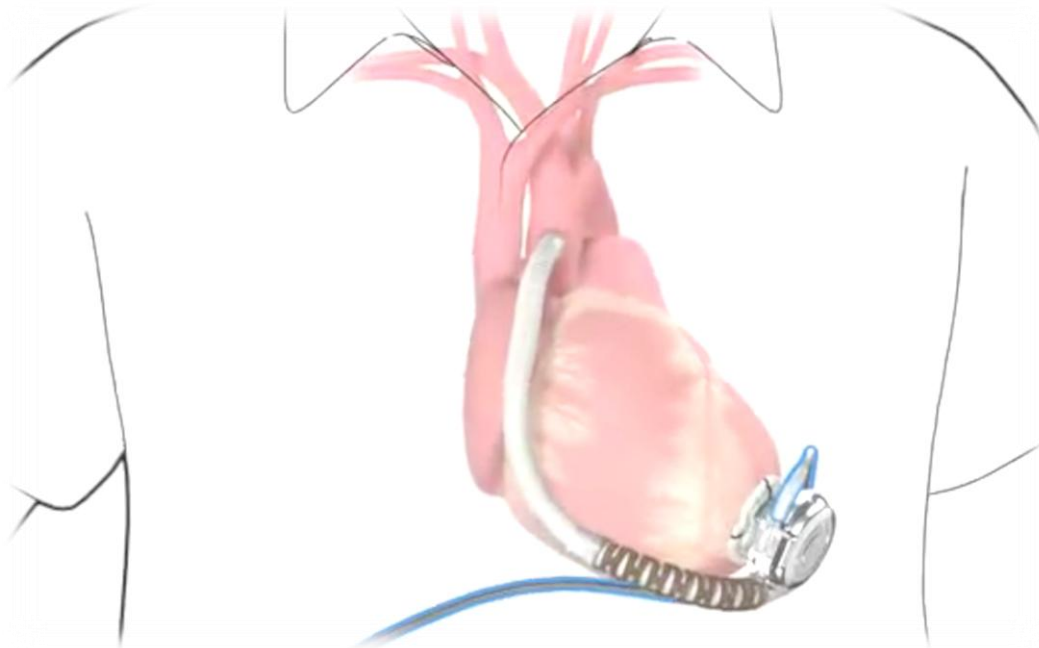




Congresso
**Novas Fronteiras
em Cardiologia**
7 a 9 de Fevereiro de 2014

Assistência Mecânica Ventricular

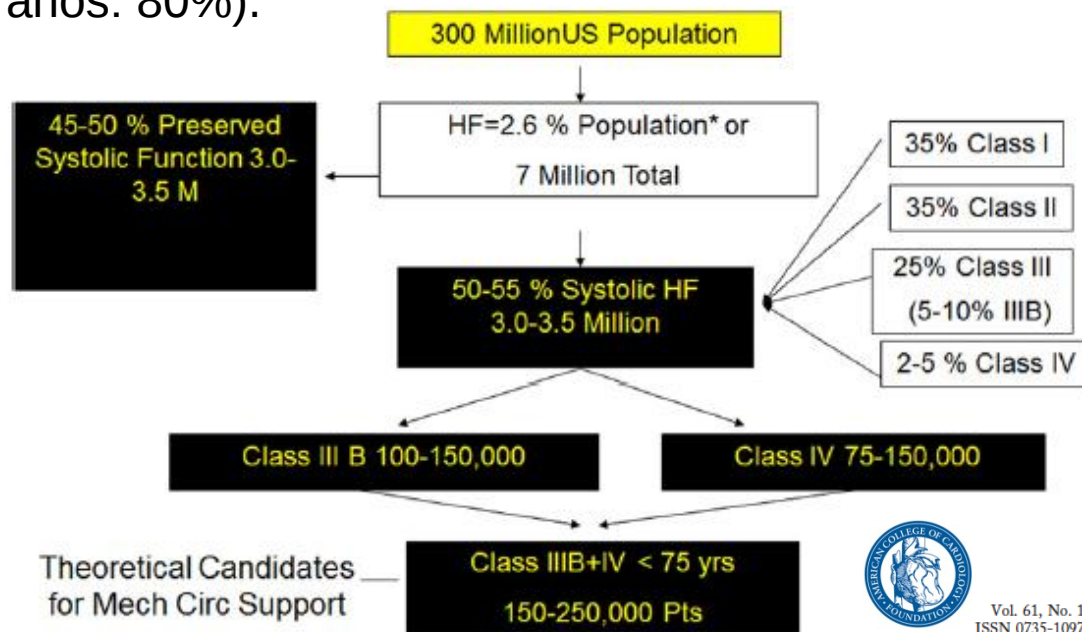


Rui Plácido
7 | Fevereiro | 2014

Insuficiência Cardíaca

- > 23 milhões de doentes a nível mundial; 1-2% indivíduos nos países desenvolvidos.
- Incidência relativamente estável; prevalência crescente.
- EUA: ~ 150 000 doentes em **estadio D** – “**end-stage HF**” (ACC / AHA)¹.
(taxa de mortalidade aos 5 anos: 80%).

ACC/AHA HF stages	
• High risk for developing HF • No structural disease	A
• Structural heart disease • No HF symptoms	B
• Structural heart disease • Prior or current HF symptoms	C
• Refractory end-stage HF requiring special interventions	D



Vol. 61, No. 12, 2013
ISSN 0735-1097/\$36.00
<http://dx.doi.org/10.1016/j.jacc.2012.08.1029>

¹Ammar KA et al. Prevalence and prognostic significance of heart failure stages: application of the American College of Cardiology/American Heart Association heart failure staging criteria in the community.

Insuficiência Cardíaca

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GOLD STANDARD

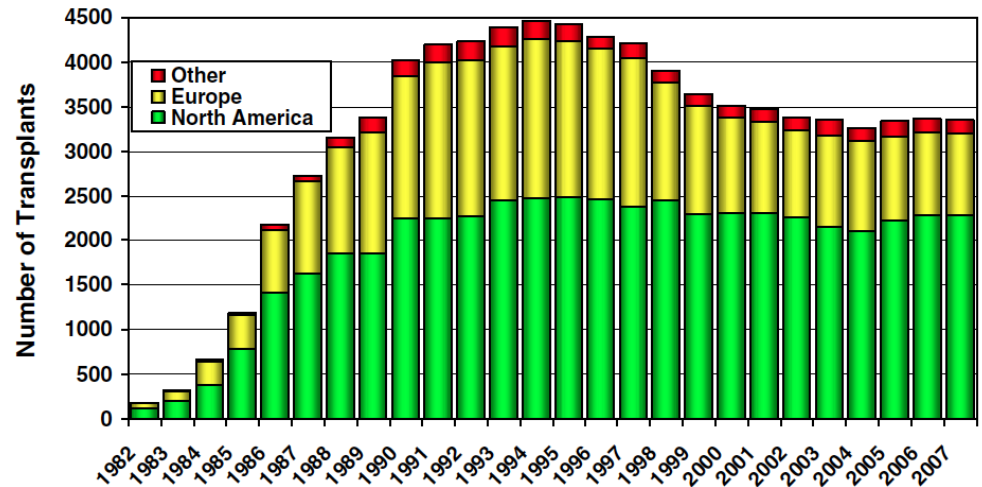
Tratamento da IC “*end-stage*”

Transplante Cardíaco

Insuficiência Cardíaca

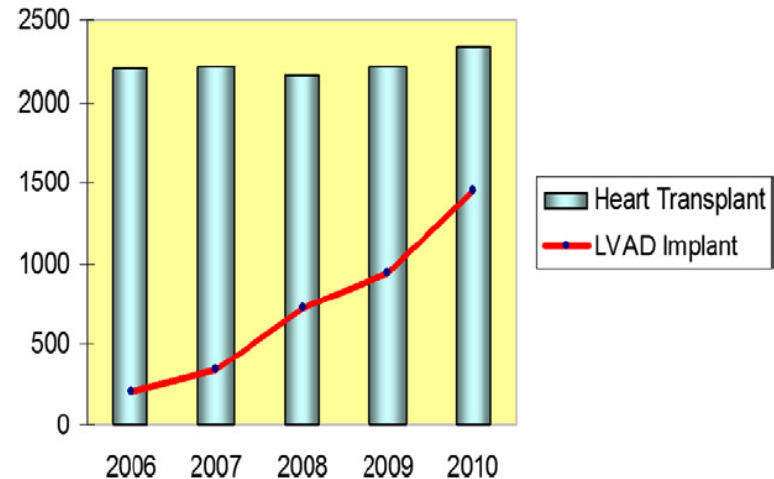
Transplante Cardíaco

- Sobrevida a 1 ano: 84%
- ↑↑ nº doentes em lista
- ~nº doentes transplantados
- Limitado número de dadores



Transplante Cardíaco

Assistência
Ventricular Mecânica

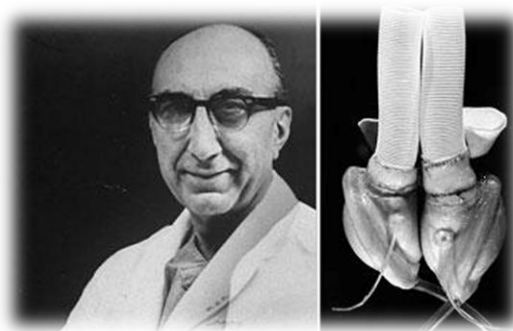


Dynamics of the Heart Transplant and LVAD
Implant Numbers in the United States 2006 to 2010

Assistência Mecânica Circulatória *Um pouco de história*

1960	1970	1980	1990	2000	2010
1963: First report of implantable artificial ventricle by Liotta 1964: NIH forms Artificial Heart Program 1966: First successful pneumatic LVAD implanted by DeBakey for post-cardiotomy wean and bridge to recovery 1969: Denton Cooley uses first TAH as bridge to transplant for postcardiotomy shock	1970: NIH forms working group to explore VADs 1977: NIH request for proposals for components of long-term implantable pumps 1978: Norman et al. report first use of LVAD as bridge to transplant for postcardiotomy stone heart syndrome	1980: NIH second request for proposals for long-term implantable LVAD 1982: Implant of first total artificial heart (Jarvik-7) intended for permanent support 1984: First successful implant of electrically-driven Novacor LVAD as bridge to transplant for chronic heart failure. 1984: CMS defines strategies for LVAD support	1992: FDA approves Abiomed 5000 as bridge to transplant 1994: FDA approves pneumatic LVAD (Thermo Cardiosystems) as bridge to transplant 1995: FDA approves electrical LVAD (Thoratec XVE) as bridge to transplant 1998: FDA approves Novacor and Thermo Cardiosystems LVADs as bridge to transplant	2001: REMATCH shows HeartMate XVE superior to optimal medical therapy for transplant-ineligible patients with advanced heart failure 2003: Landmark FDA approval of Thoratec HeartMate XVE for destination therapy 2004: Reports of SynCardia total artificial heart success as in-hospital bridge to transplant for biventricular failure leads to FDA approval 2006: Interagency Registry of Mechanically Assisted Circulatory Support (INTERMACS) established 2007: First report of continuous flow LVAD (Thoratec HeartMate II) as bridge to transplant 2008: FDA approves continuous flow LVAD (HeartMate II) for bridge to transplant 2009: Thoratec HeartMate II superior to HeartMate XVE as destination therapy	2010: FDA approves Thoratec HeartMate II for destination therapy 2010: Preliminary results of HeartWare intra-pericardial continuous flow VAD as bridge to transplant (ADVANCE study) 2011: NHLBI-sponsored REVIVE-IT study to compare LVAD with medical therapy in stable NYHA III patients

- 1964**
- National Institutes of Health, EUA
 - ***Artificial Heart Program***
 - Michael DeBakey
 - Desenvolvimento do primeiro protótipo de LVAD (*left ventricular assist device*)



Assistência Mecânica Circulatória *Um pouco de história*

1960	1970	1980	1990	2000	2010
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1966 • Implantação do primeiro LVAD



Assistência Mecânica Circulatória *Um pouco de história*

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1969 • Cooley implanta o primeiro coração artificial visando uma ponte - transplante.



Assistência Mecânica Circulatória *Um pouco de história*

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- 1982** • Implantação do primeiro **coração artificial total** (Jarvik-7®) – terapêutica definitiva.



