

Mechanical circulatory support II : LVAD



Chulalongkorn
Heart Failure

เอกราช อริยะชัยพานิชย์
Aekarach Ariyachaipanich, MD, FACC

aekarach.a@chula.ac.th



Heart Failure Essentials For Cardiology Fellows 2018

18.08.2018

Disclosure

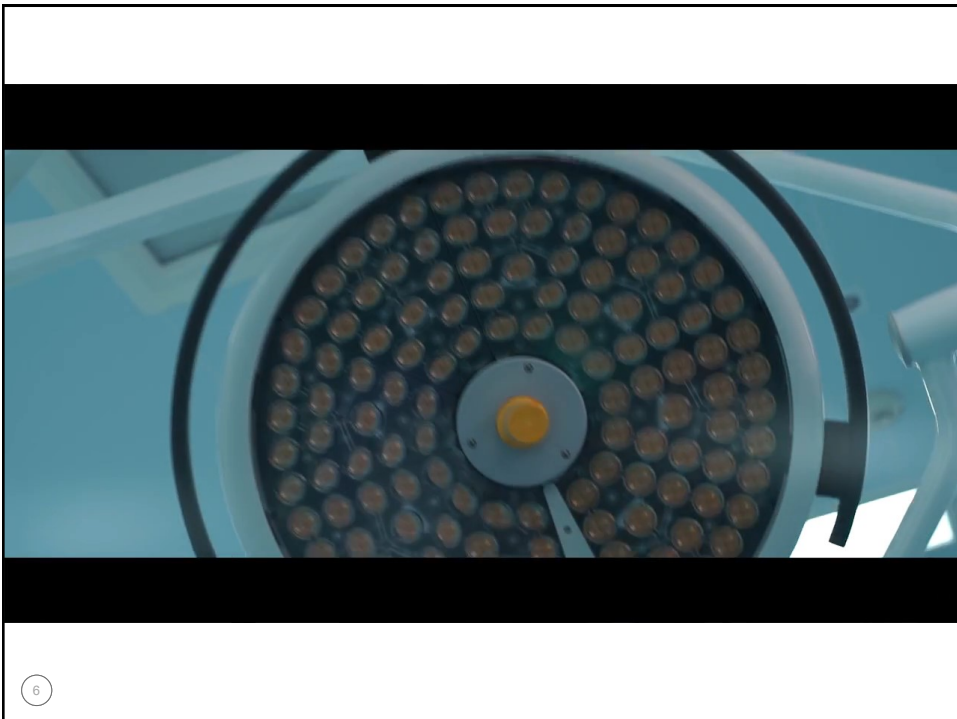
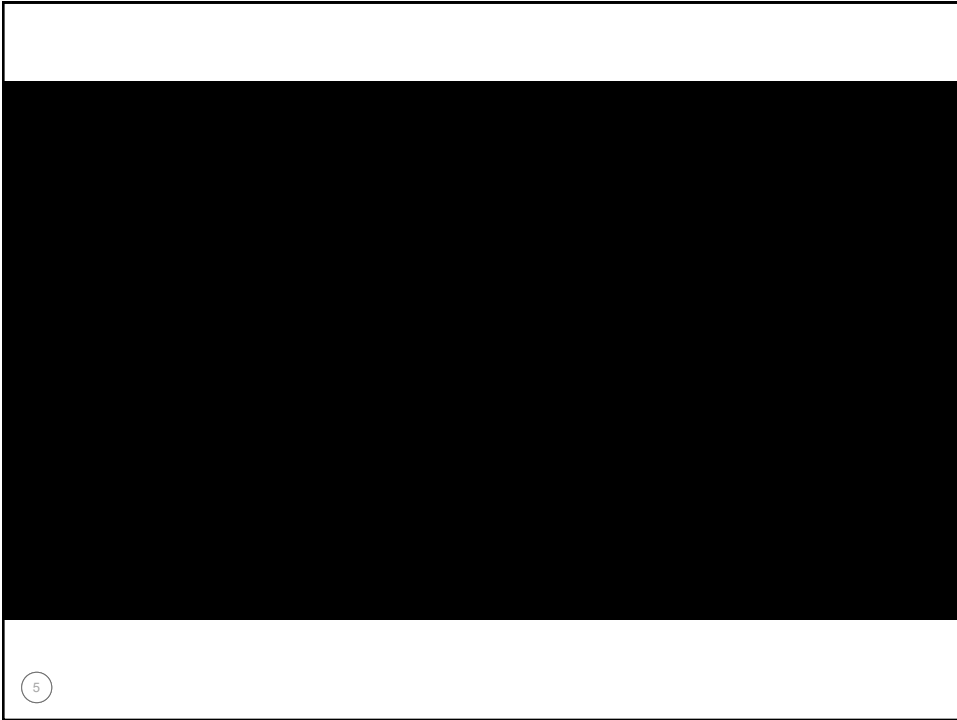
- There are no relevant financial relationships exist related to my role in this session.
- Speaker, CME service:
Berlin, Merck, Novartis, Thai-Otsuka, Roche Diagnostics, Servier
- Consultant, non-CME service:
Novartis



In 2013, the American Heart Association funded \$32 million in research related to heart failure...



We found Wesley to be excellence candidate for a heart transplant but because of the shortage of the donor organ. We were concern that he may not survive until the donor heart is available.





