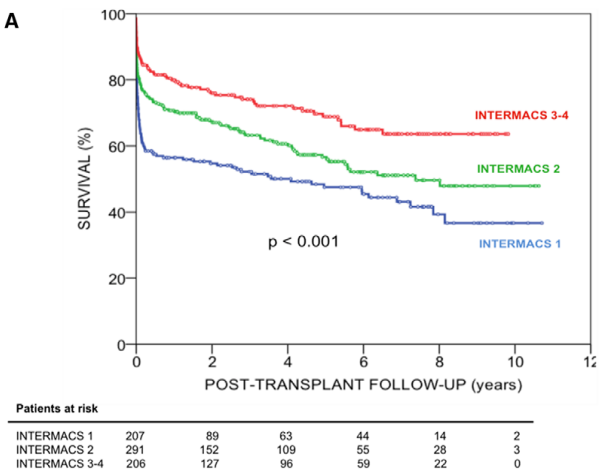
Durinka et al. ASAIO J 2014;60(2):189-92

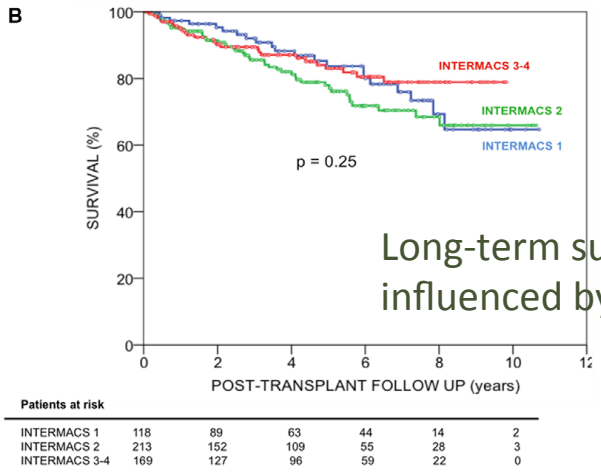
# 3.- Outcome and Destination Therapy:

## INTERMACS profile and postoperative outcome: Heart Tx

Postoperative mortality: INTERMACS 1 43%, INTERMACS 2 26,8% & INTERMACS 3-4 18%

INTERMACS 1 vs 3-4: OR 4,38 (2,51-7,66)
INTERMACS 1 vs 2: OR 2,49 (1,56-3,97)
INTERMACS 2 vs 3-4: OR 1,76 (1,02-3,03)




