



Dipartimento Cardiologico A. De Gasperis
Azienda Ospedaliera Niguarda Ca' Granda - Milano

Quando la terapia convenzionale dello shock non basta

La scelta di un supporto meccanico al circolo
in un centro di III livello: quale sistema?
L'organizzazione come deve rispondere?

TIZIANO COLOMBO

ECOCARDIOCHIRURGIA
Milano, 17 Ottobre 2012

Different Clinical Scenarios for Circulatory Mechanical Support in Acute Heart Failure

Pz acuti (spesso in shock cardiogeno)
non noti per CMP

nei quali è prevedibile un recupero di una funzione
cardiocircolatoria adeguata:

- **Miocardite acuta**
- **Postcardiotomy LOS or CS**
- **IMA in shock**
- **Altre cardiomiopatie acute (post-partum...)**



Different Clinical Scenarios for Circulatory Mechanical Support in Acute Heart Failure

Pz end-stage HF (noti) candidati a TC,
ma con ridotta possibilità di giungere rapidamente
al TC per:

- progressivo deterioramento emodinamico
scompenso acuto >> SBP >> shock
- nonostante supporto inotropo massimale e/o CPA



Quando pensare ad un supporto meccanico al circolo

Indicazione precoce



Prevenzione del danno d'organo irreversibile

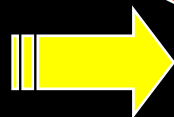
**Quadro clinico di insufficienza cardiaca acuta
più che un semplice deficit di pompa**



Reazioni sistemiche - Risposta infiammatoria



Impianto di MCS



Ulteriore danno infiammatorio



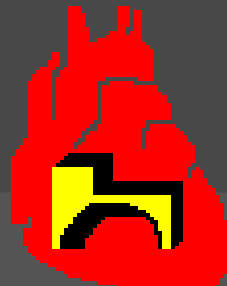


Lo Shock cardiogeno e il De Gasperis

Protocollo Operativo per lo Shock Cardiogeno

Dipartimento A. De Gasperis,
A.O. Ospedale Niguarda
Ca' Granda, Milano

Pz degenti nel Dipartimento De Gasperis;
Pz degenti in altri reparti o che giungono dal PS
Pz segnalati da altri Centri





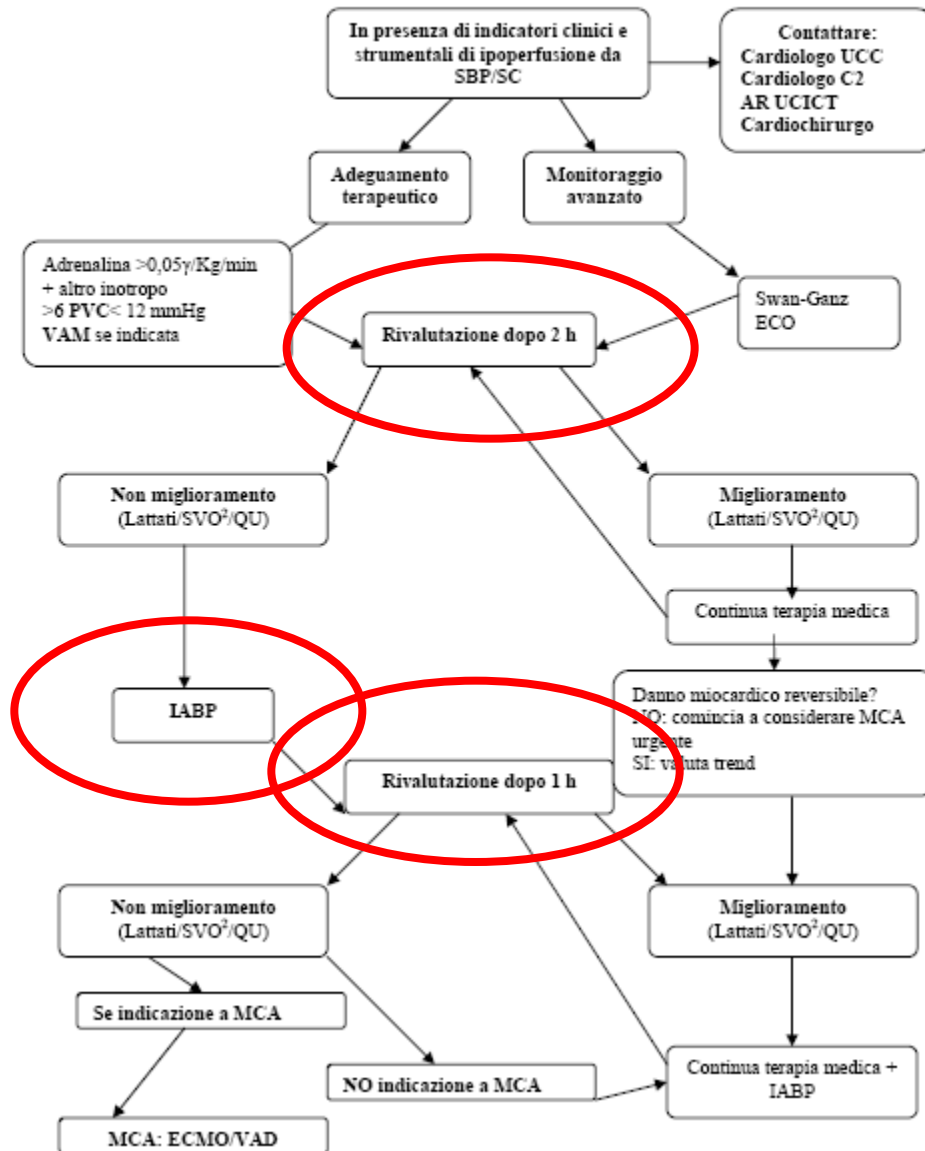
Scopi del protocollo

- identificare precocemente i pazienti affetti da SBP/SC a rapida evoluzione verso la shock o con shock conclamato
- mettere in atto con il timing più corretto tutte le misure diagnostiche e terapeutiche - farmacologiche e, quando indicato, meccaniche (IABP, VAM, CVVH, MCS) di sostegno al circolo
- per impedire l'instaurarsi di danno d'organo o arrestarne la sua progressione





FlowChart Operativa



Protocollo Operativo per lo Shock Cardiogeno

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ottimizzare il monitoraggio ed il trattamento dei pazienti con steps terapeutici a progressiva intensità ed invasività contestualmente a delle valutazioni seriate di parametri emodinamici e biologici





**ACUTE
MCS
THERAPY**

Non miglioramento
(Lattati/SVO²/QU)

IABP

Rivalutazione
dopo 1 h

Non miglioramento
(Lattati/SVO²/QU)

Se indicazione a
MCA

MCA: ECMO/VAD

HEMODYNAMIC EFFECTS

- ↑ Blood Pressure
- ↑ Cardiac Output
- ↓ PCWP
- ↑ Organ Perfusion
- ↑ Organ Function

MAP > 60 mmHg
Mixed venous O₂ > 70%

NEUROHUMORAL EFFECTS

- ↓ Renin
- ↓ Angiotensin II
- ↓ ANP
- ↓ Vasopressin
- ↓ Catecholamines
- ↓ Cytokines



Aggressive Door-to-VAD strategy : *management of cardiogenic shock*

Critical Shock Criteria (score = > 5)

Creatinine > 2.0	Need for continuous inotrope or vasopressor therapy
C.I. < 2 l/min	Need for IABP
SBP < 90	Need for VAM
MAP < 70	AST / ALT > 4 times normal
WP = > 19	Poor perfusion (PA sat < 50%)
RAP > 18	Persistent VT / VF
CK myoglobin > 50	Killip class IV
Acute decrement EF (>20%)	

Curr Opin Cardiol 2010



Aggressive Door-to-VAD strategy : *management of cardiogenic shock*

Predictors of poor survival outcomes

- Age > 70 y
- Persistent lactate levels > 10
- High RAP with low PAPs
- High RAP with low WP
- Severe Pulmonary hypertension
- Bilirubin > 3.5
- Major coagulopathy
- Active untreated infections
- Cachexia
- Life-limiting illnesses (recent cancer, severe lung disease)

**Factors portending
poor outcomes**

Curr Opin Cardiol 2010





Mechanical Circulatory Support for *Bridge to Decision* : which Device

Le metodiche di supporto vengono applicate
in ordine crescente di invasività e rischio di
complicanze iatrogene