7

Indications for MCS

- **Bridge to transplant (BTT)**
 - In a patient who is on waiting list
- **Destination therapy (DT)**
 - In a patient who is not a transplant candidate
- **Bridge to ...**
 - **To recovery:**
 - Shock, post cardiac surgery, acute MI, myocarditis
 - **To decision:**
 - Evaluation for OHT candidacy status
 - **Short term:**
 - High risk PCI, valve intervention, ablation.

Table 13.3 Patients potentially eligible for implantation of a left ventricular assist device

Patients with >2 months of severe symptoms despite optimal medical and device therapy and more than one of the following:

LVEF <25% and, if measured, peak VO_2 <12 mL/kg/min.

≥3 HF hospitalizations in previous 12 months without an obvious precipitating cause.

Dependence on i.v. inotropic therapy.

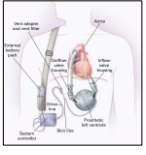
Progressive end-organ dysfunction (worsening renal and/or hepatic function) due to reduced perfusion and not to inadequate ventricular filling pressure (PCWP ≥20 mmHg and SBP ≤80–90 mmHg or CI ≤2 L/min/m²).

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; VO_2 = oxygen consumption.

REMATCH study

- Pts w chronic stg D HF who is not a transplant candidates
- N = 129
- RCT to pulsatile flow LVAD vs. OMM
- LVAD resulted
 - ↑ Survival
 - ↑ QoL
- Established destination therapy as indication for MCS



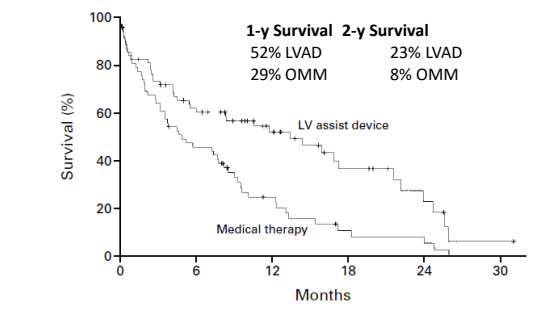
The New England
Journal of Medicine

Copyright © 2001 by the Massachusetts Medical Society

VOLUME 344 NOVEMBER 15, 2001 NUMBER 46

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

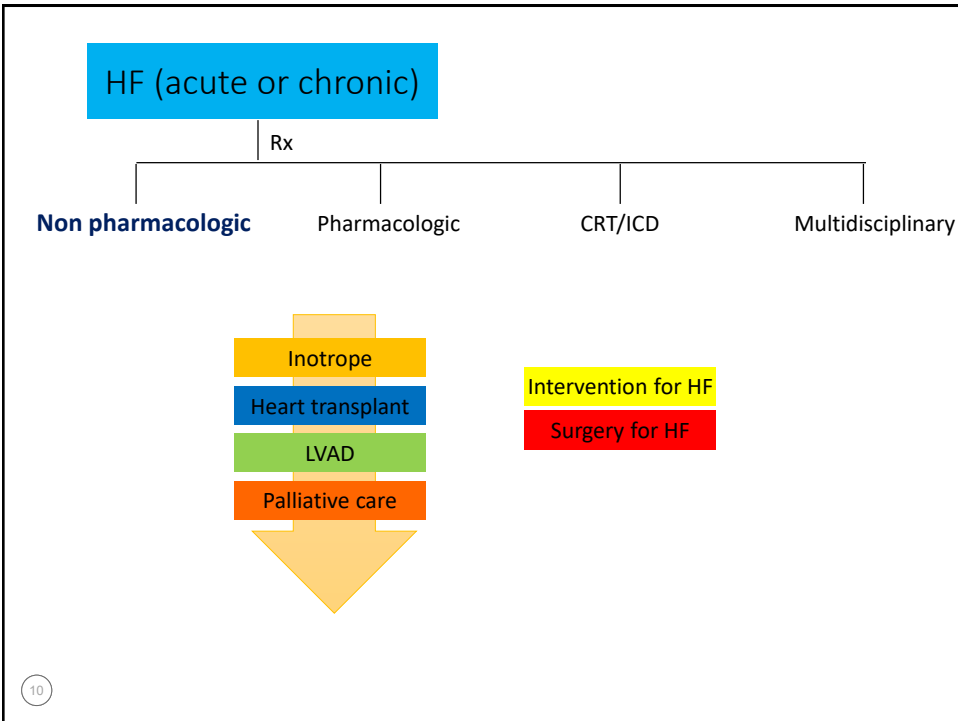
Eric A. Rose, M.D., Andrew C. Dickstein, Ph.D., Adam J. Hasselblad, M.D., Daniel P. Heitman, Ph.D., Louis H. Côté, M.D., William Gattuso, M.D., Joseph A. Long, M.D., Ph.D., Christian M. Boscovici, M.D., John W. Tamargo, M.D., Thomas J. Geisler, M.D., Scott E. Litwin, Ph.D., and Paul Meade, Ph.D., for the Rematch Evaluation of Mechanical Assistance for the Treatment of End-stage Heart Failure (REMATCH) Research Group*