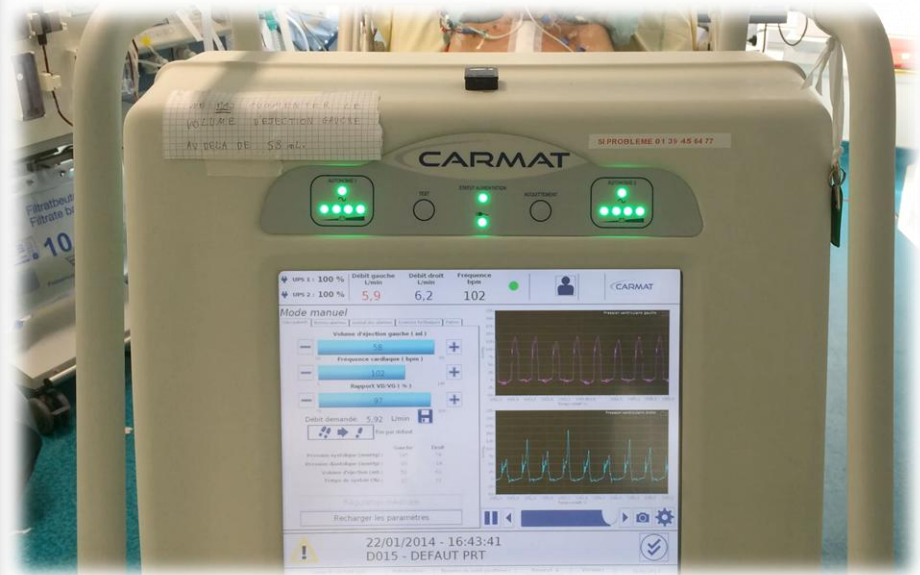
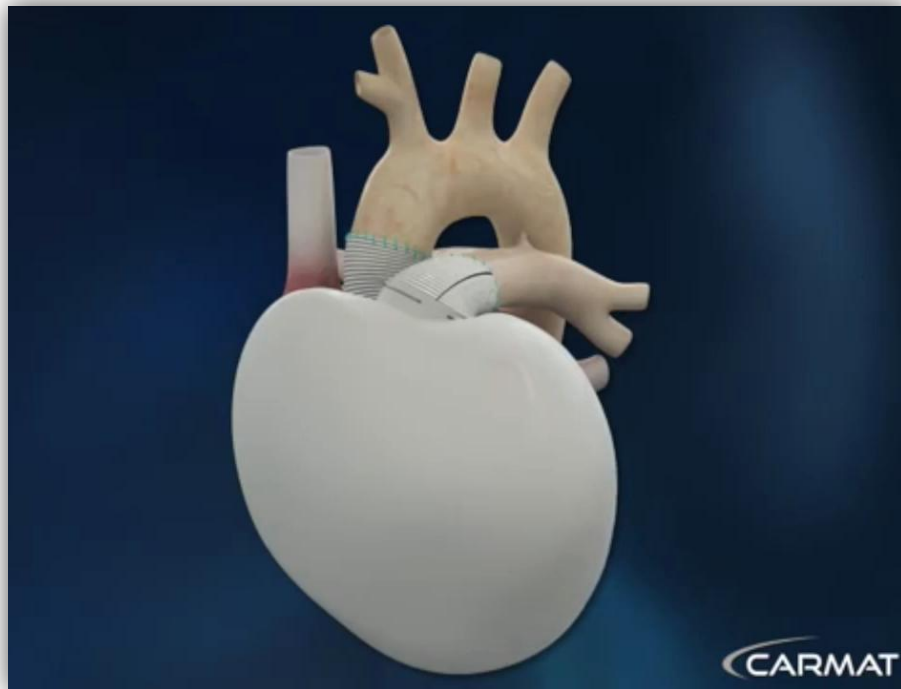
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- 1994** • FDA aprova o primeiro LVAD pneumático (ThermoCardioSystems®) – ponte para transplante



Assistência Mecânica Circulatória



18 Dezembro 2013

Implantação do primeiro coração artificial total bioprotésico auto-regulado.

CARMAT®

Hôpital Européen Georges Pompidou, Paris

Assistência Mecânica Circulatória

1. Indicações

2. Tipos de dispositivos

3. Fisiologia dos VADs

4. Complicações

5. *Outcome*



Indicações para Assistência Ventricular Mecânica



ELSEVIER

ISHLT GUIDELINES

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

The Journal of
Heart and Lung
Transplantation

<http://www.jhltonline.org>

Recommendations for surgical implantation of LVADs in patients with systolic heart failure

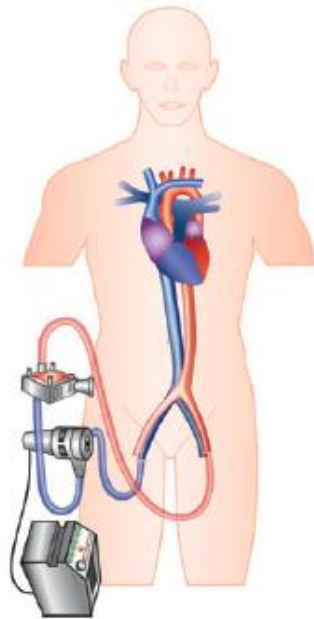
Recommendations	Class ^a	Level ^b	Ref ^c
An LVAD or BiVAD is recommended in selected patients ^d with end-stage HF despite optimal pharmacological and device treatment and who are otherwise suitable for heart transplantation, to improve symptoms and reduce the risk of HF hospitalization for worsening HF and to reduce the risk of premature death while awaiting transplantation.	I	B	254, 255, 258
An LVAD should be considered in highly selected patients ^d who have end-stage HF despite optimal pharmacological and device therapy and who are not suitable for heart transplantation, but are expected to survive >1 year with good functional status, to improve symptoms, and reduce the risk of HF hospitalization and of premature death.	IIa	B	254

Table 4 Guideline recommendations of percutaneous assist devices in cardiogenic shock complicating myocardial infarction

Indication	Assist device	European Guidelines	American Guidelines	German–Austrian Guidelines
Cardiogenic shock	IABP	IIb/B Intraaortic balloon pumping may be considered in patients with cardiogenic shock (Killip class IV)	IIa/B Haemodynamic support for patients with cardiogenic shock after STEMI who do not quickly stabilize with pharmacological therapy	↑ In patients undergoing fibrinolysis ⇔ In patients undergoing PCI ↑ In patients with mechanical complications
	Left ventricular assist devices	IIb/C LV assist devices may be considered for circulatory support in refractory shock in patients with cardiogenic shock (Killip class IV)	IIb/C Alternative left ventricular (LV) assist devices for circulatory support may be considered in patients with refractory cardiogenic shock.	Routine use not recommended

Indicações para Assistência Ventricular Mecânica

Ponte

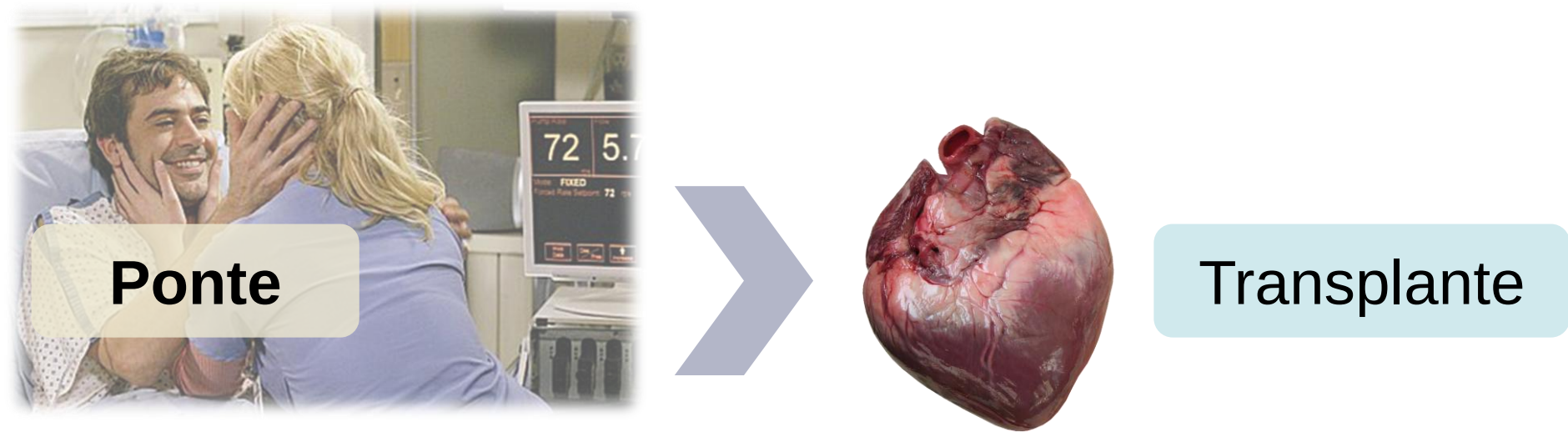


Recuperação



- Utilização de suporte mecânico circulatório para manter o doente vivo até **recuperação da função cardíaca.**

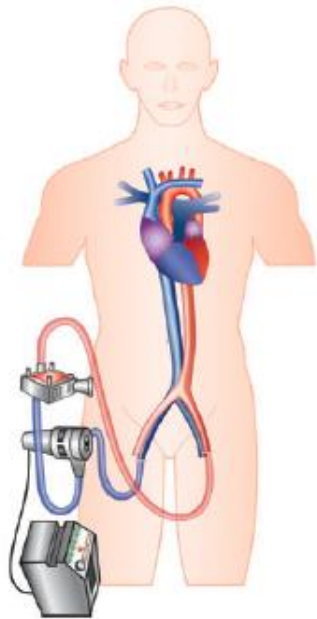
Indicações para Assistência Ventricular Mecânica



- Utilização de suporte mecânico circulatório para manter **o doente em lista de transplante** e com elevado risco de mortalidade, vivo até ao aparecimento de um dador.

Indicações para Assistência Ventricular Mecânica

Ponte



Decisão



- Utilização de suporte mecânico circulatório em doentes com colapso circulatório agudo e risco elevado de mortalidade imediata, até à **avaliação clínica completa e utilização de opções terapêuticas adicionais**.

40%

intermacs™

Interagency Registry for Mechanically
Assisted Circulatory Support

HOME

Indicações para Assistência Ventricular Mecânica

‘Destination Therapy’



- Utilização de suporte mecânico circulatório como **terapia definitiva** em doentes com IC avançada **contra-indicados** para transplante.

Indicações para Assistência Ventricular Mecânica

Critérios Gerais

Criteria for Inclusion Into Destination Therapy Clinical Trials

Trial	DEMATCH, 2001 (11)	HeartMate II, 2009 (12)
Clinical scenario	1. NYHA class IV for at least 90 days despite best medical therapy or 2. Inotrope dependence	1. NYHA class IIIB or IV for at least 45 days despite best medical therapy or for the 60 days before enrollment or 2. Intra-aortic balloon pump for 7 days or 3. Inotrope dependence for at least 14 days before enrollment.
LVEF	<25%	<25%
Peak oxygen consumption	≤ 12 ml/kg/min	≤ 14 ml/kg/min or <50% predicted