LVAD

anche in
sinergismo



Strategy for Cardiogenic Shock: short-term support as a BTB for advanced durable VAD

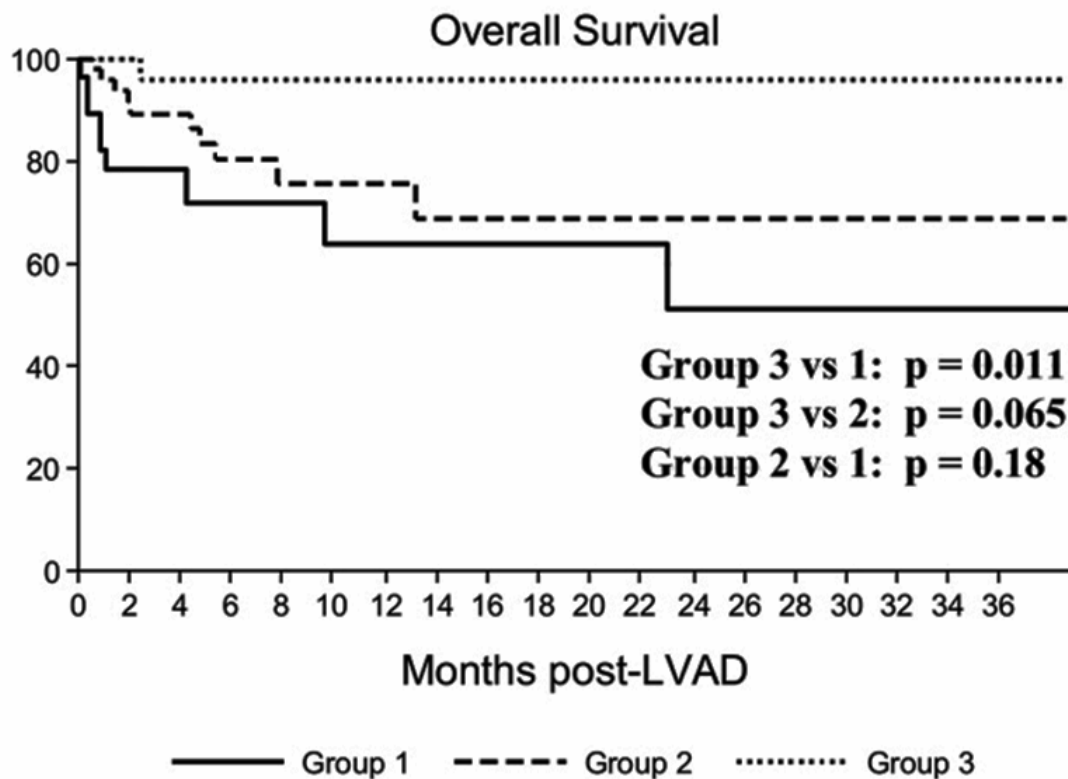
➤ Emergency Implantation of permanent LVAD

- Morbidity and mortality increased (till 64 – 80%)
- Poor outcomes in pts with MSOF

These patients need MCS both for resuscitation and to
reverse end-organ ischemic insult
before LVAD placement



Clinical outcomes for continuous-flow left ventricular assist device patients stratified by pre-operative INTERMACS classification



INTERMACS 4-7 (98.5%)

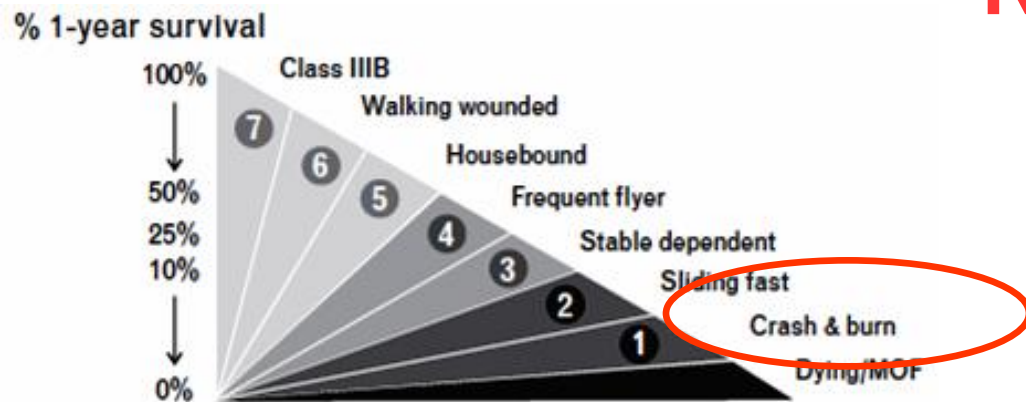
INTERMACS 2-3 (68.8%)

INTERMACS 1 (51.1%)

Numbers at risk	Baseline	6 mos	12 mos	18 mos	24 mos	30 mos	36 mos
Group 1	28	10	9	6	5	3	3
Group 2	49	25	12	7	7	7	4
Group 3	24	18	6	5	5	4	3

INTERMACS Profile	June 2006-Dec 2008	Jan 2009-June 2010
1	34.7	17.3
2	40.2	45.2
3	13	19.5
4	8.4	11.5
5	1.3	3.3
6	1	2.1
7	1.4	1.1

Riduzione impianti in classe I



ISHLT Meeting 2011, San Diego

SHORT-TERM DEVICES

“bridge to decision”

Bridge to bridge

Temporary support for post CPB heart failure

If recovery does not occur, it's possible to switch toward a long term device

Bridge to heart transplantation

Long standing HF, severe AMI or giant cells myocarditis not expected to recover

To allow the patient to wait for early heart transplantation



Recovery

AMI, fulminant myocarditis, postpartum cardiomyopathy, postcardiotomy shock

To allow the heart to rest, expecting short-term recover

2009 ACCF / AHA Heart Failure Guidelines

**Extracorporeal devices can be used
for short-term circulatory support
in patients who are expected to recover
from a major cardiac insult
(myocardial ischemia,
postcardiotomy shock,
fulminant myocarditis)**

JACC 53, 2009



ESC 2012

Heart Failure Guidelines

...other forms of short-term temporary MCS may be used in selected patients with AHF (including IABP, percutaneous cardiac support, ECMO)

MCS can be used as a ‘bridge to decision (BTD)’ in patients...where full evaluation has not been possible and in whom death will occur without MCS



Mechanical Circulatory Support for *Bridge to Decision* : which Device

Easy to place

Rapidly stabilize patient's hemodynamics

Be transported easily with the patient

Allow time to address

REV of cardiac dysfunction

major end organ dysfunction (renal, hepatic)