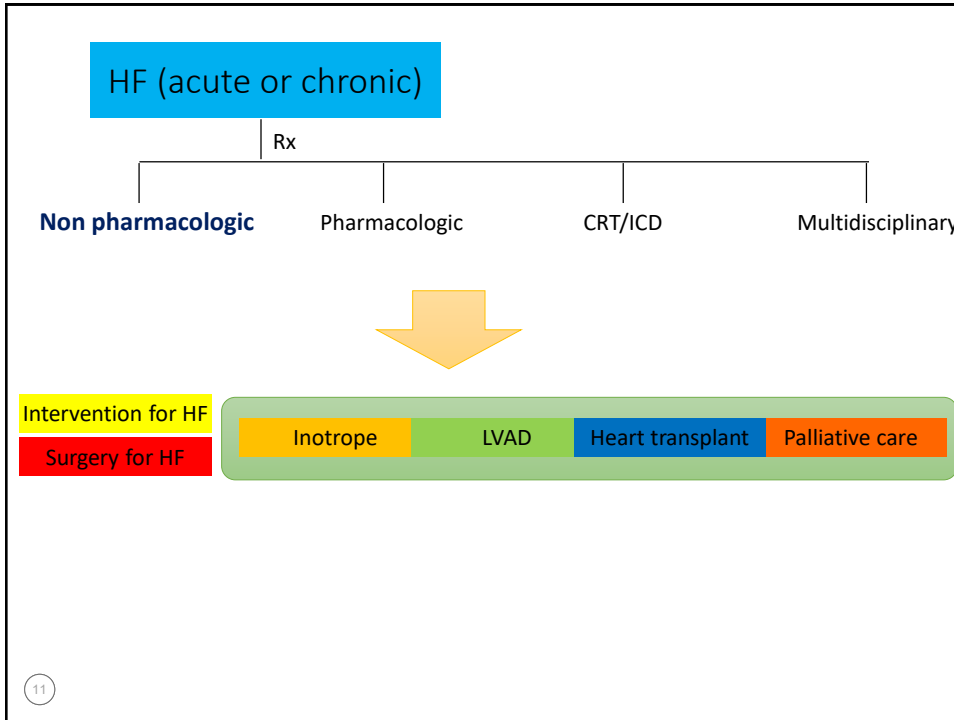


		1-y Survival		2-y Survival	
		52% LVAD	29% OMM	23% LVAD	8% OMM

No. AT Risk						
LV assist device	68	38	22	11	5	1
Medical therapy	61	27	11	4	3	0

NEJM 2001; 345:1435-43





Landmarks in MCS

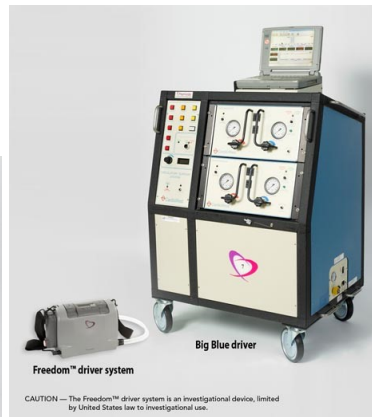
1960	1970	1980	1990	2000	2010
<p>1963: First report of implantable artificial ventricle by Licitia</p> <p>1964: NIH forms Artificial Heart Program</p> <p>1966: First successful pneumatic LVAD implanted by DeBakey for post-cardiotomy wean and bridge to recovery</p> <p>1969: Denton Cooley uses first TAH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

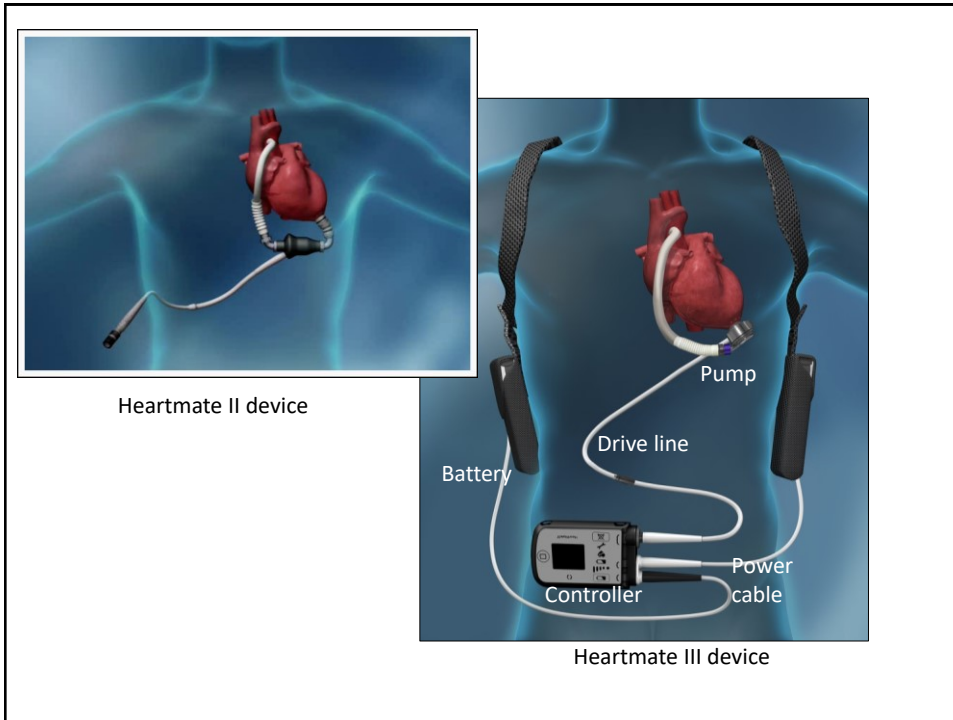
Figure 1. Historical perspective on mechanical circulatory support. This timeline marks the seminal events in mechanical circulatory support over the previous 5 decades, from the first reported use of an artificial ventricle in 1963 to the current generation of continuous-flow pumps. ADVANCE indicates Evaluation of the HeartWare Ventricular Assist Device for the Treatment of Advanced