JACC Vol. 61, No. 12, 2013

March 26, 2013:1209-21

Critérios hemodinâmicos $CI < 2L/min/m^2$

Indicações para Assistência Ventricular Mecânica

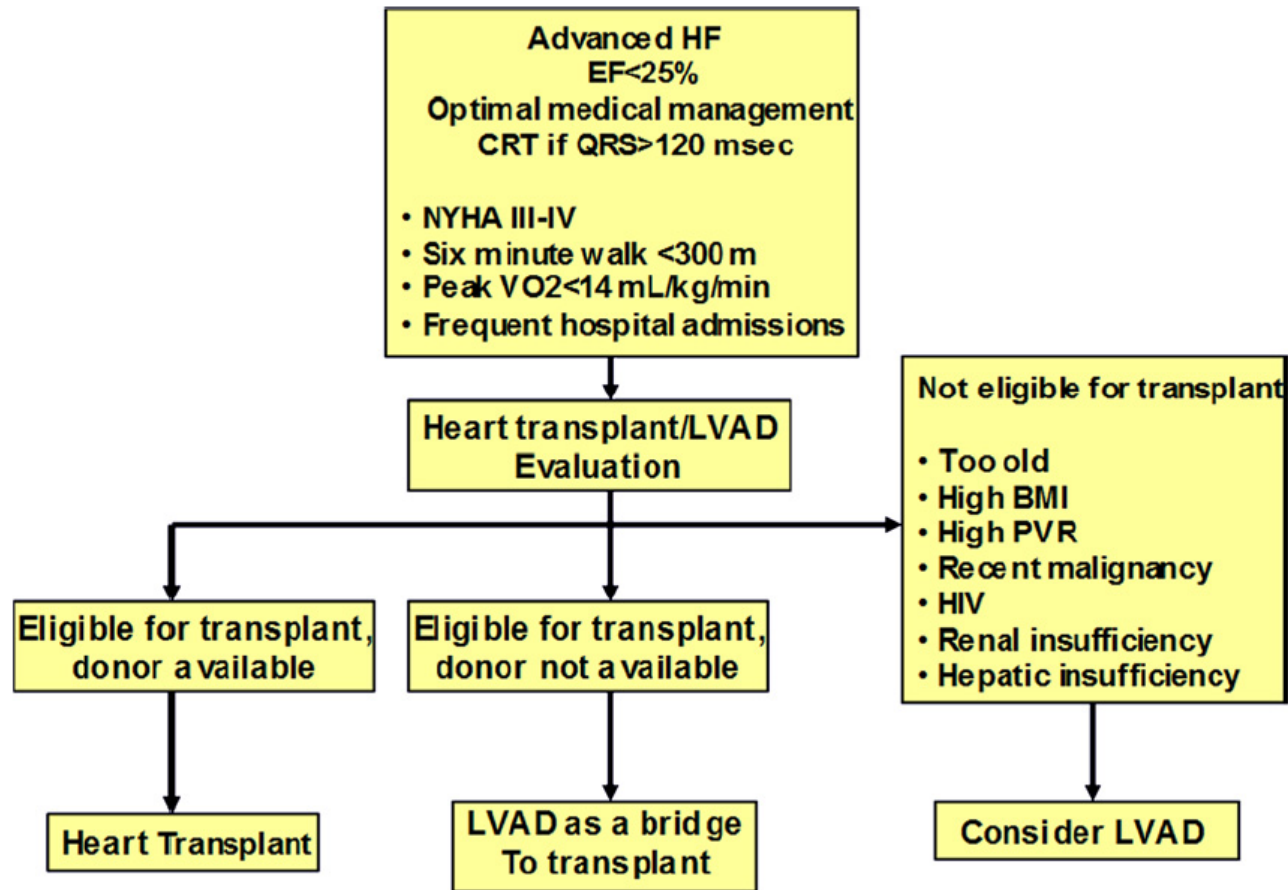


Device Strategy at Time of Implant	Implant Date Period							
	Pre 2011		2011		2012 (Jan-Jun)		Total	
	n	%	n	%	n	%	n	%
BTT Listed	1245	39.8%	421	22.6%	189	21.0%	2155	32.4%
BTT Likely	994	25.6%	417	22.4%	196	21.8%	1607	24.2%
BTT Moderate	392	10.1%	186	9.9%	79	8.8%	657	9.9%
BTT Unlikely	127	3.2%	75	4.0%	23	2.5%	225	3.3%
Destination Therapy	714	18.4%	725	38.9%	395	44.0%	1834	27.6%
BTR	57	1.4%	16	0.8%	9	1.0%	82	1.2%
Rescue Therapy	33	0.8%	9	0.4%	4	0.1%	46	0.6%
Other	14	0.3%	12	0.6%	1	0.4%	27	0.4%
Total	3876	100.0%	1861	100.0%	896	100.0%	6633	100.0%

- 67% Ponte – Transplante cardíaco
- 28% '*Destination therapy*'
- 1% Ponte – Recuperação

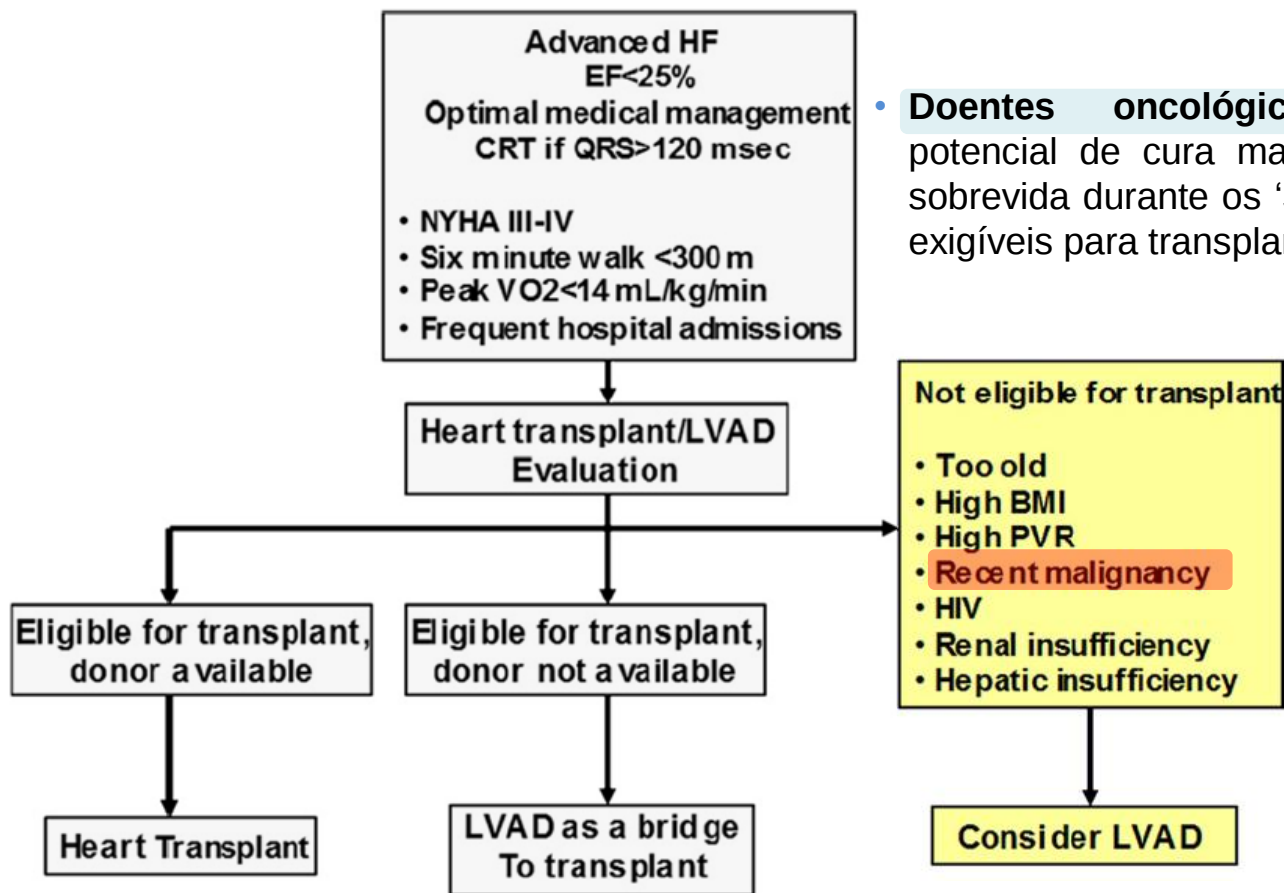
Indicações para Assistência Ventricular Mecânica

- Processo de Avaliação



Indicações para Assistência Ventricular Mecânica

- **Processo de Avaliação**

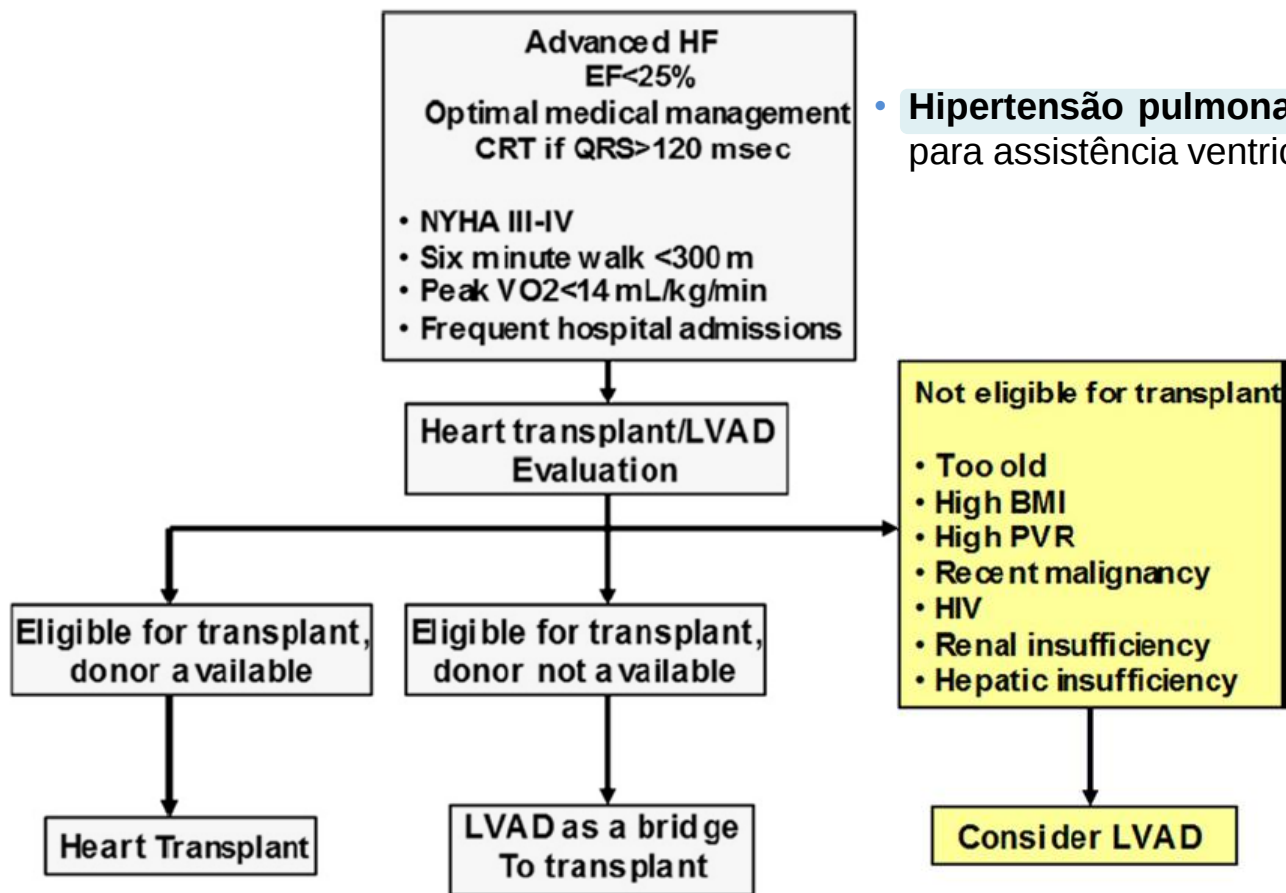


- **Doentes oncológicos** que apresentam potencial de cura mas cuja probabilidade de sobrevida durante os '5 anos livres de doença', exigíveis para transplante, é remota.



Indicações para Assistência Ventricular Mecânica

- Processo de Avaliação



- **Hipertensão pulmonar** não é contra-indicação para assistência ventricular mecânica.