neurologic status

transplant candidacy



Mechanical Circulatory Support for *Bridge to Decision* : which Device

**Percutaneous or Surgical
microaxial flow pump** (Impella R)

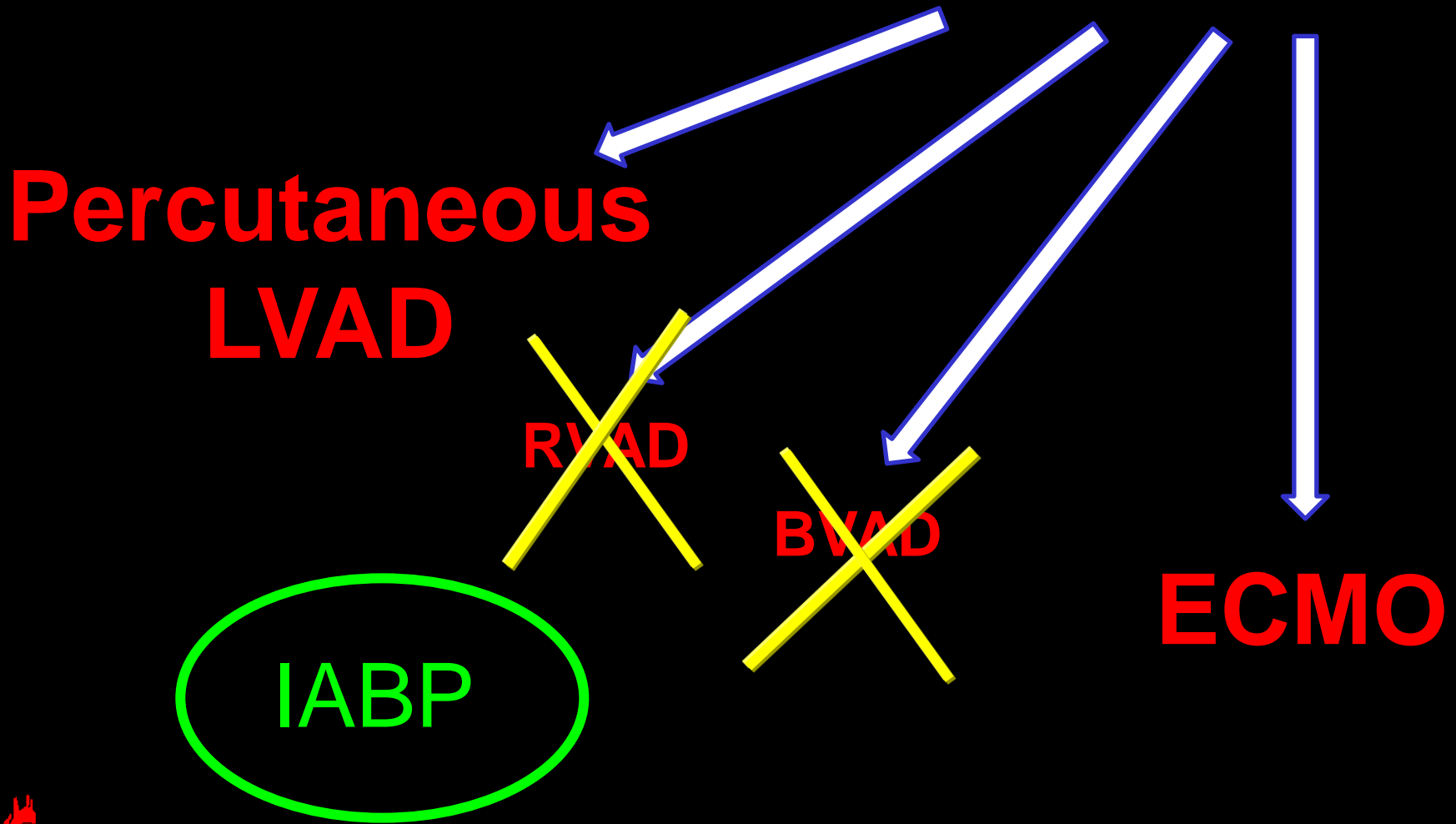
Percutaneous VAD (Tandem Heart System Pump)

Centrifugal pumps (Levitronix CentriMag)

~~**Pulsatile extracorporeal pumps** (Abiomed)~~



Mechanical Circulatory Support for *Bridge to Decision* : which Modality

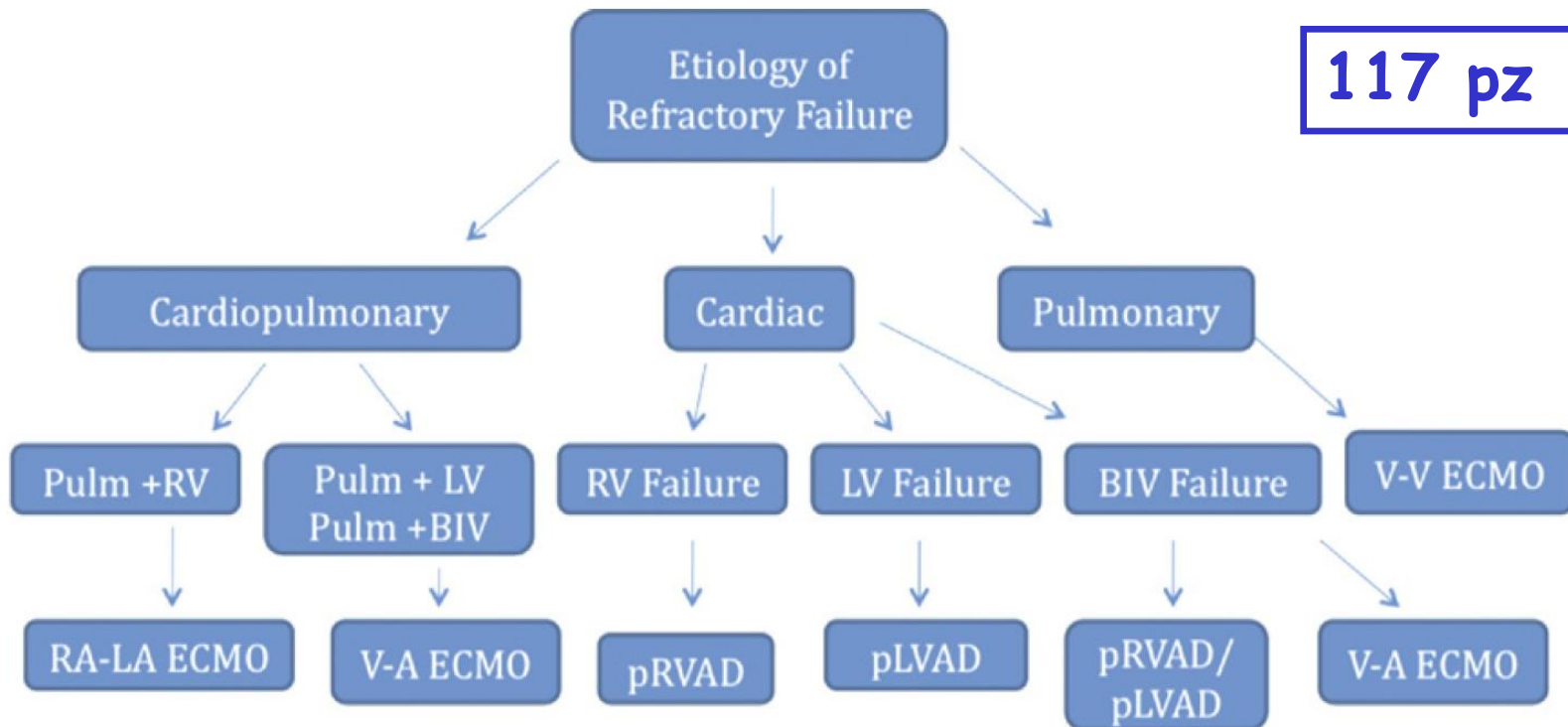


The Percutaneous Ventricular Assist Device in Severe Refractory Cardiogenic Shock

Biswajit Kar, MD,*† Igor D. Gregoric, MD,* Sukhdeep S. Basra, MD,‡ Gary M. Idelchik, MD,*
Pranav Loyalka, MD*

Houston, Texas

117 pz



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Houston, Texas

Hemodynamic and Biochemical Values in All Patients in Cardiogenic Shock

Value	Pre-pVAD	With pVAD	p Value
Cardiac index, l/(min·m ²)	0.52 (0.8)	3.0 (0.9)	<0.001
SBP, mm Hg	75 (15)	100 (15)	<0.001
DBP, mm Hg	30 (20)	65 (20)	<0.001
MAP, mm Hg	45 (20)	81 (15)	<0.001
HR, beats/min	105.1 ± 18.0	85.7 ± 12.9	<0.001
SVO ₂ , %	49 (11.5)	69.29 (10)	<0.001
PCWP, mm Hg	31.52 ± 10.20	17.29 ± 10.82	<0.001
Pulmonary arterial pressure, mm Hg	39.16 ± 12.10	26.70 ± 7.99	<0.001
Lactic acid, mg/dl	24.5 (74.25)	11.0 (12)	<0.001
LDH, U/dl	602 (630)	416.5 (335)	0.101
pH	7.22 ± 0.14	7.44 ± 0.06	<0.001
Creatinine, mg/dl	1.5 (0.95)	1.2 (0.9)	0.009
BUN, mg/dl	39.72 ± 17.88	30.35 ± 15.54	0.108
Urine output, ml/day	70.3 (70)	1200 (1620)	<0.001
Hemoglobin	11 (2.65)	10.25 (1.8)	<0.001
AST	125 (363.75)	75 (169)	0.02
ALT	75 (317)	55.5 (316.75)	0.06