Type / terminology of MCS

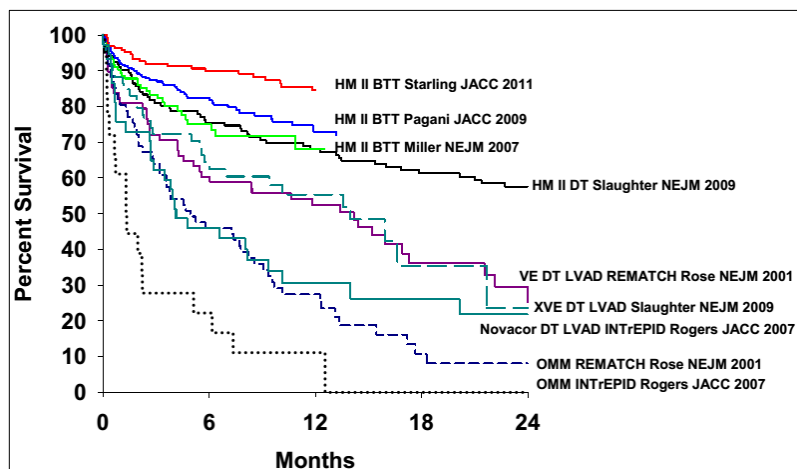
- **Duration of support:** Non-durable (short-term) vs nondurable (long-term)
- **Flow characteristic:** Pulsatile vs Continuous
- **Degree of support:** Partial support vs Full support
- **Implant approach:** Percutaneous vs Surgical
- **Pump location:** Intra vs Extracorporeal
- **Type:** LVAD, RVAD, ECMO, TAH
- **Generation:**
 1. pulsatile flow
 2. Continuous flow – axial
 3. Continuous flow – centrifugal

Total Artificial Heart





VAD survival outcome



Outcome

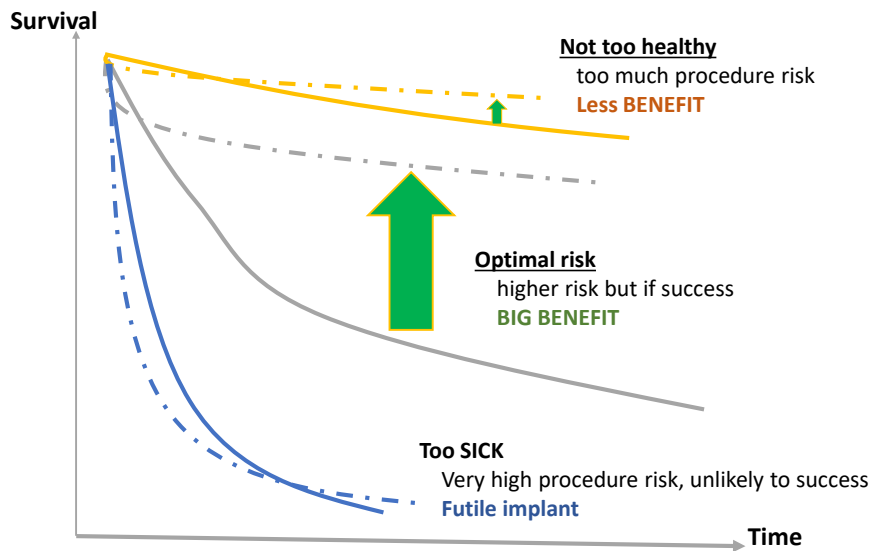
- 1-year survival = 70-80%
 - Improve quality of life
- **High event rate** (1st year event)*
 - Infection 5-25%
 - RV failure 10%
 - Stroke 10%
 - GI Bleeding 5%
 - Pump thrombosis/malfunction rare
 - Aortic insufficiency



* Data from HM II device

JACC. 2009;54:312-21.

3 months too early is better than 5 mins too late



Adapt from circ 2011;123:1559.

INTERMACS profile

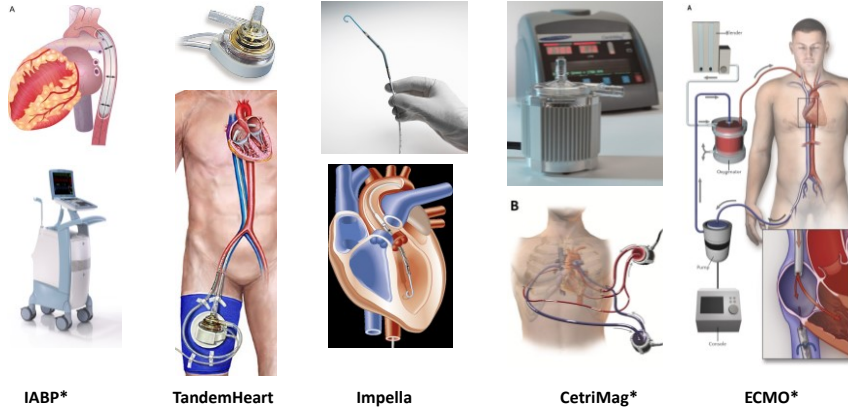
Level	INTERMACS Description	NYHA Class	Suggested timing for definite treatment
1	Critical cardiogenic shock "Crash and burn"	IV	Hours
2	Progressive decline despite inotropic support "Sliding fast on inotropes"	IV	Hours to days
3	Stable but inotrope dependent, can be in hospital or at home "Dependent stability"	IV	Week to months
4	Resting symptoms. Recurrent decompensatory. "Frequent flyer"	IV ambulatory	Variable
5	Exertion intolerant, comfort at rest, symptoms with minimal ADL. "Housebound"	IV ambulatory	Variable
6	Exertion limited, possible ADL but meaningful activity limit. "Walking wounded"	III	Variable
7	Advanced NYHA III "Placeholder"	III	Variable

J Heart Lung Transplant 2009;28:535.