Assistência Mecânica Circulatória

1. Indicações

2. Tipos de dispositivos

3. Fisiologia dos VADs

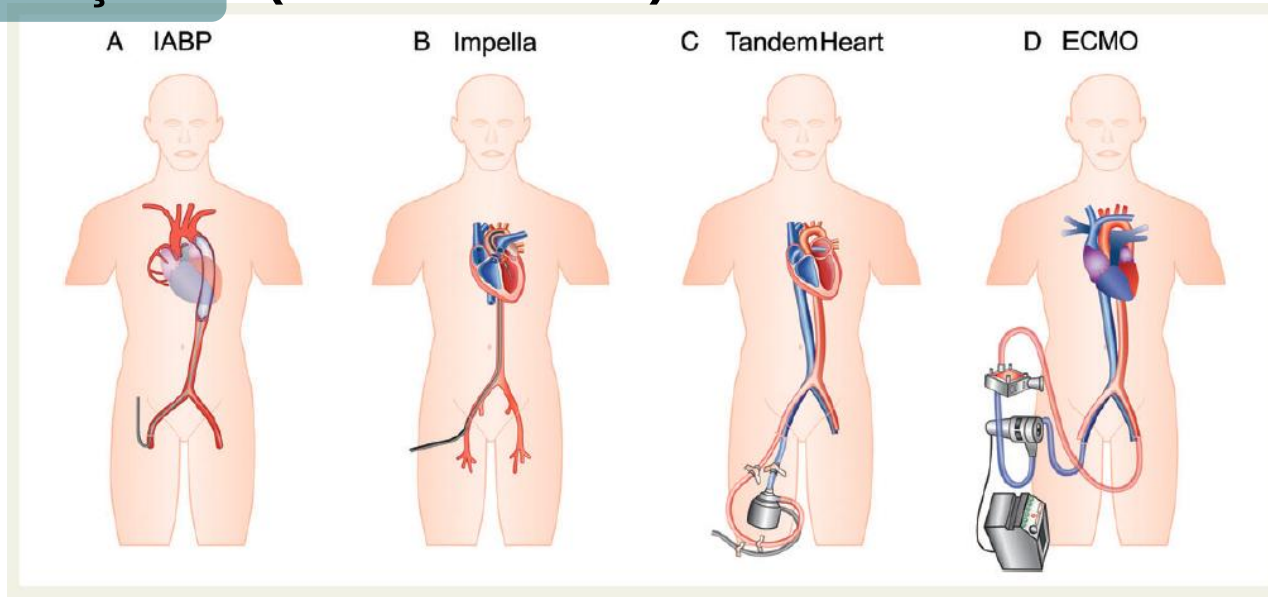
4. Complicações

5. *Outcome*

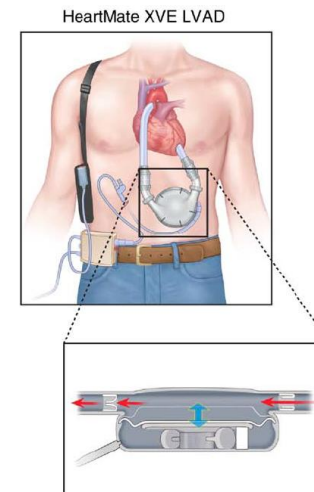
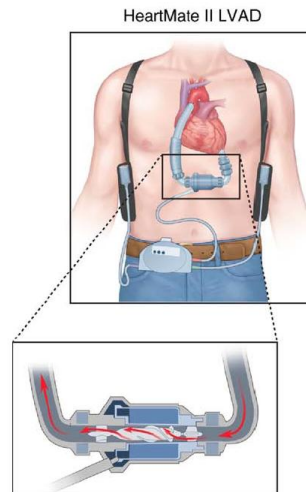
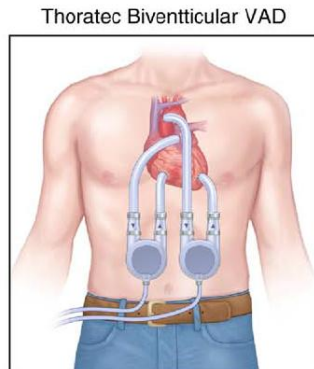
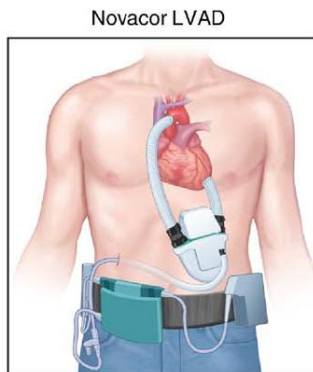


Tipos de Dispostivos de Assistência Mecânica Circulatória

Curta Duração (~ Percutâneos)



Longa Duração



Tipos de Dispostivos de Assistência Ventricular

Bombas

Fluxo Pulsátil

Fluxo Contínuo

JACC Vol. 54, No. 18, 2009
October 27, 2009:1647-59

Volume-Displacement Pumps (First-Generation Devices)

Rotary Blood Pumps (Second-Generation Devices)

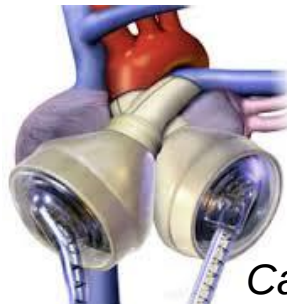
Axial Flow Pumps

Centrifugal Flow Pumps

Method of displacement	Pulsatile chamber or sac that fills passively or by suction and is compressed by external pusher plate	Continuous flow driven by a spinning rotor around a central shaft	Continuous flow driven by a hydrodynamic or electromagnetic suspended spinning rotor
Blood pressure	Cyclic, pulsatile flow	Constant, nonpulsatile flow	Constant, nonpulsatile flow
Valve	Inflow and outflow prosthetic valves	No valves	No valves
Devices implanted during cardiac surgery	HeartMate XVE, Novacor, Thoratec PVAD or IVAD, Abiomed 5000, LionHeart*	HeartMate II, Jarvik 2000,* MicroMed DeBakey,* Incor*	VentrAssist,* HVAD,* Terumo Dura Heart,* HeartWare,* HeartQuest,* MTIHeart LVAD*

Corações Artificiais Ortotópicos

Coração Parcial

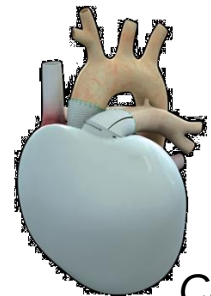


CardioWest

Coração Total



Abiomed



Carmat

Tipos de Dispostivos de Assistência Ventricular

Bombas

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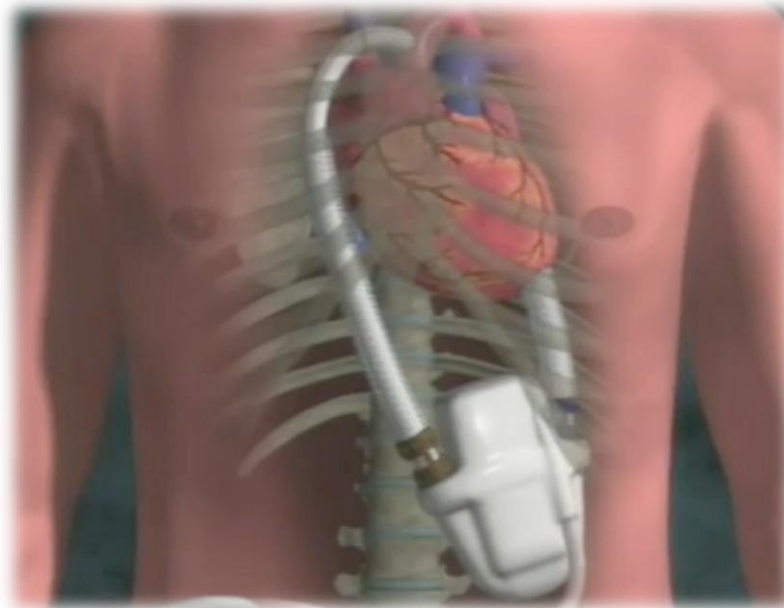
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- Cânulas de 'inflow' e 'outflow'
- Válvulas unidireccionais
- Bomba
- Bateria e Sistema de controlo
- Pneumáticos
- Electro-mecânicos



Tipos de Dispostivos de Assistência Ventricular

Bombas

Fluxo Pulsátil

Fluxo Contínuo

JACC Vol. 54, No. 18, 2009
October 27, 2009:1647-59

Volume-Displacement Pumps (First-Generation Devices)

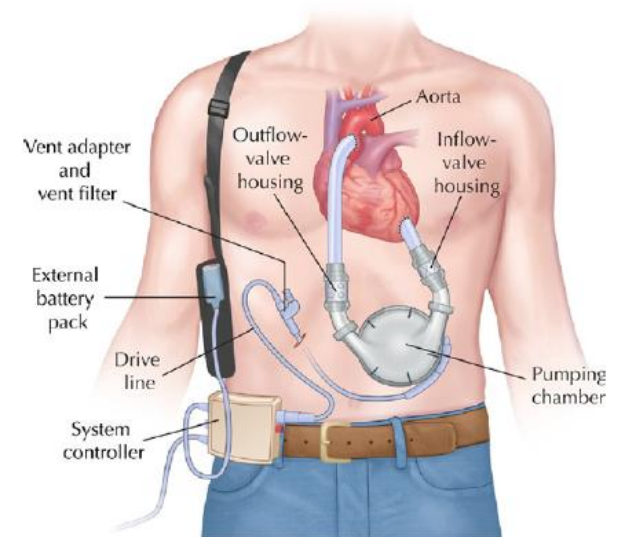
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- Tipicamente não sincronizados com actividade eléctrica cardíaca
- Regulados com VS fixo e FC variável
- Desvantagens: tamanho, peso, abordagem cirúrgica



HeartMate XVE LVAD

Tipos de Dispositivos de Assistência Ventricular

Bomba
s

Fluxo Pulsátil

Fluxo Contínuo

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Volume-Displacement Pumps
(First-Generation Devices)

Rotary Blood Pumps (Second-Generation Devices)

Axial Flow Pumps

Centrifugal Flow Pumps

Method of displacement	Pulsatile chamber or sac that fills passively or by suction and is compressed by external pusher plate	Continuous flow driven by a spinning rotor around a central shaft	Continuous flow driven by a hydrodynamic or electromagnetic suspended spinning rotor
Blood pressure	Cyclic, pulsatile flow	Constant, nonpulsatile flow	Constant, nonpulsatile flow
Valve	Inflow and outflow prosthetic valves	No valves	No valves
Devices implanted during cardiac surgery	HeartMate XVE, Novacor, Thoratec PVAD or IVAD, Abiomed 5000, LionHeart*	HeartMate II, Jarvik 2000,* MicroMed DeBakey,* Incor*	VentrAssist,* HVAD,* Terumo Dura Heart,* HeartWare,* HeartQuest,* MTIHeart LVAD*



Thoratec PVAD™
biventricular

Tipos de Dispostivos de Assistência Ventricular

Bombas

Fluxo Pulsátil

Fluxo Contínuo

JACC Vol. 54, No. 18, 2009
October 27, 2009:1647-59

Volume-Displacement Pumps (First-Generation Devices)

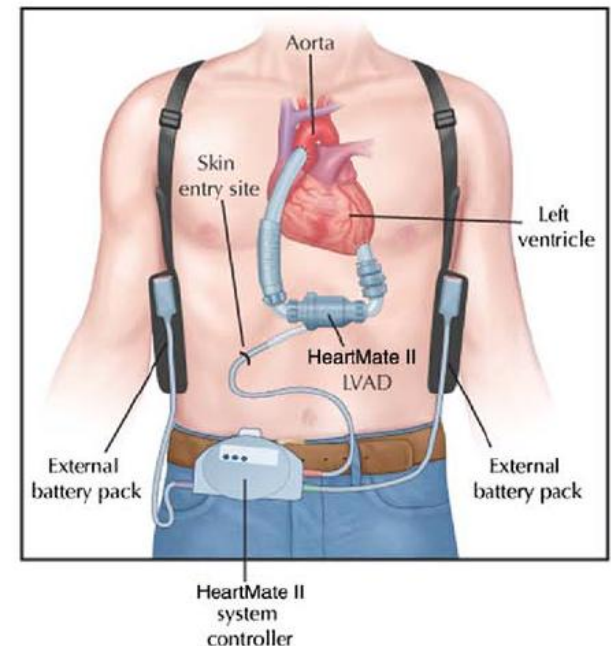
Rotary Blood Pumps (Second-Generation Devices)

Axial Flow Pumps

Centrifugal Flow Pumps

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- O sangue acelera através de motor sem rolamentos
- Sistemas avalvulados
- Ausência de câmaras complacentes
- Vantagens: reduzido tamanho, implantação cirúrgica menos invasiva, menos vibração e maior durabilidade.