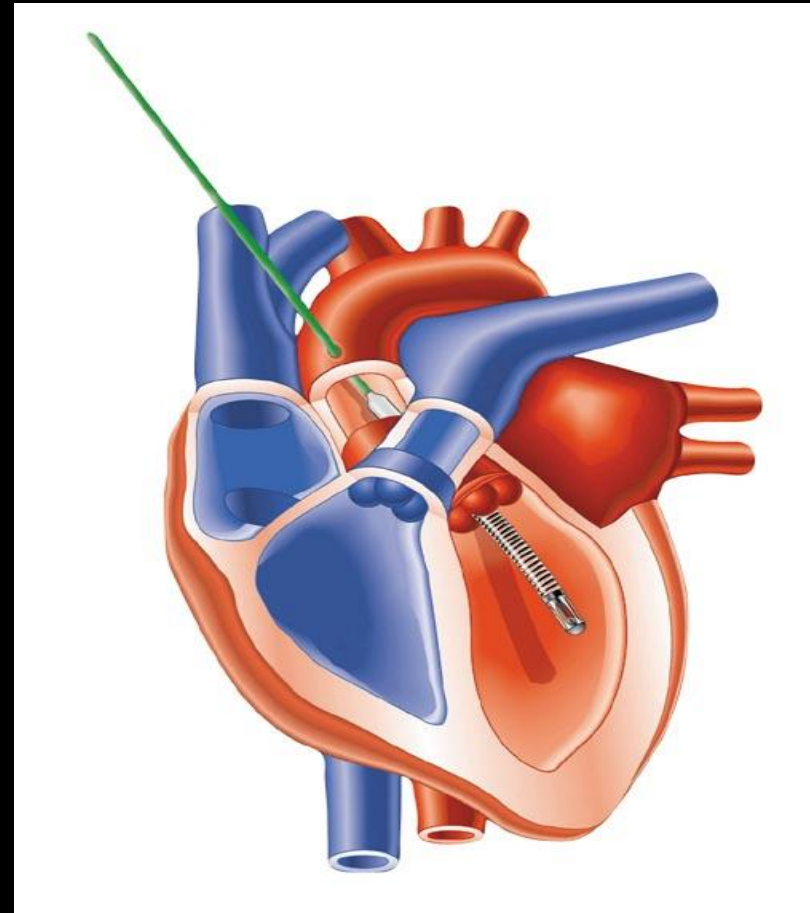
Pompe microassiali: Impella

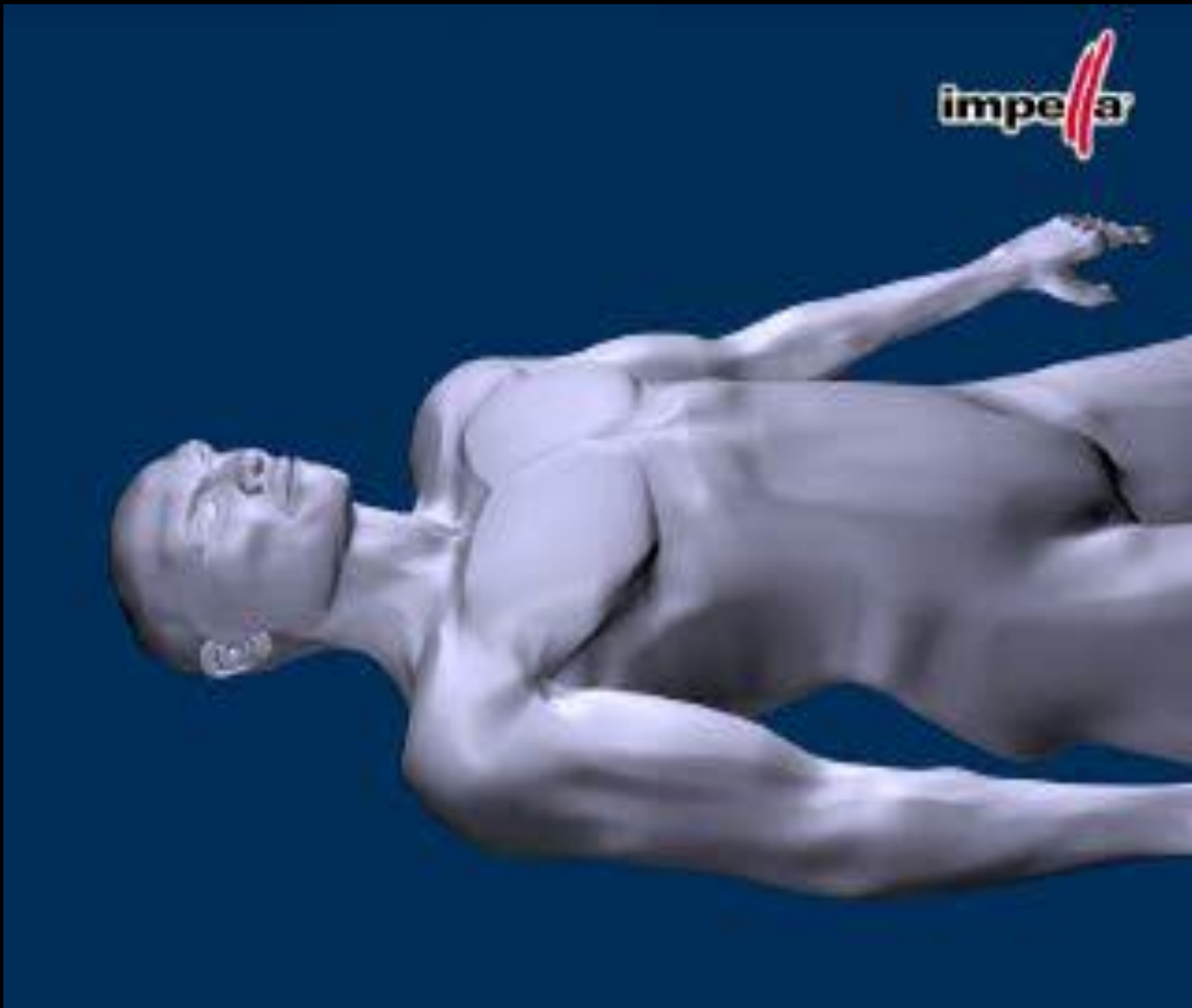
Impella Recover LD/LP (5.0 – 2.5 l/min)

Non necessita CEC

Limitata esposizione materiale
estraneo-sangue

No scoagulazione sistemica





Impella Periferico



Pompe microassiali: Impella

Indicazioni convenzionali

Supporto monoventricolare sx (Impella LD/LP)

- Sindrome Postcardiotomica
- Shock Cardiogeno post IMA
- Miocardite Acuta Fulminante

Supporto monoventricolare dx (Impella RD)