INTERMACS 1

- **Critical cardiogenic shock - "Crash and burn"**
 - Dying in front of you – hours
 - Even IABP is not enough
- **Need to save end-organ, hemodynamics**
- **Bridge to**
 - To long term LVAD (too sick now)
 - To transplant/ transplant evaluation
- **Temporary MCS**
 - Centrimag, ECMO, TandemHeart, Impella

Short-term MCS



IABP*

TandemHeart

Impella

CetriMag*

ECMO*

Short-term MCS

Improve hemodynamics but not outcomes

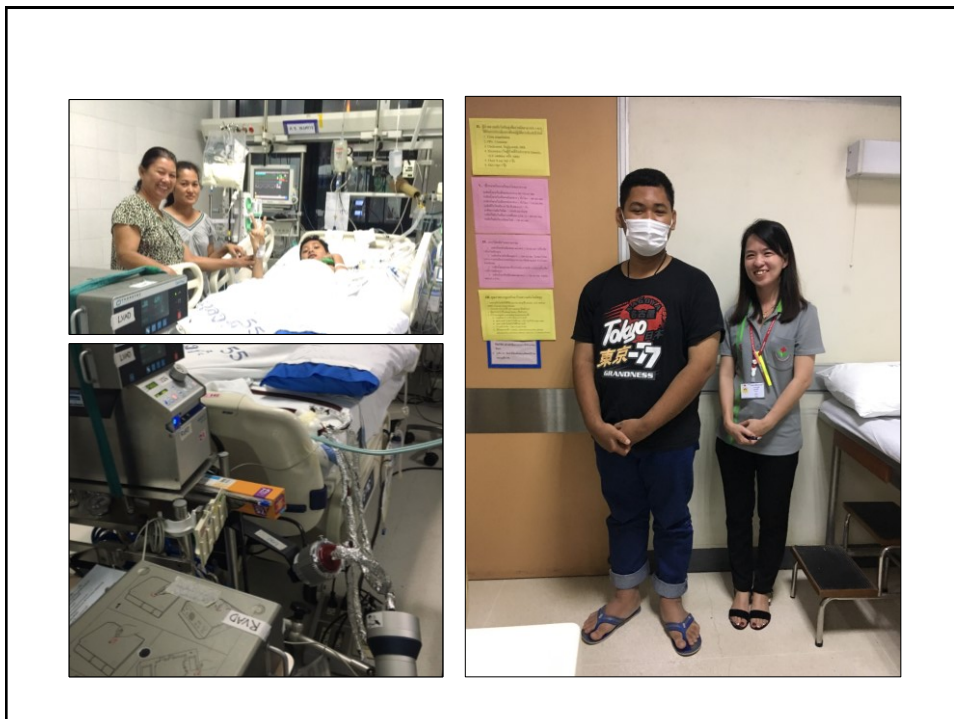
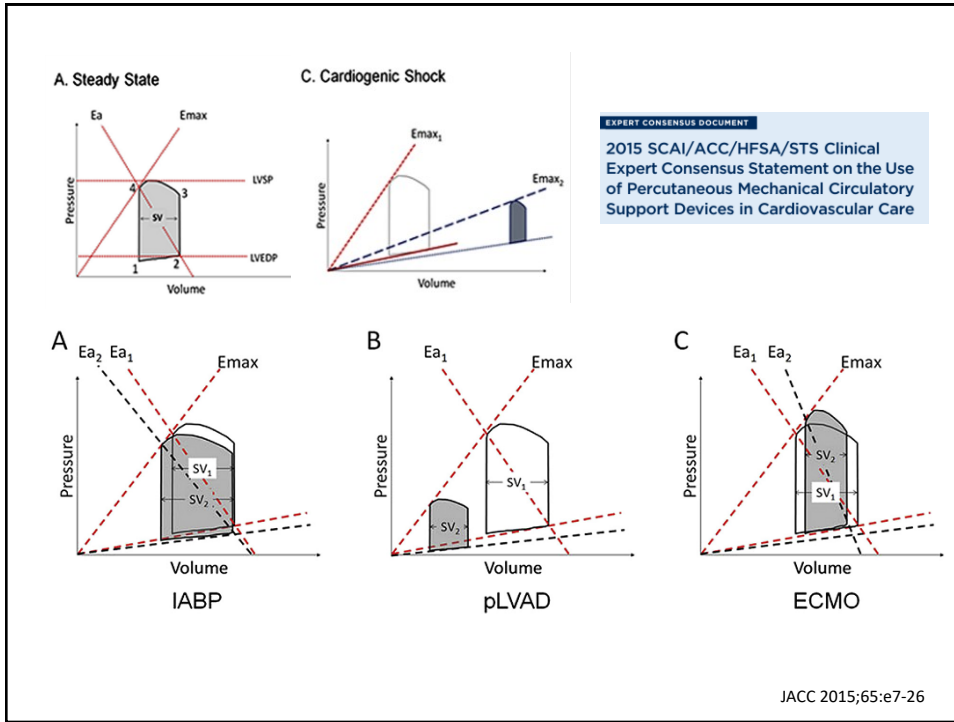
	IABP	ECMO	TandemHeart	Impella 2.5	Impella 5.0
Pump mechanism	Pneumatic	Centrifugal	Centrifugal	Axial flow	Axial flow
Cannula size	7.9 Fr	18–21 Fr inflow; 15–22 Fr outflow	21 Fr inflow; 15–17 Fr outflow	13 Fr	22 Fr
Insertion technique	Descending aorta via the femoral artery	Inflow cannula into the right atrium via the femoral vein, outflow cannula into the descending aorta via the femoral artery	21 Fr inflow cannula into left atrium via femoral vein and transseptal puncture and 15–17 Fr outflow cannula into the femoral artery	12 Fr catheter placed retrogradely across the aortic valve via the femoral artery	21 Fr catheter placed retrogradely across the aortic valve via a surgical cutdown of the femoral artery
Hemodynamic support	0.5 – 1.0 L min ⁻¹	>4.5 L min ⁻¹	4 L min ⁻¹	2.5 L min ⁻¹	5.0 L min ⁻¹
Implantation time	+	++	+++	++	++++
Risk of limb ischaemia	+	+++	+++	++	++
Anticoagulation	+	+++	+++	+	+
Haemolysis	+	++	++	++	++
Post-implantation management complexity	+	+++	++++	++	++
Optional active cooling in post-cardiopulmonary resuscitation patients	No	Yes	(Yes)	No	No