Tipos de Dispostivos de Assistência Ventricular

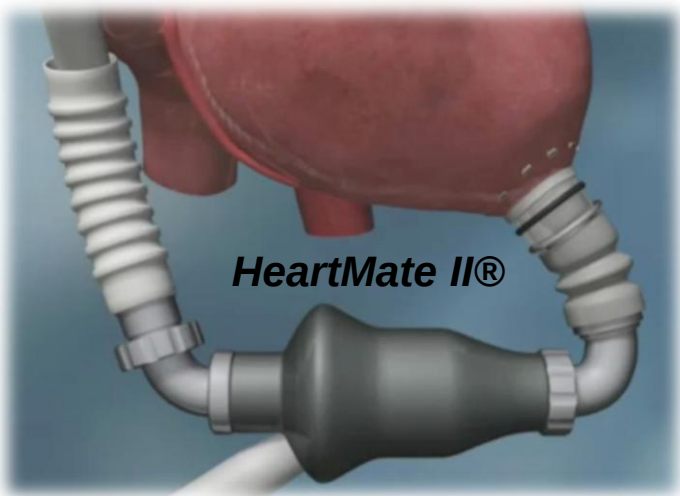
Bombas

Fluxo Pulsátil

Fluxo Contínuo

JACC Vol. 54, No. 18, 2009
October 27, 2009:1647-59

		Rotary Blood Pumps (Second-Generation Devices)	
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Bombas de fluxo axial
Deslocamento do sangue ao longo do eixo do rotor



Bombas centrífugas
Aceleração circunferencial do sangue

Tipos de Dispostivos de Assistência Ventricular

Bombas

Fluxo Pulsátil

Fluxo Contínuo

JACC Vol. 54, No. 18, 2009
October 27, 2009:1647-59

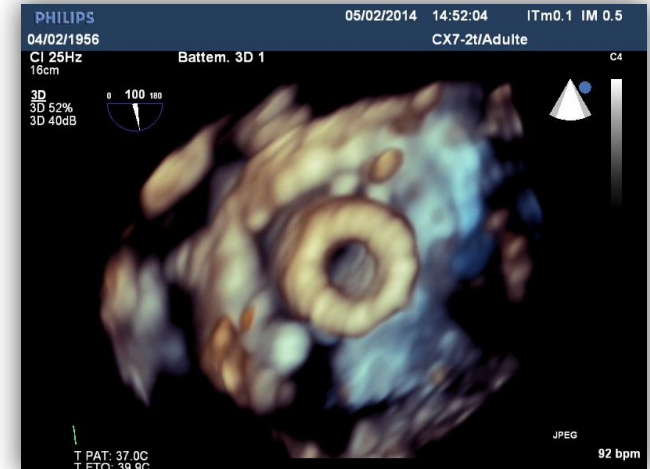
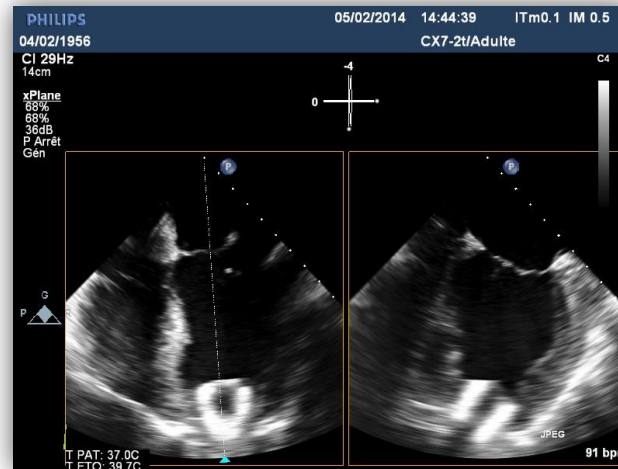
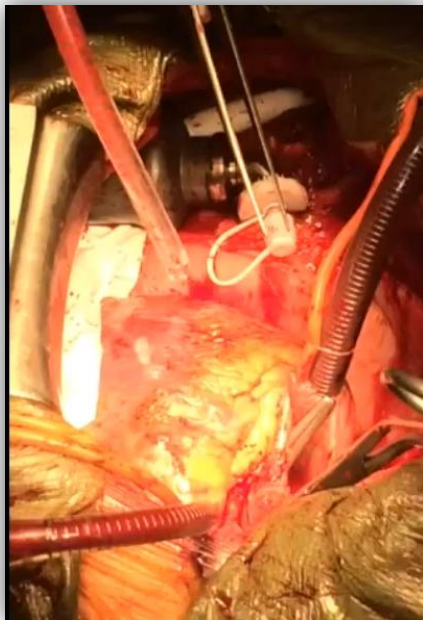
Volume-Displacement Pumps (First-Generation Devices)

Rotary Blood Pumps (Second-Generation Devices)

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HeartMate II®

Assistência Mecânica Circulatória

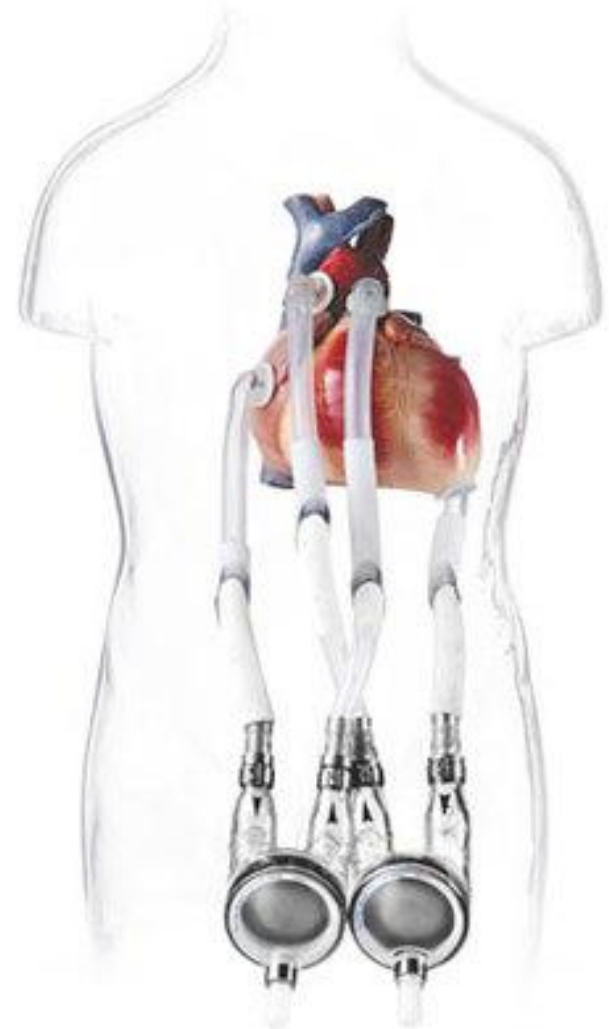
1. Indicações

2. Tipos de dispositivos

3. Fisiologia dos VADs

4. Complicações

5. *Outcome*



Fisiologia dos VADs

Objectivo Principal
VADs

Função de Bomba
Cardíaca

↓ 'stretching'
miocárdico



'Remodeling' reverso

Alterações da função miocitária

↓ *Miocitólise*

↓ *Citocinas*

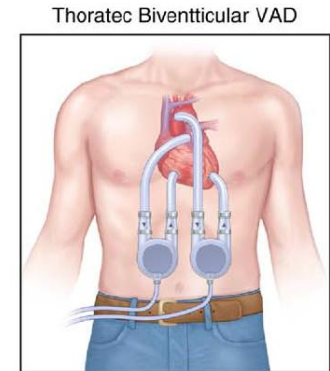
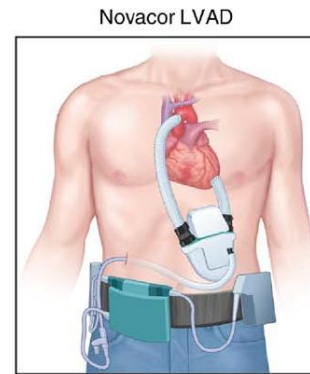
*'Disease-altering
pharmacological regimens
in VAD patients'*



Ponte – Recuperação

Fisiologia dos VADs

- Suporte ventricular mecânico por:
Descarga de pressão
Descarga de volume
- **Assistência monoventricular**
- **Assistência biventricular**



Sob condições ótimas, o **ventrículo nativo** é um conduto passivo através do qual a **bomba mecânica** é preenchida durante o ciclo cardíaco.

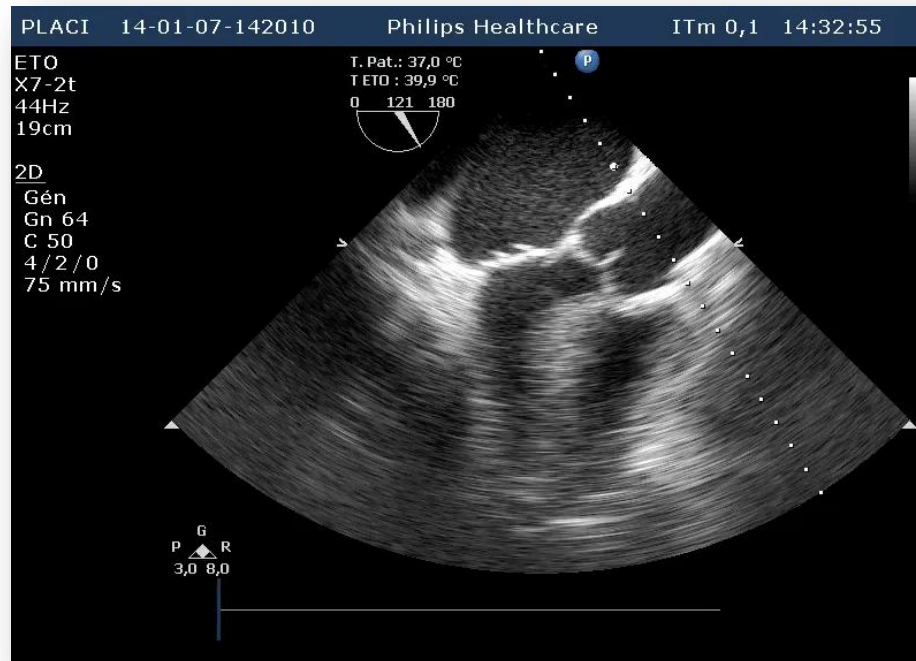
O ventrículo '*descomprimido*' deve contribuir pouco para o débito cardíaco sistêmico.

Fisiologia dos VADs

Volume sistólico gerado pelo ventrículo *descomprimido*
→ abertura valvular aórtica e/ou pulmonar (ecocardiografia)

2 Hipóteses:

- Recuperação da função ventricular
- Descarga inadequada do ventrículo nativo – ‘*difusão do device*’

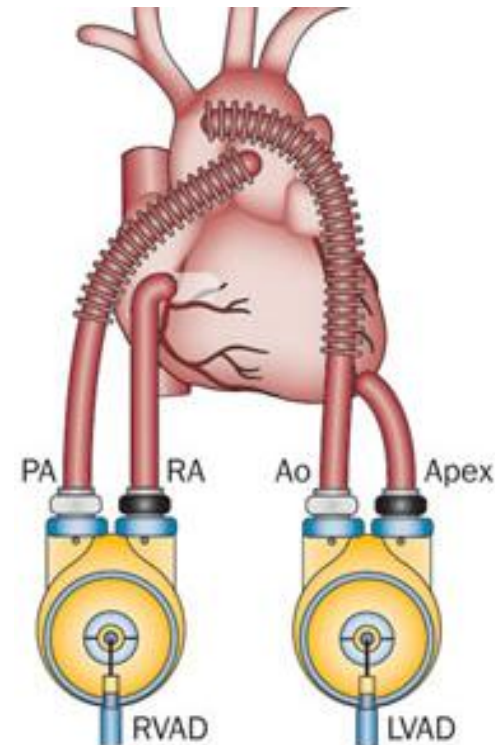


Fisiologia dos VADs

Suporte Biventricular

- Sistema de 2 bombas independentes
- Débitos diferentes $(Q_{LVAD} + Q_{LV}) / (Q_{RVAD} + Q_{RV}) > 1$
(circulação brônquica)

-  **Recuperação ventricular desproporcional**



Fisiologia dos VADs

Edema Pulmonar

Descarga Ventricular Esquerda

Inadequada

- ↑ Carga - - -> Isquemia miocárdica
- Lesão pulmonar



Cânula de descarga ventricular esquerda

Assistência Mecânica Circulatória

1. Indicações

2. Tipos de dispositivos

3. Fisiologia dos VADs

4. Complicações

5. Outcome

Falha
mecânica

Infecção

Trombose

Hemorragia

Insuficiência
a VD



Complicações

Falha mecânica

- Pode surgir em qualquer componente do VAD.
- Importante causa de mortalidade e morbidade, especialmente no suporte prolongado (*'destination'* e ponte-transplante).
- Estudo REMATCH (2001): 35% dos doentes experienciaram falha no sistema nos 24 meses após a implantação.
- Nos últimos anos, a segurança e durabilidade dos VADs tem sido otimizada.

Infecção

Trombose

Hemorragia

Insuficiência a VD



Complicações

Falha
mecânica

Infecção

Trombose

Hemorragia

Insuficiênci
a VD

- Principal causa de morte dos doentes com VADs.
- 2 semanas – 2 meses após implantação.
- Flora saprófita da pele >> Enterococcus >> Gram (-)
- Ponto de partida mais frequente: orifício de entrada da '*driveline*' percutânea.