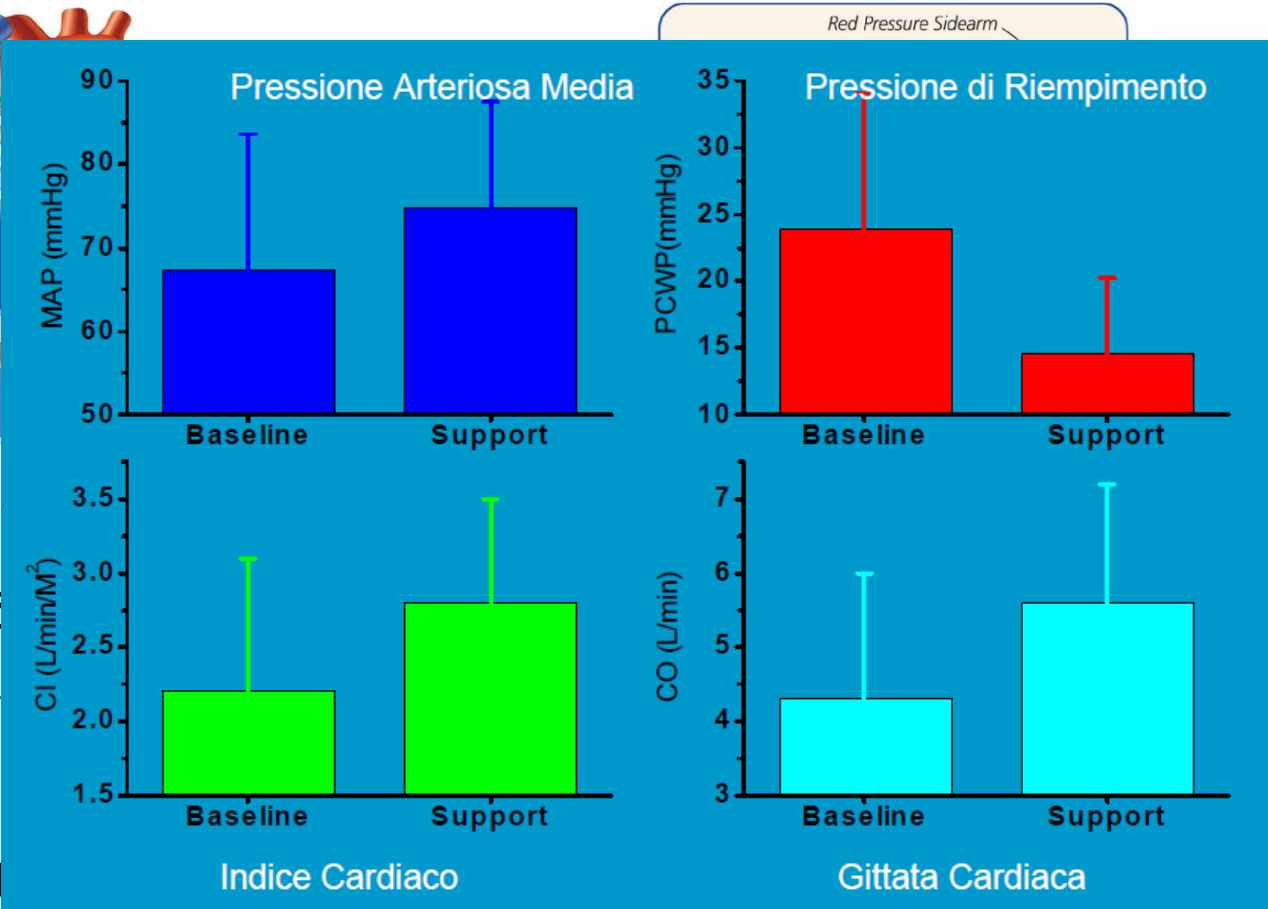
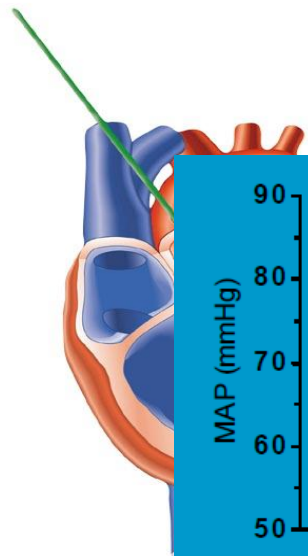
- Insufficienza VD post TCx/ LVAD

Supporto biventricolare

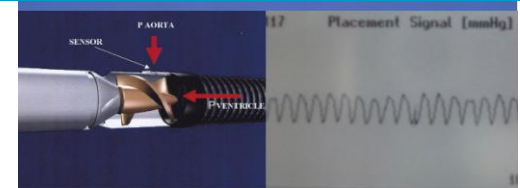
- Miocardite Acuta Fulminante



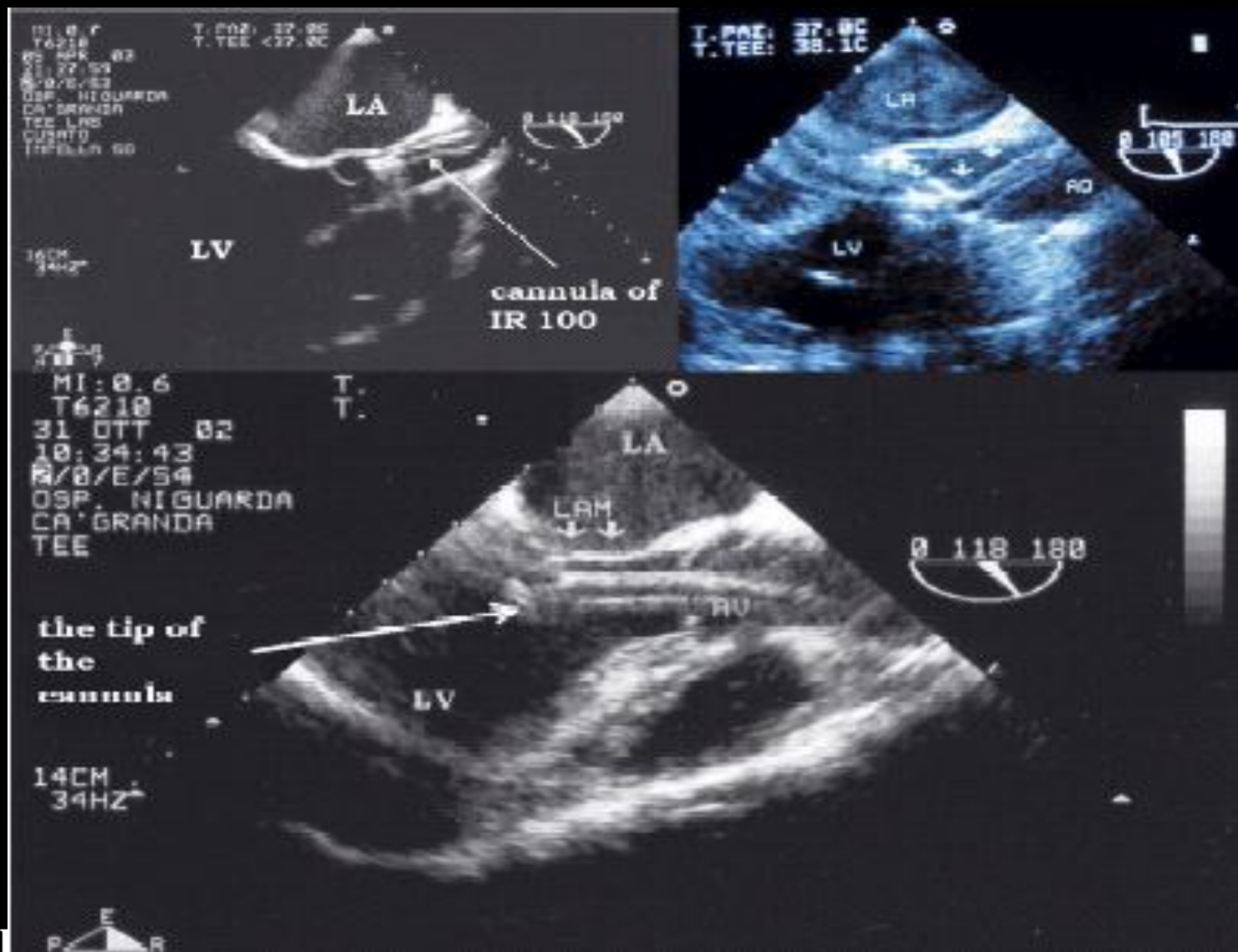
Pompe Microassiali IMPELLA



- Portata
 - 2,5-5
- Cannula
 - peri
- Durata
 - 2 set
- Scoagulazione sistemica:
 - aPTT > 60 sec