ECMO, extracorporeal membrane oxygenation; IABP, intra-aortic balloon pump; +, ++, +++, +++++, relative qualitative grading concerning time ('implantation time'), risk ('risk of limb ischaemia'), intensity ('anticoagulation'), 'post-implantation management complexity', and severity ('haemolysis'). Modified from Oueneel and Henriques.⁴²

Mechanical circulatory support in cardiogenic shock

Karl Werdan^{1*}, Stephan Gieten¹, Henning Ebel¹, and Judith S. Hochman²

Eur Heart J 2014;35:156-167.



INTERMACS 2-3

INTERMACS 2

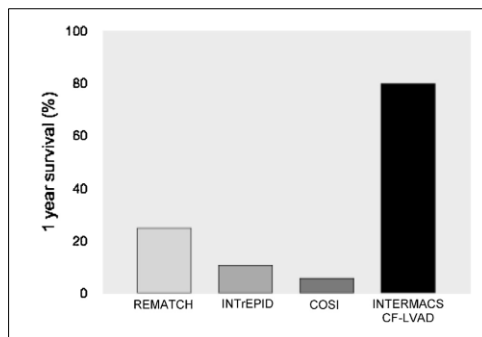
- Progressive decline despite inotropic support
- “Sliding fast on inotropes”
- Days to week

INTERMACS 3

- Stable but inotrope dependent, can be in hospital or at home
- “Dependent stability”
- Weeks to months

Most appropriate use of long term LVADs
Mean HTx waiting time in Thailand = 80 days

INTERMACS 2-3



- 1-year survival of patients on continuous inotropic support compared to those supported with a durable continuous flow left ventricular assist device.
 - REMATCH 25%
 - INTrEPID 11%
 - COSI 6%
 - LVAD 80%

INTERMACS 4-7

- NYHA IV, IIIb, III
- Uncertainty time frame
- Less sick patients

- ROADMAP study
- REVIVE study

**Potential benefit in functional capacity and QoL
But risks of stroke, bleeding, infection.**

ROADMAP study

- Prospective, non-randomized, **observational study**
- EF < 25%, INTERMACS 4-7
- **Significant different in primary endpoint.**
- HM II is related to
 - ↑ QoL
 - ↑ adverse events

REVIVE-IT - “clinical hold”

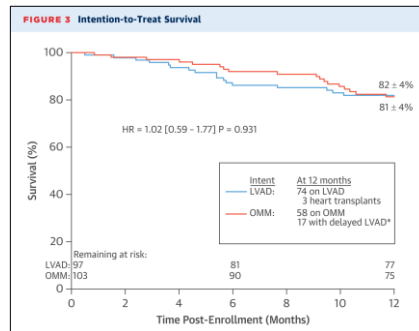


TABLE 4 Primary Endpoint and Components that Prevented Success

	OMM (n = 82)*	LVAD (n = 85)†	Odds Ratio (95% Confidence Interval) p = 0.012
Alive at 12 months on original therapy with increase in 6MWD by 75 m	17 (21)	33 (39)	2.4 (1.2-4.8)
First event that prevented success:	65 (79)	52 (61)	
Death within 1 yr	18 (22)	17 (20)	
Delayed LVAD	18 (22)‡	NA	
Delta 6MWD <75 m	29 (35)	33 (39)	
Urgent transplant	0	2 (2)	

JACC 2015;66:1747-61

More than half of patient underwent LVAD placement are INTERMACS 2-3

Table 1 – Current distribution of durable mechanical circulatory support devices across INTERMACS levels.