Treatment

Driveline Infection

Treatment: optimize nutrition, wound care, driveline immobilization, vacuum-assisted closure system, creation of new driveline exit site (if refractory)
Antibiotics: topical and systemic antibiotics (gram positive organisms–staphylococcal)

Pump Pocket Infection

Treatment: exploration and drainage of pocket, placement of drainage catheter and culture fluid
Antibiotics: broad spectrum antibiotics for gram positive (including MRSA) and negative organisms

Pump Endocarditis

Treatment: replacement of VAD with alternative assist device or cardiac transplantation (if stable)
Antibiotics: broad spectrum antibiotics for gram positive (including MRSA) and negative organisms
Antifungal: may need antifungal therapy

Complicações

Falha
mecânica

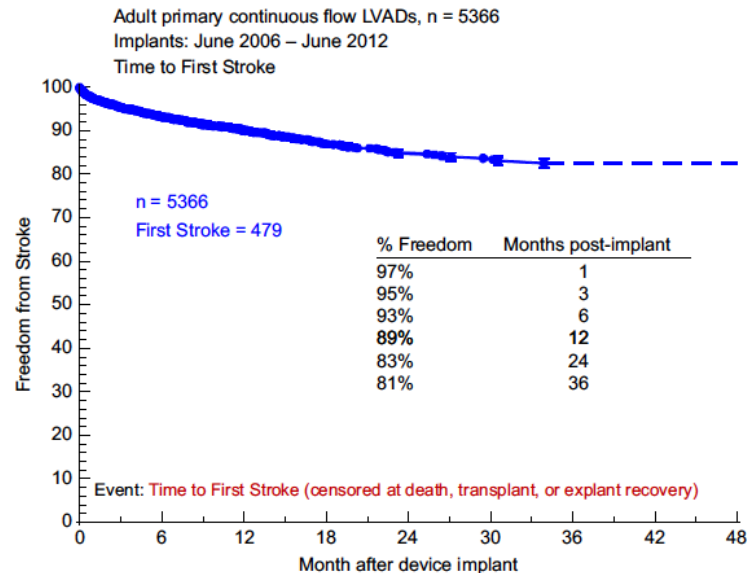
Infecção

Trombose

Hemorragia

Insuficiênci
a VD

- Os VADs são susceptíveis a eventos tromboembólicos devido às suas propriedades não totalmente hemocompatíveis.
- **Complicações neurológicas** (AVCs isquêmicos e AITs):
 - Prevalência variável de acordo com os estudos e tipo de *devices*.
- Nos últimos anos os materiais têm vindo a ser optimizados (↓ trombogenicidade)



Complicações

Falha
mecânica

Infecção

Trombose

Hemorragia

Insuficiência
a VD

- Os VADs são susceptíveis a eventos tromboembólicos devido às suas propriedades não totalmente hemocompatíveis.
- **Complicações neurológicas** (AVCs isquêmicos e AITs):
 - Prevalência variável de acordo com os estudos e tipo de *devices*.
- Nos últimos anos os materiais têm vindo a ser optimizados (↓ trombogenicidade)
- Prevenção farmacológica dos eventos tromboembólicos:
 - Variável de acordo com o tipo de *device*

	HeartMate XVE	WorldHeart Novacor	Thoratec VAD System	HeartMate II	Jarvik 2000
Position	Internal	Internal	Internal or external	Internal	Internal
Patient size	Large	Large	Small to large	Small to large	Small
Power	Electric	Electric	Pneumatic	Electric	Electric
Capability	LVAD	LVAD	LVAD, RVAD, or BIVAD	LVAD	LVAD
Duration	Yrs	Yrs	Possibly yrs	Yrs	Possibly yrs
Recommended anticoagulation					
Antiplatelet therapy	Yes	No	No	Yes	No
Warfarin therapy	No	Yes	Yes	Yes	Yes

Complicações

Falha
mecânica

Infecção

Trombose

Hemorragia

Insuficiênci
a VD

- **Antiagregação** plaquetária / **anticoagulação** sistêmica
- **Doença de *von Willebrand*** adquirida

↑ Incidência de hemorragia gastrointestinal em doentes portadores de VADs de fluxo contínuo.

↓ pressão pulso ---> hipoperfusão relativa do intestino ---> **angiodisplasia**

Complicações

Falha
mecânica

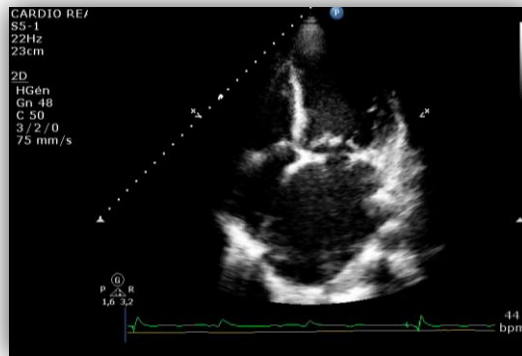
Infecção

Trombose

Hemorragia

Insuficiência
a VD

- **Falência ventricular direita pós-colocação de LVAD**
Associada a elevada mortalidade e re-operação.



A maioria dos doentes em choque cardiogénico ou insuficiência cardíaca avançada refractários à terapêutica médica podem ser suportados apenas com assistência ventricular esquerda



20% de risco de falência ventricular direita

Adequada selecção dos candidatos a assistência monoventricular esquerda

(Ainda não estão estabelecidos quais os critérios ideais predizentes de falência ventricular direita pós-colocação de LVAD)

Complicações

Falha mecânica

Infecção

Trombose

Hemorragia

Insuficiência a VD

1216 Miller and Guglin
Patient Selection for VADs

JACC Vol. 61, No. 12, 2013
March 26, 2013:1209–21

Table 3 Risk Factors for RV Failure After LVAD Implantation

			Risk Factors for Post-VAD RV Failure	
Fisrt Author, Year (Ref. #)	n	No. of RV Failures (%)	Factors Related to Pre-Operative RV Dysfunction	Factors Unrelated to Pre-Operative RV Dysfunction
Pulsatile LVADs				
Kormos et al., 1996 (78) Novacor	40	17 (42.5)	1. Greater need for inotropic agents 2. Lower RVEF/inotropic need ratio 3. None of the patients with RVEF >20% developed RV failure 4. Higher creatinine	1. Lower mixed venous oxygen saturation 2. Pulmonary edema 3. Poor mental status 4. Fever without infection
Fukamachi et al., 1999 (38) HeartMate I	100		1. Lower pre-operative mean pulmonary arterial pressure 2. Lower RV stroke work index 3. Elevated aspartate aminotransferase	1. Younger age 2. Female 3. Smaller patients 4. Myocarditis
Kavarana et al. 2002 (39) HeartMate I	69	21 (30.4)	1. Higher bilirubin 2. Trend toward lower preoperative RV stroke work index	1. Intra-operative bleeding
Ochiai et al., 2002 (40) 189 HeartMate I (77%) and 56 Novacor (23%)	245		1. Non-ischemic cause 2. Preoperative circulatory support 3. Low mean and diastolic pulmonary arterial pressure 4. Low RV stroke work 5. Low RV stroke work index	1. Female 2. Small body surface area
Dang et al., 2006 (33) HeartMate I	108	42 (38.9)	1. Elevated intra-operative central venous pressure 2. Intra-operative lower systolic and mean blood pressure 3. Lower intra-operative pulmonary arterial pressure	1. Female
Santambrogio, et al., 2006 (44) Novacor	48	8 (16)	1. Higher aspartate aminotransferase 2. Higher alanine aminotransferase. Higher blood urea nitrogen 3. Higher blood urea nitrogen 4. Higher creatinine 5. Lower pulmonary arterial pressure	1. Pre-operative mechanical ventilation

Assistência Mecânica Circulatória

1. Indicações

2. Tipos de dispositivos

3. Fisiologia dos VADs

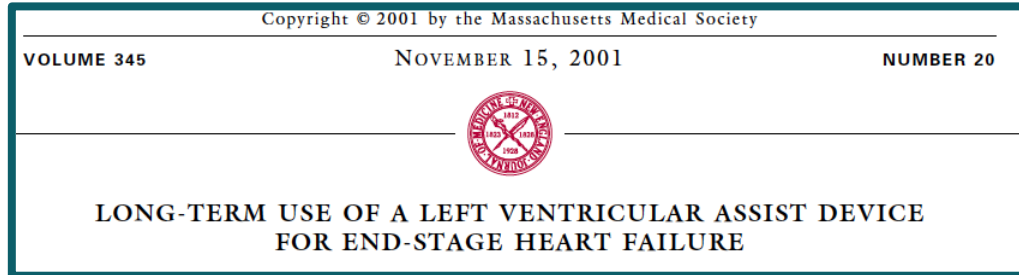
4. Complicações

5. Outcome



Outcome – ‘The Rise of The Machines’

REMATCH trial



- **Grupo dos devices** - ↓ 48% risco mortalidade (qualquer causa)
- Sobrevivência a **1 ano**:
 - Grupo dos devices: 52%
 - Grupo da terapêutica médica: 28%
- Sobrevivência aos **2 anos**:
 - Grupo dos devices: 23%
 - Grupo da terapêutica médica: 8%

- Primeiro estudo multicêntrico a avaliar o benefício em termos de sobrevida do uso da assistência ventricular mecânica.
- 129 doentes com IC classe IV NYHA contraindicados para transplante randomizados para LVAD *versus* terapêutica médica

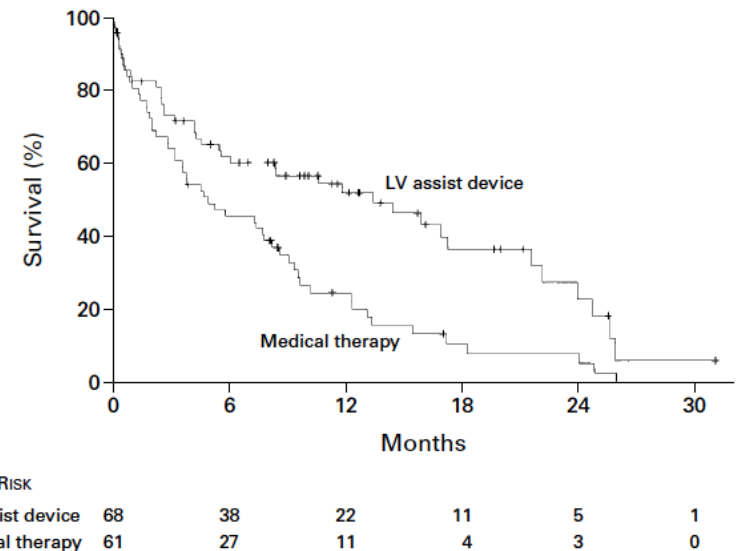


Figure 2. Kaplan–Meier Analysis of Survival in the Group That Received Left Ventricular (LV) Assist Devices and the Group That Received Optimal Medical Therapy.

Outcome – ‘The Rise of The Machines’

REMATCH trial

Copyright © 2001 by the Massachusetts Medical Society

VOLUME 345

NOVEMBER 15, 2001

NUMBER 20



LONG-TERM USE OF A LEFT VENTRICULAR ASSIST DEVICE
FOR END-STAGE HEART FAILURE

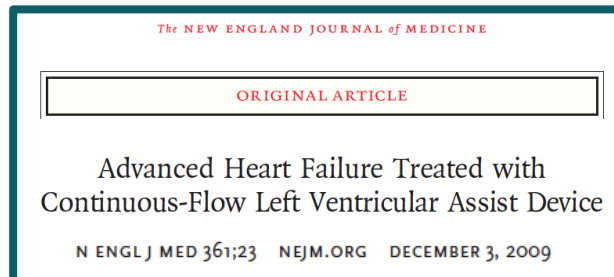
- **Grupo dos devices** – principais causas de morte
 - Sepsis (41%)
 - Falha do sistema (17%)

- Primeiro estudo multicêntrico a avaliar o benefício em termos de sobrevida do uso da assistência ventricular mecânica.
- 129 doentes com IC classe IV NYHA contraindicados para transplante randomizados para LVAD *versus* terapêutica médica