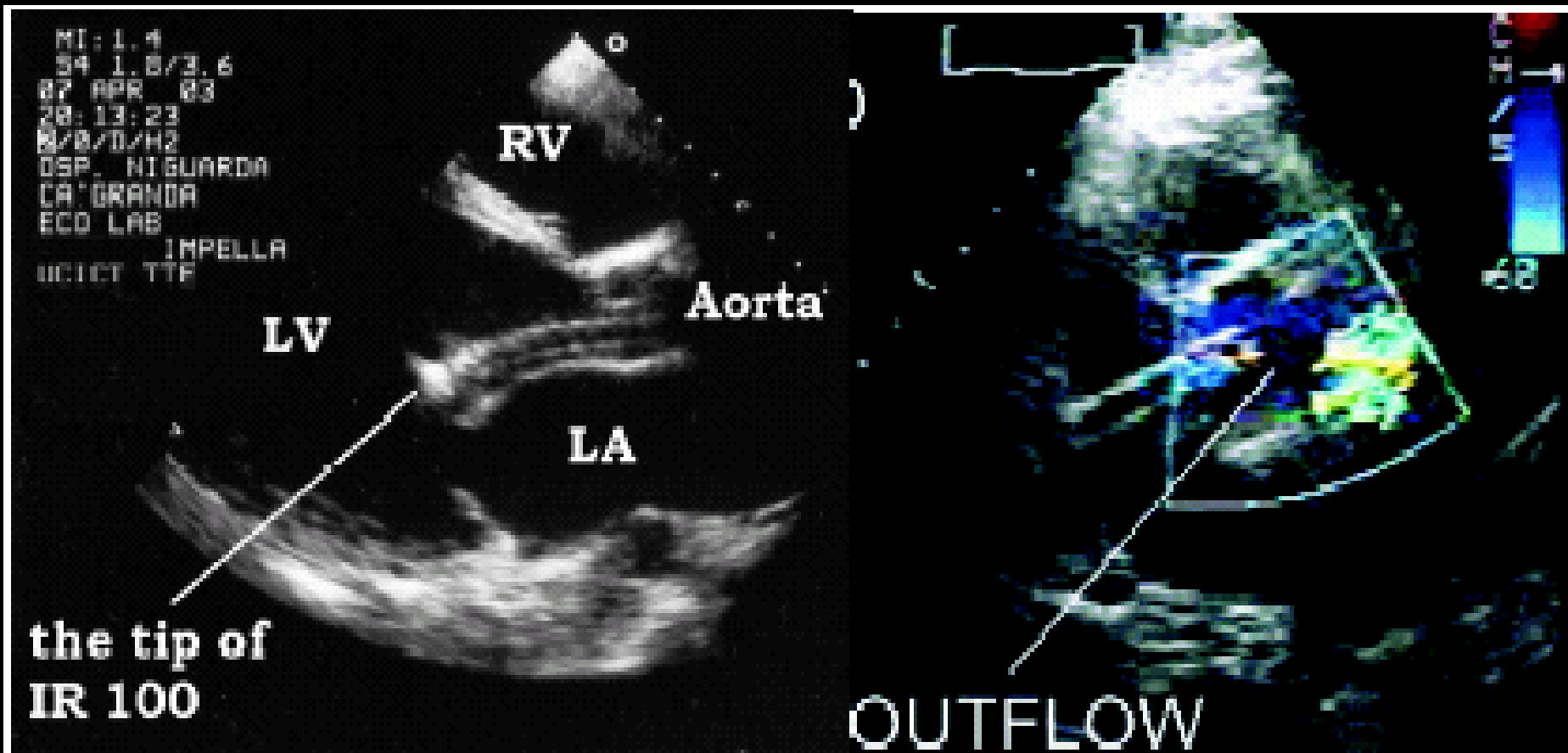


Pompe microassiali: Impella Valutazione Ecocardiografica



Pompe microassiali: Impella

Valutazione Ecocardiografica



Pompe microassiali Impella

Comparative outcomes in cardiogenic shock patients managed with Impella microaxial pump or extracorporeal life support

Yoan Lamarche, MD,^a Anson Cheung, MD,^a Andrew Ignaszewski, MD,^a Jennifer Higgins, MD,^a Annemarie Kaan, MCN RN,^a Donald E. G. Griesdale, MD, MPH,^b and Robert Moss, MD^a

(J Thorac Cardiovasc Surg 2011;142:60-5)

61 pts	30-day mortality	discharged
Impella	38 %	59 %
ECLS	44 %	41 %

Both provided adequate support in pts with CS

Axial flow pump > univentricular failure

ECLS > biventricular failure



Tandem Heart pVAD



60th Annual Scientific Session & Expo

E316

JACC April 5, 2011

Volume 57, Issue 17



CARDIAC FUNCTION AND HEART FAILURE

**CLINICAL EXPERIENCE WITH THE USE OF TANDEM HEART PVAD IN PATIENTS UNDERGOING
CARDIOPULMONARY RESUSCITATION**

**Results : survival after pVAD implantation at 1 and 6 months
was 41.1% and 33.9%**



The Percutaneous Ventricular Assist Device in Severe Refractory Cardiogenic Shock

Tandem Heart pVAD

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Houston, Texas

J Am Coll Cardiol 2011

Ischemic and Non Ischemic Cardiomyopathy patients implanted with Tandem Heart pVAD
(Total 117; M 80 :F 37)
30 Day mortality: 40.2%, 6 Month Mortality : 45.3%



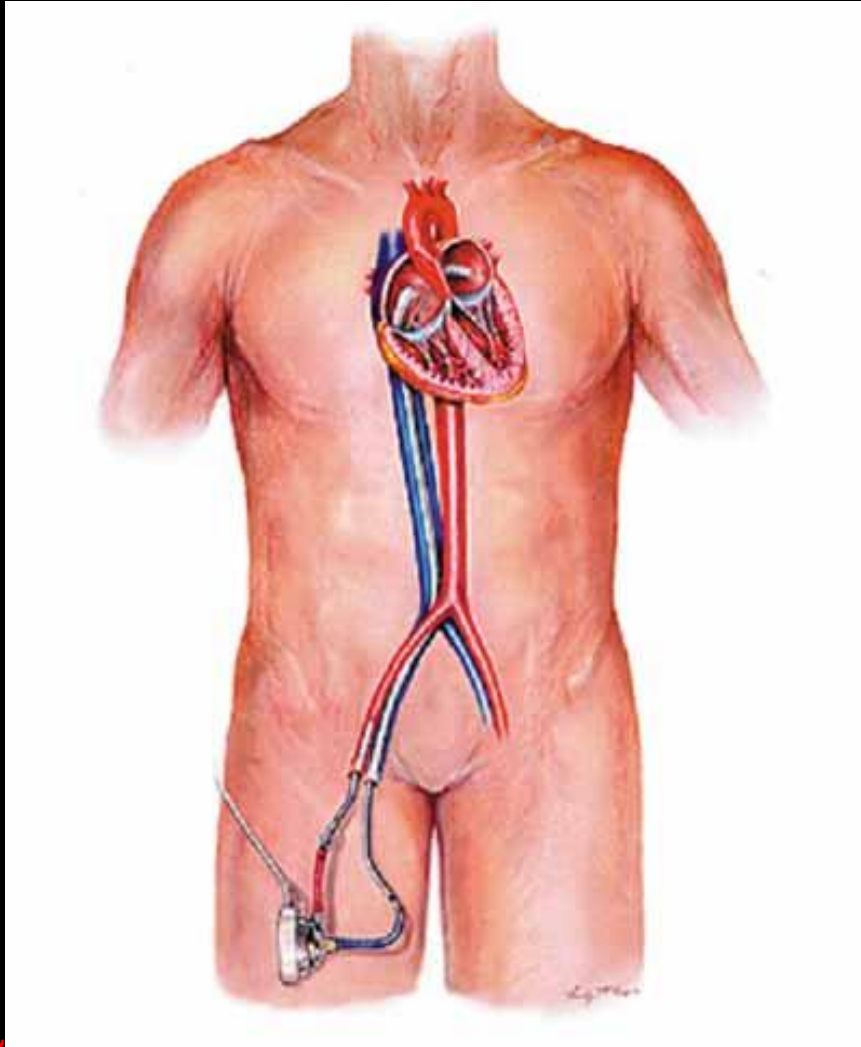
Ischemic Cardiomyopathy
(80 patients :M 61: F 19)
30 Day Mortality 43.8%, 6 Month Mortality: 50%

Non Ischemic Cardiomyopathy
(37 patients: M 19: F 18)
30 Day Mortality: 32%, 6 Month Mortality: 35%