INTERMACS Level	Definition	% Of durable MCS
1	Critical cardiogenic shock	14.3%
2	Progressive decline	36.0%
3	Stable but inotrope dependent	29.6%
4	Resting symptoms	14.5%
5	Exertion-intolerant	3.0%
6	Exertion-limited	1.2%
7	Advanced NYHA Class 3	0.7%

INTERMACS, Interagency Registry for Mechanically Assisted Circulatory Support; MCS, mechanical circulatory support; NYHA, New York Heart Association.

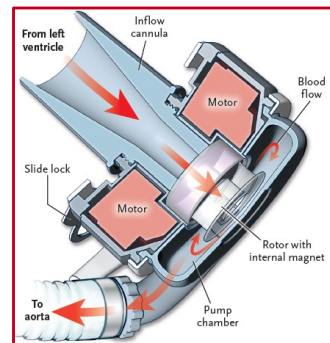
HeartMate 3™ LVAS

THE NEW ENGLAND JOURNAL of MEDICINE

ORIGINAL ARTICLE

A Fully Magnetically Levitated Circulatory Pump for Advanced Heart Failure

Mandeep R. Mehra, M.D., Yoshifumi Naka, M.D., Nir Uriel, M.D., Daniel J. Goldstein, M.D., Joseph C. Cleveland, Jr., M.D., Paolo C. Colombo, M.D., Mary N. Walsh, M.D., Carmelo A. Milano, M.D., Chetan B. Patel, M.D., Ulrich P. Jorde, M.D., Francis D. Pagani, M.D., Keith D. Aaronson, M.D., David A. Dean, M.D., Kelly McCants, M.D., Akinobu Itoh, M.D., Gregory A. Ewald, M.D., Douglas Horstmanshof, M.D., James W. Long, M.D., and Christopher Salerno, M.D., for the MOMENTUM 3 Investigators*



- **Wide** blood-flow passages to reduce shear stress
- **Frictionless** with absence of mechanical bearings
- **Intrinsic Pulse** designed to reduce stasis and avert thrombosis

Caution – HeartMate 3 LVAS is an investigational device. Limited by Federal (United States) law to investigational use

SIM-HM3-1116-0003 | Item approved for global use

Baseline Characteristics - 2

Characteristic	HeartMate 3 (n=152)	HeartMate II (n=142)
Left ventricular ejection fraction - %	17.1 ± 5.0	17.3 ± 4.9
Arterial blood pressure - mmHg		
Systolic*	110 ± 16	106 ± 12
Diastolic	67 ± 10	66 ± 10
Mean arterial pressure* - mmHg	81 ± 10	79 ± 9
PCWP - mmHg	23 ± 9	22 ± 9
Cardiac index - liters/min/m ² of body surface area	1.9 ± 0.5	2.0 ± 0.7
PVR - Wood Units	3.3 ± 1.7	3.0 ± 1.6
Right atrial pressure - mmHg	10 ± 6	11 ± 7
Serum sodium - mmol/liter	135.6 ± 3.9	134.9 ± 4.2
Serum creatinine - mg/ml	1.4 ± 0.4	1.4 ± 0.4
INTERMACS Profile** - no (%)		
1	1 (1)	4 (3)
2	50 (33)	44 (31)
3	76 (50)	69 (49)
4	22 (14)	23 (16)
5-7†	2 (1)	2 (1)
Intended Use of device at implant – no (%)		
Bridge to Transplant (BTT)	41 (27)	37 (26)
Bridge to Candidacy	27 (18)	27 (18)
Destination Therapy (DT)	84 (55)	78 (55)

* Systolic blood pressure (P= 0.01) and Mean arterial pressure (P=0.04) were statistically significantly.

** one subject in HM3 group expired prior to INTERMACS Assessment;

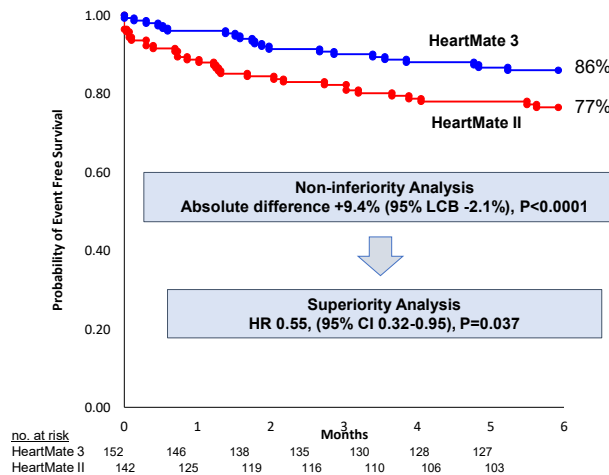
† There were no subjects with INTERMACS 6 and 7 in either groups; PCWP denotes pulmonary capillary wedge pressure and PVR pulmonary vascular resistance

Caution – HeartMate 3 LVAS is an investigational device. Limited by Federal (United States) law to investigational use

NLM-HM3-1116-0003 | Item approved for global use.

Primary End Point Analysis (ITT)

Survival at 6 months free of disabling stroke or reoperation to replace or remove the pump



LCB, lower confidence boundary, HR, hazard ratio, and CI, confidence interval

Caution – HeartMate 3 LVAS is an investigational device. Limited by Federal (United States) law to investigational use

NLM-HM3-1116-0003 | Item approved for global use.