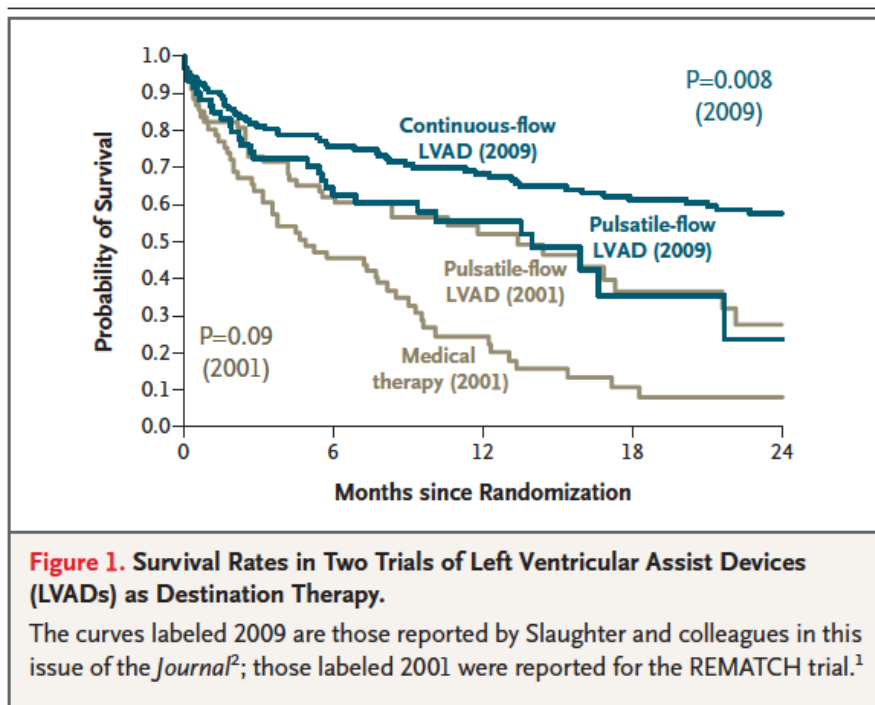
CAUSE OF DEATH	MEDICAL- THERAPY GROUP	LVAD GROUP	TOTAL
	no. of patients		
Left ventricular dysfunction	50	1	51
Sepsis	1	17	18
Failure of LVAD	0	7	7
Miscellaneous noncardiovascular causes	0	5	5
Cerebrovascular disease	0	4	4
Miscellaneous cardiovascular causes	1	2	3
Pulmonary embolism	0	2	2
Acute myocardial infarction	1	0	1
Cardiac procedure	1	0	1
Perioperative bleeding	0	1	1
Unknown	0	2	2
Total	54	41	95

Outcome

HeartMate I destination therapy trial



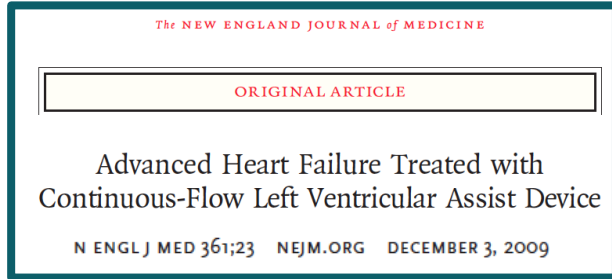
- Primeiro estudo comparativo entre devices de fluxo pulsátil e contínuo.
- 200 doentes com IC terminal randomizados para LVAD de fluxo pulsátil (HeartMate I) vs contínuo (HeartMate II); '*destination therapy*'.



- Sobrevivência a **1 ano**:
 - Grupo fluxo pulsátil: 58%
 - Grupo fluxo contínuo: 68%
- Sobrevivência aos **2 anos**:
 - Grupo fluxo pulsátil: 24%
 - Grupo fluxo contínuo: 55%
- **REMATCH trial (2001) vs HeartMate I destination therapy trial (2009)**:
 - a taxa de sobrevivência dos doentes com device de fluxo pulsátil foi sobreponível

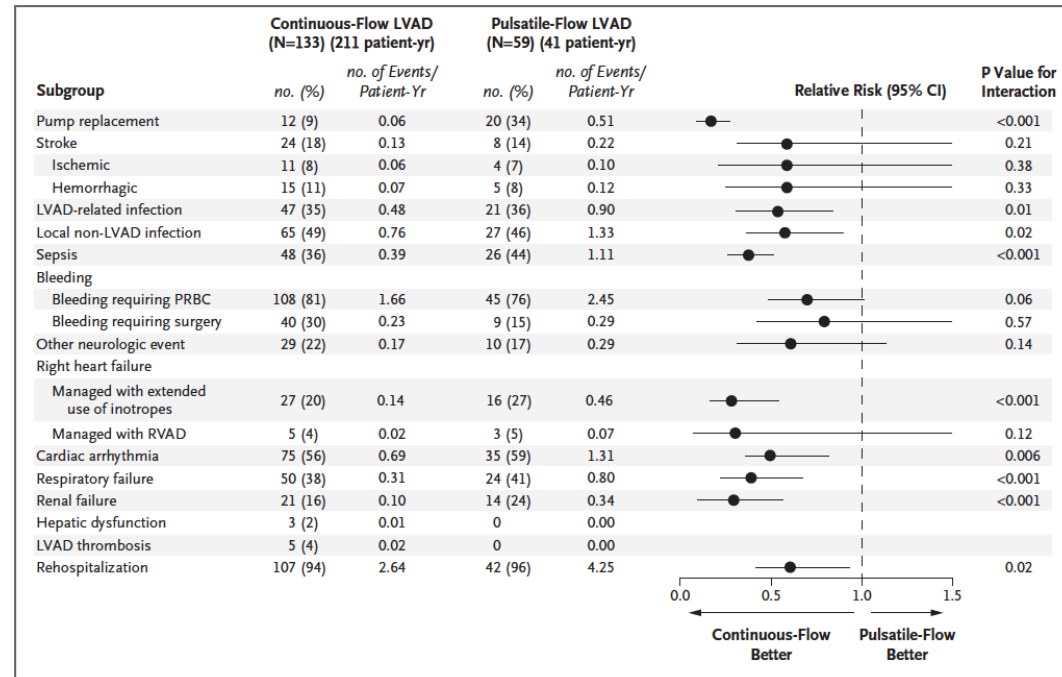
Outcome

HeartMate I destination therapy trial



- Primeiro estudo em comparativo entre devices de fluxo pulsátil e contínuo.
- 200 doentes com IC terminal randomizados para LVAD de fluxo pulsátil (HeartMate I) vs contínuo (HeartMate II); '*destination therapy*'.

- Grupo dos devices de fluxo contínuo
 - ↓ efeitos adversos (infecções, falha mecânica).

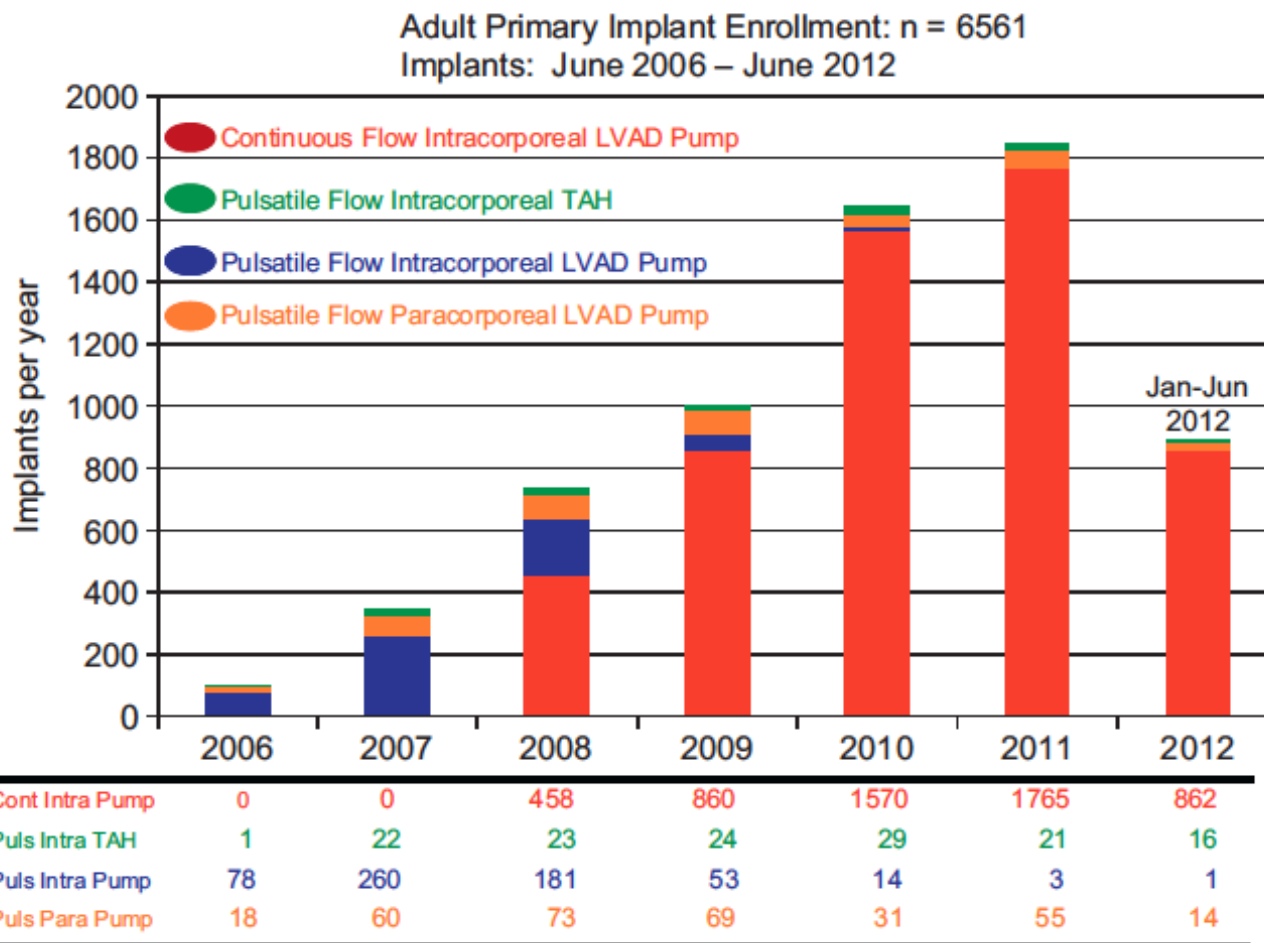


Outcome

Fifth INTERMACS annual report: Risk factor analysis from more than 6,000 mechanical circulatory support patients

J Heart Lung Transplant 2013;32:141–156

© 2013 International Society for Heart and Lung Transplantation.



Outcome

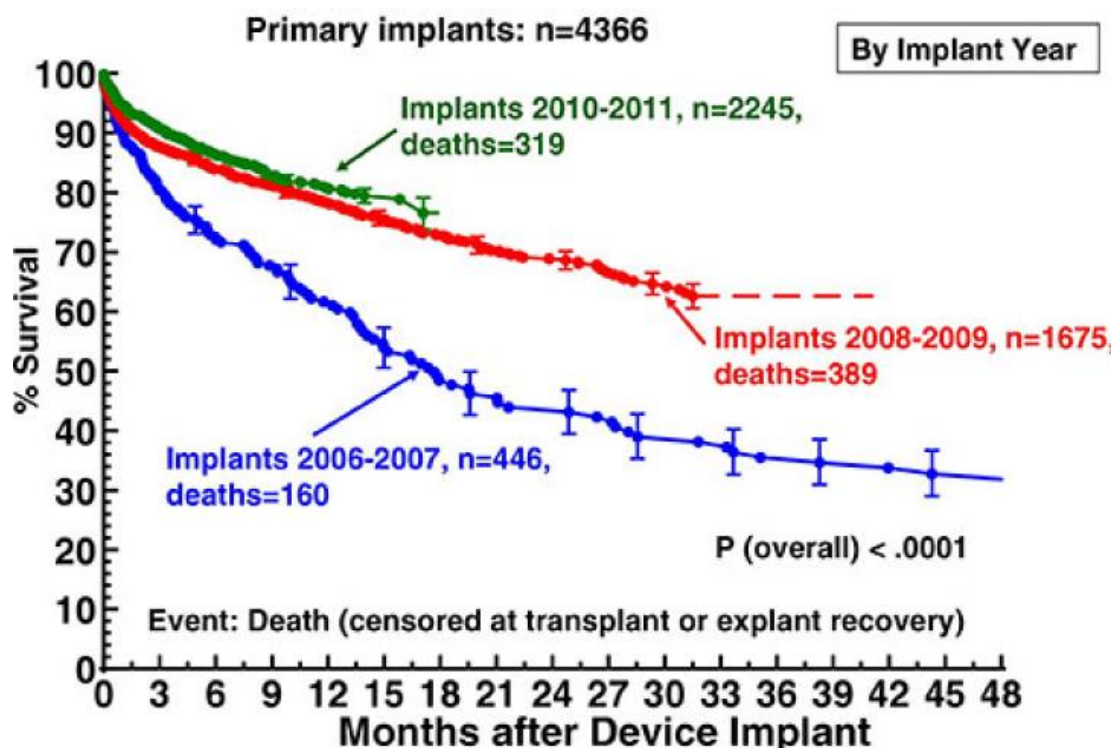
- ↑ **Sobrevivência global** dos doentes em assistência ventricular mecânica desde 2006.