Long-term survival was not influenced by INTERMACS profile

Barge-Caballero et al. Circ Heart Fail 2013:6:763-772

# 3.- Outcome and Destination Therapy:

# INTERMACS profile and postoperative outcome: VADs

Intermacs **Continuous Flow LVAD/BiVAD Implants: 2008 – 2013, n = 9372**

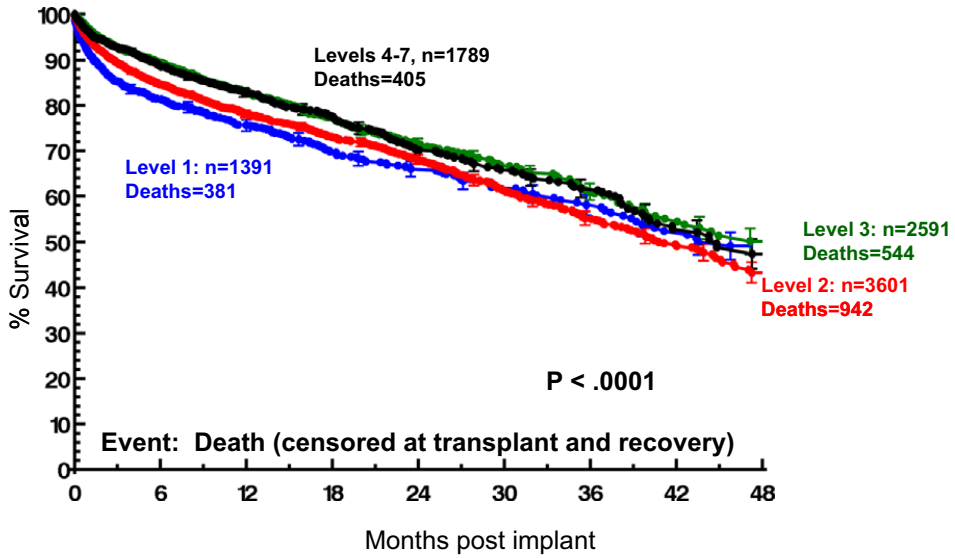
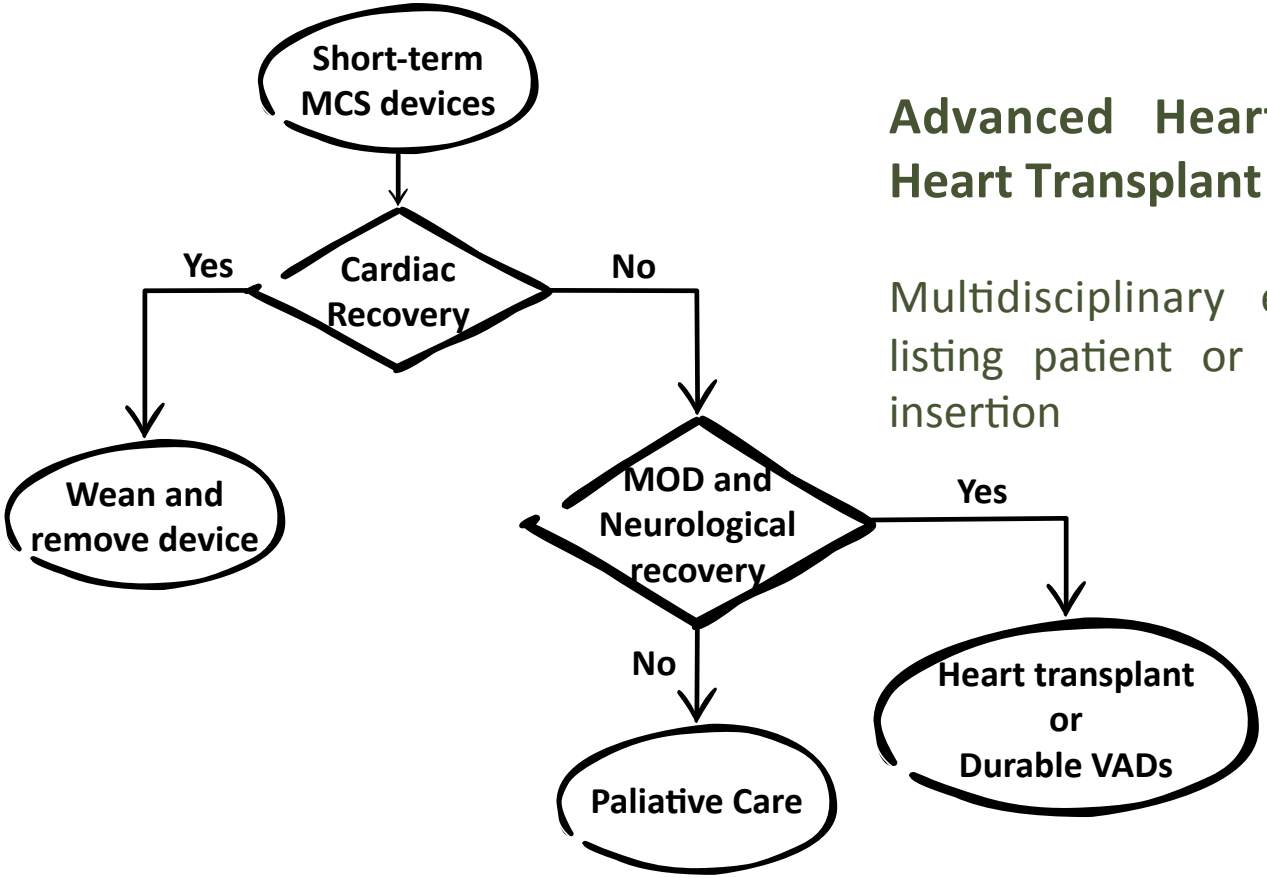



**Table 7** CF-LVAD/BiVAD Implants: January 2008 to December 2013 ($N$ = 9,372)

| | Implant date era | | | |
|---|---|---|---|---|
| | 2008–2010 | | 2011–2013 | |
| Patient profile at time of implant | *n* | % | *n* | % |
| 1 Critical cardiogenic shock | 464 | 16.0% | 927 | 14.3% |
| 2 Progressive decline | 1,250 | 43.0% | 2,351 | 36.4% |
| 3 Stable but inotrope-dependent | 659 | 22.7% | 1,932 | 29.9% |
| 4 Resting symptoms | 370 | 12.7% | 941 | 14.6% |
| 5 Exertion-intolerant | 84 | 2.9% | 192 | 3.0% |
| 6 Exertion-limited | 49 | 1.7% | 79 | 1.4% |
| 7 Advanced NYHA Class 3 | 30 | 1.0% | 43 | 1.0% |
| Total | 2,906 | 100.0% | 6,465 | 100.0% |

Sixth INTERMACS annual report. J Heart Lung Transplant 2014;33:555-564

## 3.- Outcome and Destination Therapy:




**Advanced Heart-Failure and Heart Transplant Team:**

Multidisciplinary evaluation and listing patient or durable VAD insertion

# Conclusions:

- Cardiogenic shock mortality remain very high
- Short-term MCS devices are useful in Refractory CS, but optimal timing and device selection are under investigation
- End-organ recovery and improve in clinical profile is associated with better prognosis
- Heart Team: healthcare providers have to cooperate to improve survival of CS