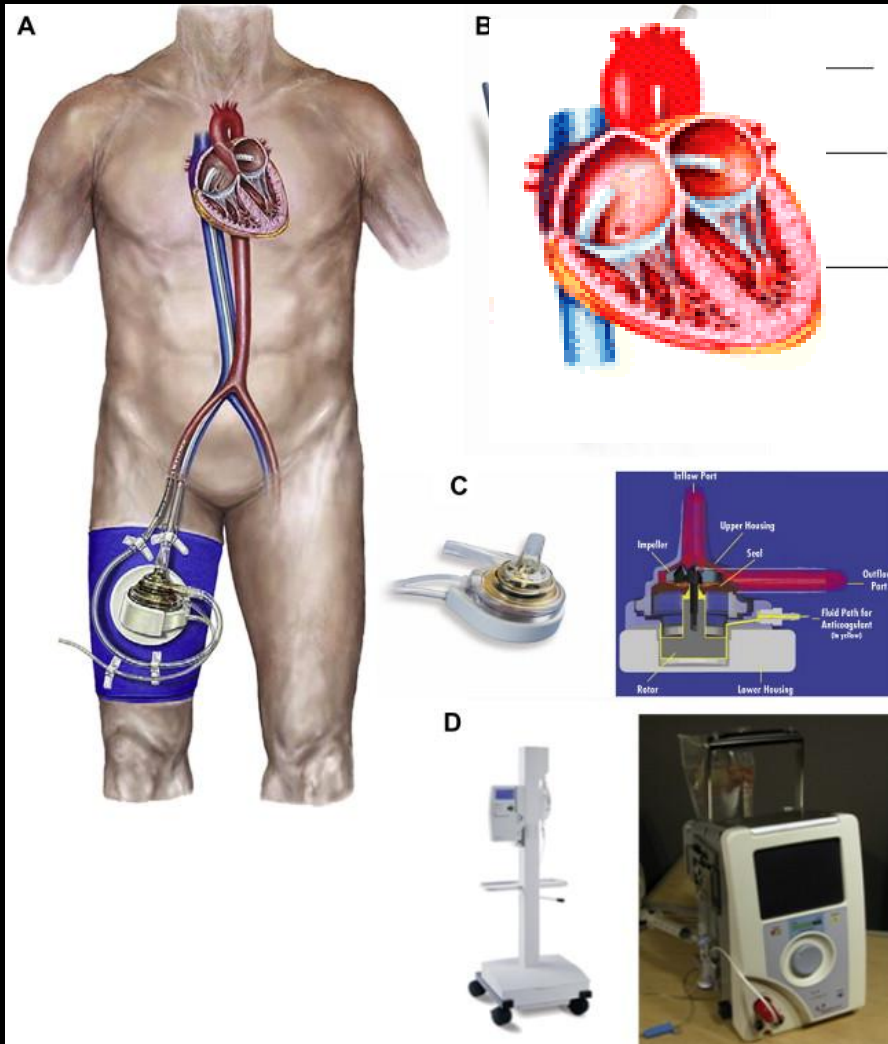
**Mortality rate significantly lower than the ranges accounted for
in previous trials such as the Shock Trial registry**




Tandem Heart pVAD



Tandem Heart pVAD



- Centrifugal Pump
- Inflow cannula into LA via femoral vein and transeptal puncture
- Outflow cannula into femoral artery
-  CO by 3.5 – 4 l/min



Pompe centrifughe

Forma di assistenza al circolo più frequentemente utilizzata

Semplicità di impianto e di utilizzo

Elevati flussi (fino 10L/min)

Possibilità di supporto mono e biventricolare

Diverse possibilità di cannulazione

LVAD Inflow: AS, apice VS Outflow: aorta asc, art fem, arco ao, art succl

Impianto senza utilizzo CEC

Basso grado di anticoagulazione (eparina ev, PTT 40-60'')

Costo inferiore rispetto ad altri sistemi di supporto



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Levitronix Centrimag

Magnetic levitation technology

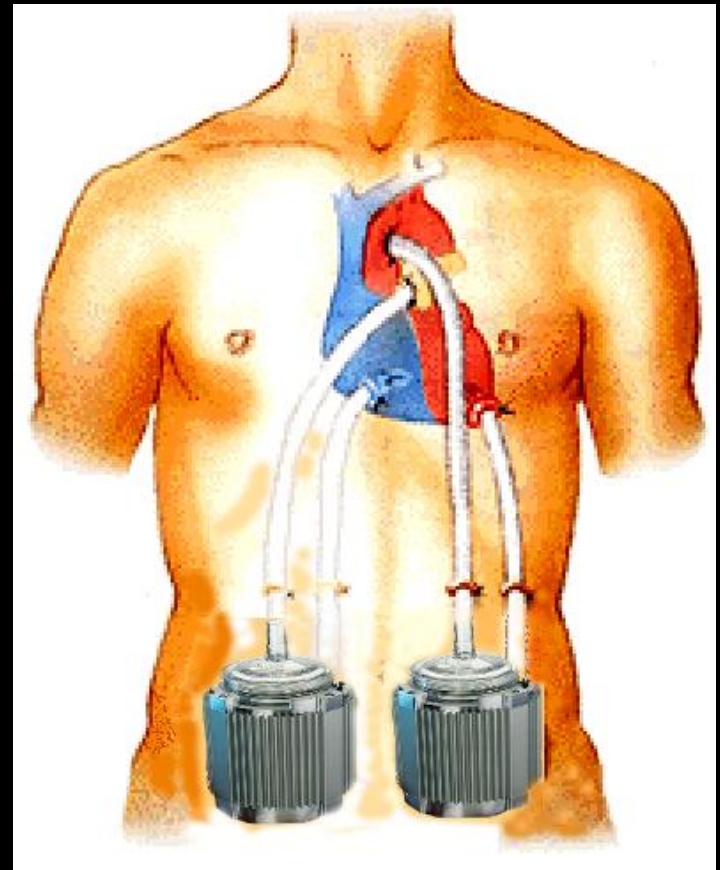
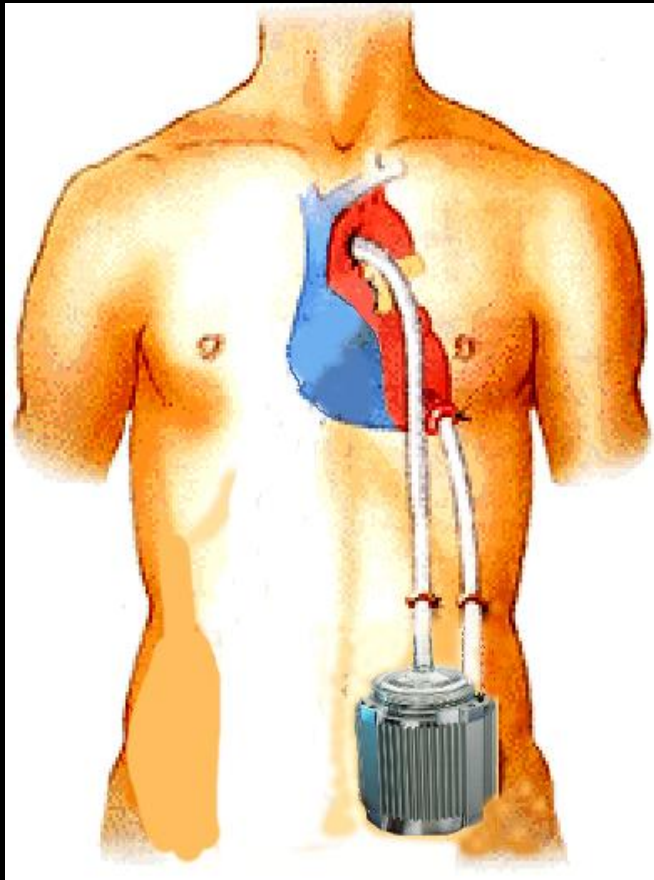


- Absence of**
- **mechanical or contact bearings**
 - **flexible valves**
 - **blood sacs**