- **Sobrevivência a 1 ano:**

2010-2011: 82%

2006-2007: 62%

~ **Transplante Cardíaco**



Outcome

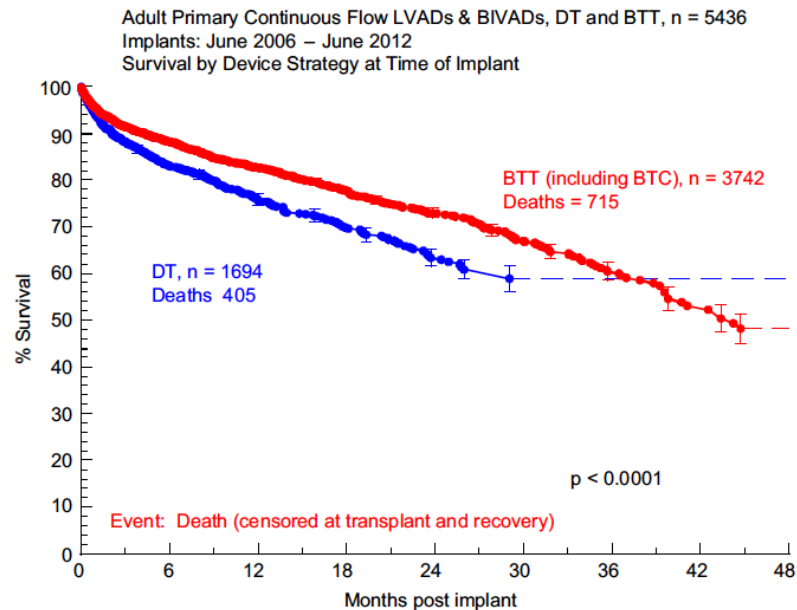
- ↑ **Sobrevivência global** dos doentes em assistência ventricular mecânica desde 2006.

- **Sobrevivência a 1 ano:**

2010-2011: 82%

2006-2007: 62%.

~ **Transplante Cardíaco**



- **Doentes em 'destination therapy'**

++ Comorbilidades

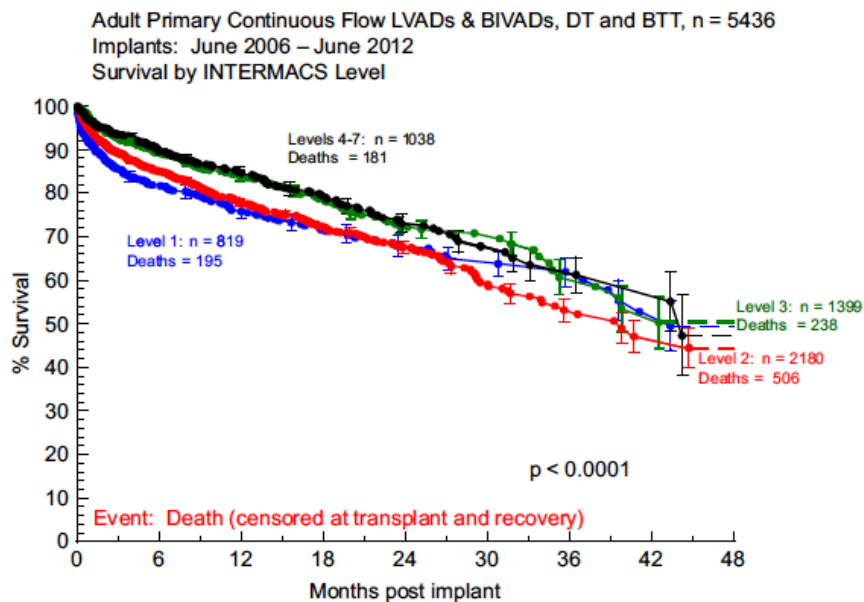
Sem 'rescue therapy' em caso de complicação de device

Outcome

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.



- Os doentes colocados em assistência com perfil 1 e 2 são os que apresentam pior prognóstico.



Constituem cerca de 80% dos doentes

Outcome

INTERMACS Patient Profiles (20)

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

NEWS AND VIEWS

Semin Thoracic Surg 24:8-10 © 2012

Are We Ready to Implant Left Ventricular Assist Devices In “Less Sick” Patients?

Should “*Less Sick Heart Failure Patients*” Be a Target for VAD Therapy?”

‘Destination Therapy’ neste subgrupo de doentes

↑ qualidade de vida / capacidade funcional ?

↑ sobrevida ?

This study is currently recruiting participants.

Verified November 2013 by University of Michigan

RE[♥]VIVE IT

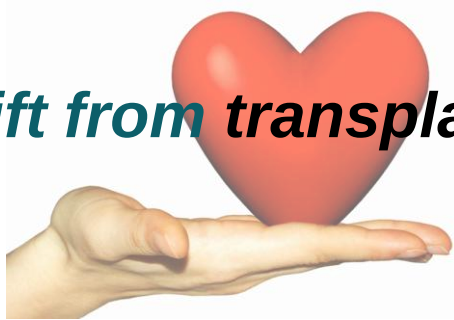
**RANDOMIZED EVALUATION OF VAD INTERVENTION
BEFORE INOTROPIC THERAPY**

Objectivo: demonstrar que a colocação estratégica de um dispositivo de suporte mecânico ventricular em doentes com IC avançada antes da existência de critérios de maior gravidade pode melhorar a sobrevida e a capacidade funcional.

This is a randomized trial of the HeartMate II® Left Ventricular Assist System (LVAS) versus best medical therapy in patients with advanced heart failure (HF) and whose illness is not severe enough to qualify for transplant or permanent left ventricular assist device (LVAD) therapy based on current guidelines.

Outcome

Shift from transplant to destination therapy?



- O *outcome* global dos doentes com devices de fluxo contínuo é semelhante ao *outcome* dos doentes com transplante de coração aos **2 anos**¹.
- Sobrevivência a longo-prazo
 - Transplante cardíaco: → 30 anos
 - *Devices* de fluxo contínuo: ??

¹Stehlik J, Edwards LB, Kucheryavaya AY, Benden C, Christie JD, Dobbels F, et al. The Registry of the International Society for Heart and Lung Transplantation: Twenty-eighth Adult Heart Transplant Report – 2011. J Heart Lung Transplant. 2011;30:1078–94.

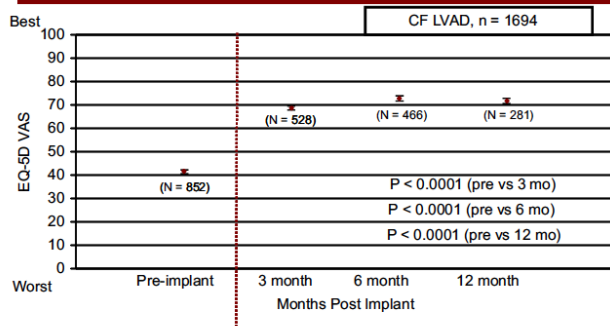
Quality of Life

QOL antes e após implante de device – ‘destination therapy’

Fifth INTERMACS annual report

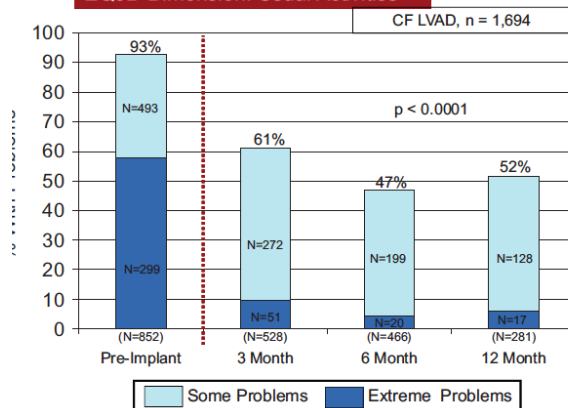
June 2006 – June 2012: Destination Therapy

EQ5D Visual Analog Scale (VAS) across time (mean $\pm$ SE)



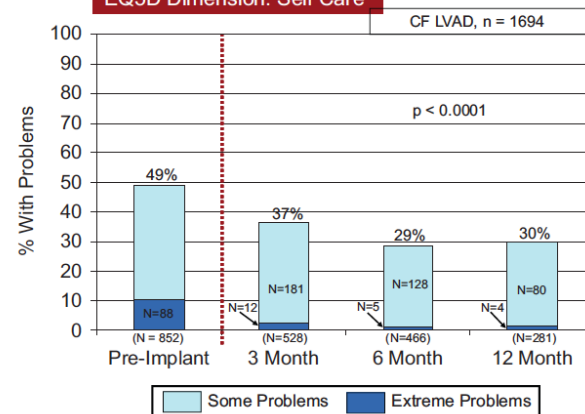
June 2006–June 2012: Destination Therapy

EQ5D Dimension: Usual Activities



June 2006 – June 2012: Destination Therapy

EQ5D Dimension: Self Care



- Melhoria significativa da QOL global.
- A magnitude de melhoria na QOL ultrapassa a alcançada pelas **terapêuticas farmacológicas** ou de **ressincronização cardíaca** em doentes com IC avançada^{1,2}

¹Abraham WT, Fisher WG, Smith AL, Delurgio DB, Leon AR, Loh E, Kocovic DZ, Packer M, Clavell AL, Hayes DL, Ellestad M, Trupp RJ, Underwood J, Pickering F, Truex C, McAtee P, Messenger J; MIRACLE Study Group. Multicenter InSync Randomized Clinical Evaluation. Cardiac resynchronization in chronic heart failure. N Engl J Med. 2002 Jun 13;346(24):1845-53.

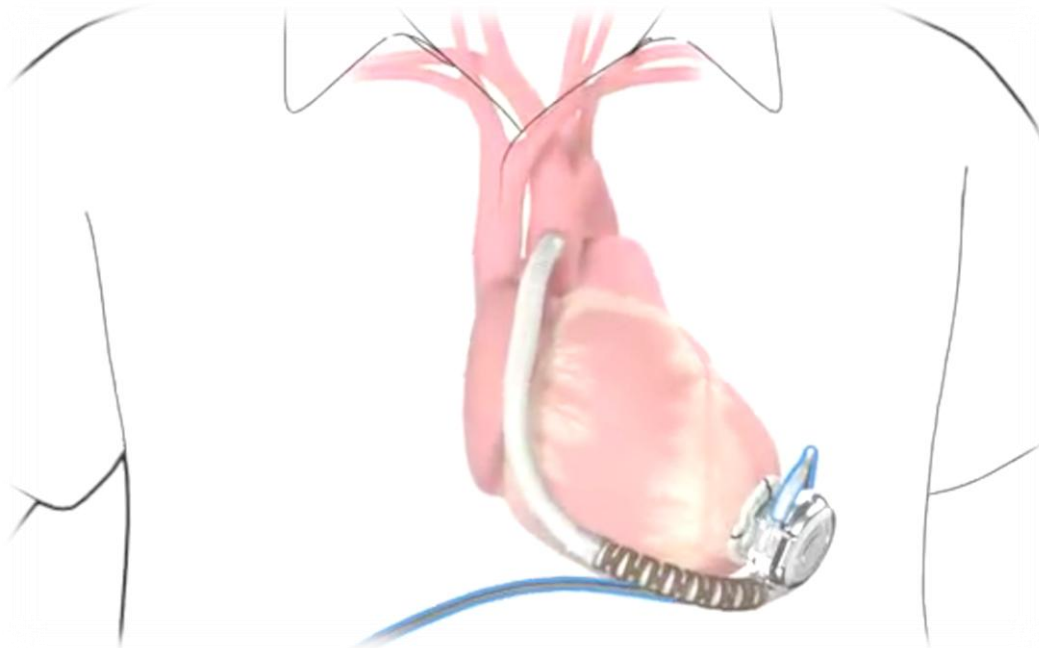
²Slaughter MS, Rogers JG, Milano CA, Russell SD, Conte JV, Feldman D, Sun B, Tatooles AJ, Delgado RM 3rd, Long JW, Wozniak TC, Ghumman W, Farrar DJ, Frazier OH; HeartMate II Investigators. Advanced heart failure treated with continuous-flow left ventricular assist device. N Engl J Med. 2009 Dec 3;361(23):2241-51

Conclusões

- Os dispositivos implantáveis para assistência ventricular mecânica têm revolucionado a abordagem terapêutica da IC avançada.
- Nos últimos 10 anos, estudos prospectivos têm demonstrado de forma consistente uma melhoria significativa na sobrevida e capacidade funcional dos doentes com IC.
- A durabilidade e eficiência dos dispositivos de assistência torna-os uma opção viável para doentes contra-indicados para transplante cardíaco, podendo vir a substituí-lo na totalidade num futuro próximo.



Obrigado



Rui Plácido
7 | Fevereiro | 2014