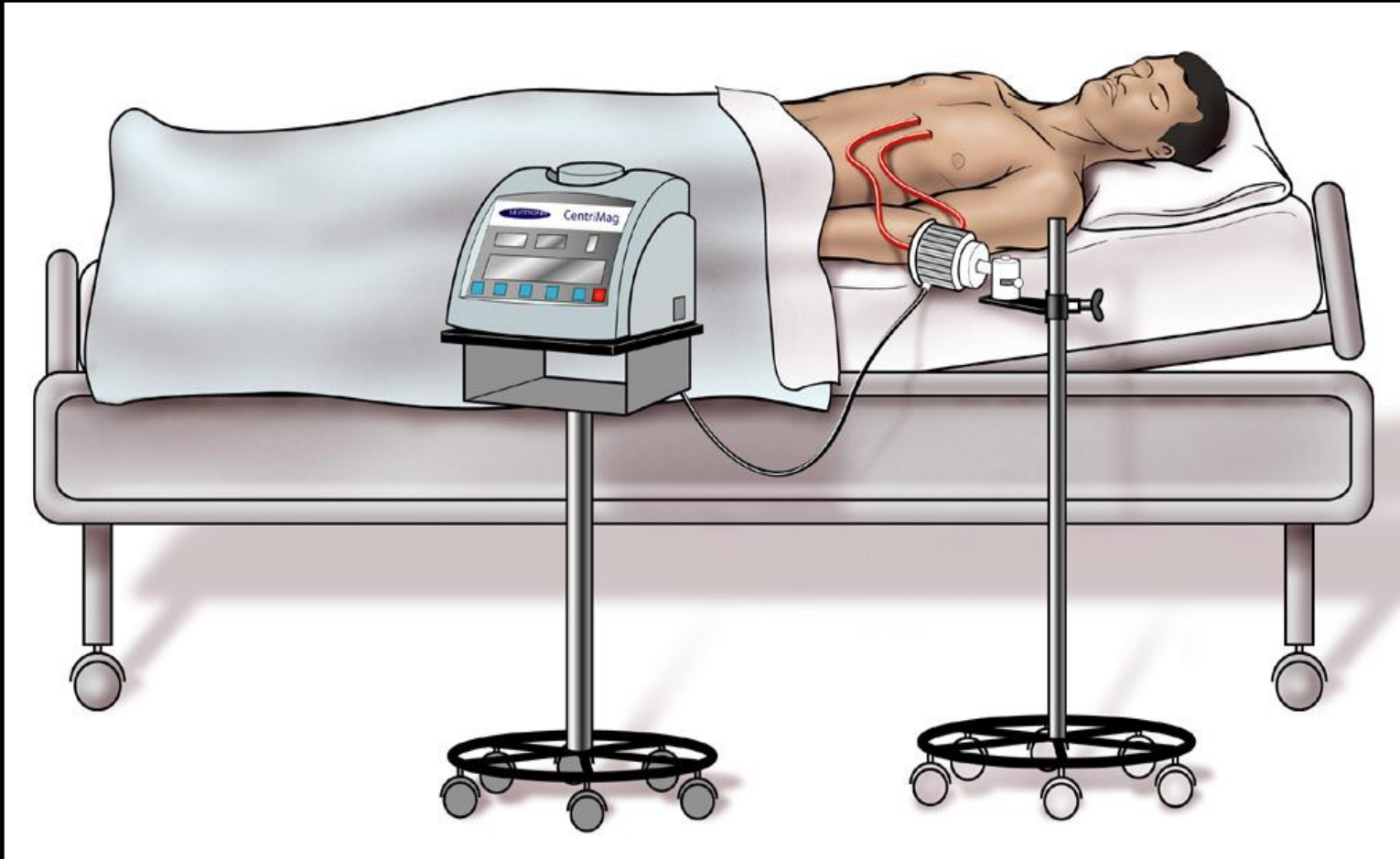
Levitronix Centrifugal Pump

Modalità di assistenza postcardiotomy shock



Levitronix Centrifugal Pump

Assistenza in Terapia Intensiva









Mechanical Circulatory Support for *Bridge to decision* : which Device



ExtraCorporeal Membrane Oxygenation (ECMO)



Short Term Device quale?

	ECMO (Biomedicus, Rotaflow, CardioHelp, LifeBridge)	CentriMAG (Levitronix)	Tandem Heart	Impella Recover	
					
Portata	Fino a 8 l/min	Fino a 7 l/min	Fino a 6 l/min	Fino a 2,5 l/min	Fino a 5 l/min
Cannulazione	Periferica / Centrale	Periferica / Centrale	Periferica	Periferica	Periferica / Centrale
Durata max del supporto	10 giorni	2 settimane	2 settimane	2 settimane	
Anticoagulazione	ACT > 180	ACT > 160	ACT > 180	aPTT > 60 sec	

Performance sovrapponibili
Esperienza del Centro
Matching Paziente/Device





Short Term Device quale?

Complications of percutaneous VAD

	Tandem Heart	Impella	ECMO
• Limb ischemia	+++	++	+++
• Hemolysis	++	++++	+++
• Bleeding risks	+++	++	++++
• Contraindications	Periph arterial disease RV failure	Periph arterial disease RV failure LV thrombus Severe AS	Periph arterial disease Contraind to anticoagulation



L'organizzazione come deve rispondere ?



Rete di collaborazione



Rete di collaborazione

FINALITA'

- Individuare i
rendere
monit
pz in
- Utilizza
valuta

Protocollo Operativo per lo Shock Cardiogeno

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di
iologici



Mechanical Circulatory Support for *Bridge to decision* : L'organizzazione come deve rispondere ?

Modello hub and spoke

Interprovincial spoke-to-hub transport using the Impella recover LP 5.0 LV assist device as bridge to long-term circulatory support

Can J Cardiol 2010

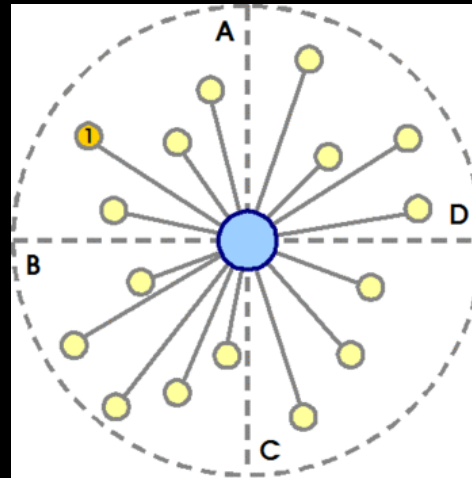
- ❖ Multilevel approach required for acute heart failure**
- ❖ Pts need to be appropriately stabilized**
- ❖ Resource allocation**



Modello *Hub & Spoke*

Aumento del
numero di
impianti

Learning curve
più breve per i
centri spoke



Riduzione del
tasso
di complicanze

↓ **COSTO**

↑ **EFFICACIA**

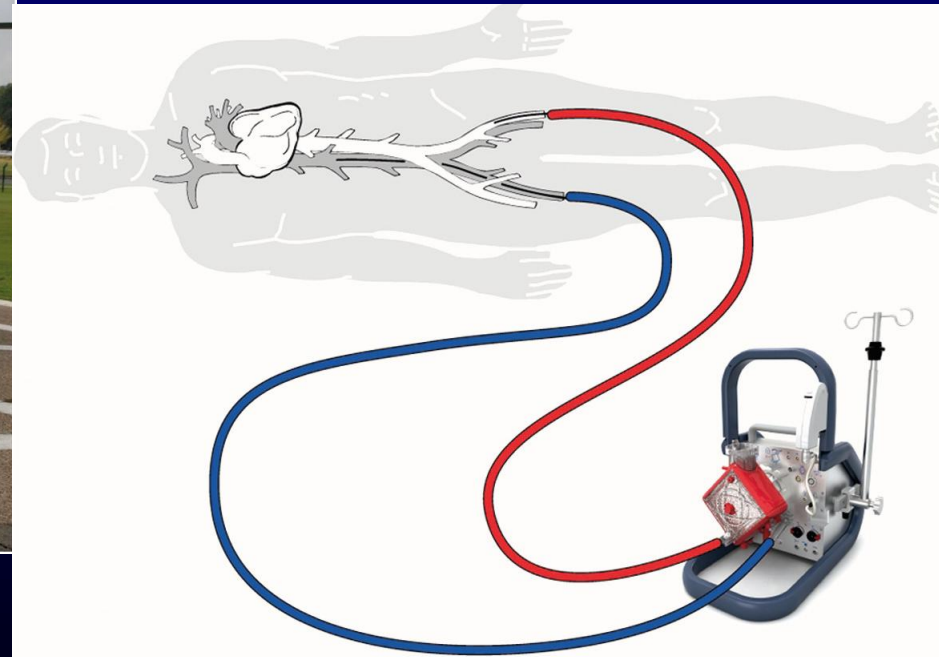
Mechanical Circulatory Support for *Bridge to decision* : L'organizzazione come deve rispondere ?

Modello hub and spoke

Newer minimized ECLS systems

Rapid insertion

Facilitated interhospital transport



Cardiohelp



ACUTE HEART FAILURE

Pompe microassiali bridge to

Short term support

Pompe centrifughe

Supporto > 24h
Trend Danno Renale
Trend Neurologico



TxC



Device long-term