Key Adverse Events: Pump Thrombosis, Neurological Events, Bleeding

	HeartMate 3 (n=151)		HeartMate II (n=138)		RR	95% CI for RR	P Value
	n (%)	no. of Events	n (%)	no. of Events			
Suspected or Confirmed Pump Thrombosis	0 (0)	0	14 (10)	18	N/A	N/A	< 0.0001
All Stroke	12 (7)	12	15 (10)	17	0.73	0.35-1.51	0.39
Hemorrhagic Stroke	4 (2)	4	8 (5)	8	0.46	0.14-1.48	0.18
Ischemic Stroke	8 (5)	8	9 (6)	9	0.81	0.32-2.05	0.66
Disabling Stroke	9(6)	9	5(3)	5	1.65	0.57-4.79	0.36
Other Neurologic Events*	9 (6)	9	8 (5)	8	1.03	0.41-2.59	0.95
Bleeding	50 (33)	100	54 (39)	98	0.85	0.62-1.15	0.29
Bleeding Requiring Surgery	15 (9)	15	19 (13)	21	0.72	0.38-1.36	0.31
Gastrointestinal Bleeding	24 (15)	47	21 (15)	36	1.04	0.61-1.79	0.87

No Pump Thrombosis in the HeartMate 3 LVAS group

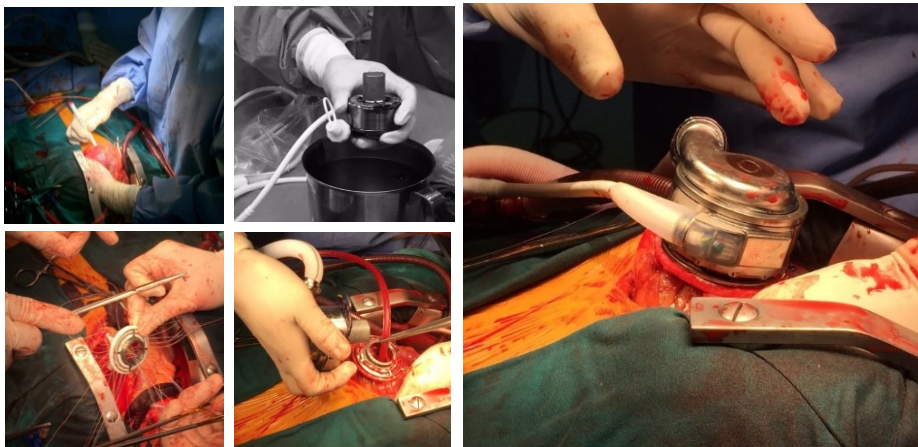
Similar Stroke and Bleeding rates in both groups

RR, denotes Relative Risk and CI, confidence interval
*Includes transient ischemic attacks and neurologic events other than stroke

Caution – HeartMate 3 LVAS is an investigational device. Limited by Federal (United States) law to investigational use

HM3-1116-0003 | Item approved for global use

Surgical Implant



Experience of Durable LVAD in Thailand

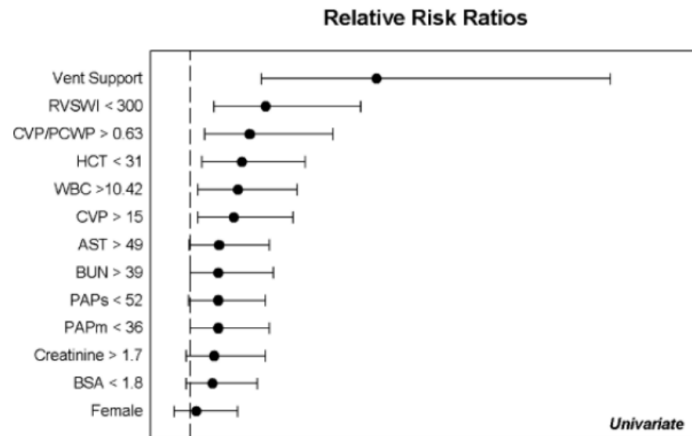
- Since 2014
- ~ 10 pts
 - Heartmate II
 - Heartmate III



Evaluate patient for LVAD

- Relatively the same as HTx eval
 - Medical, surgical, psychosocial
 - Patient and care-giver
- Contraindication
 - Active infection
 - Cannot take coumadin
 - HFpEF
 - Severe RV failure
 - Irreversible end-organ dysfunction – dialysis, cirrhosis
- Earlier referral is better

Univariate Predictors of RV failure

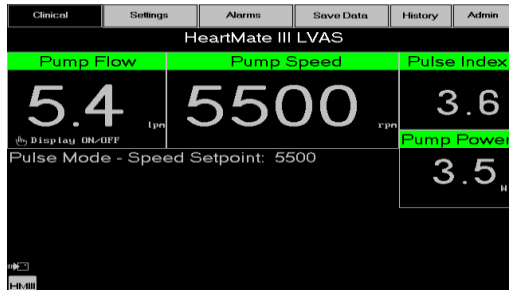


Thorac Cardiovasc Surg 2010;139:1316-24.

Evaluate patient with LVAD

- Always evaluate patient not the pump
- High suspicious for
 - Hemolysis, bleeding, infection, RV failure, stroke
 - HF, arrhythmia, ischemic, valve
- OPD
 - Continuous flow = No pulses
 - Doppler BP = 70-80 mmHg
 - Anticoagulation INR 2-2.5
 - Drive line dressing daily
 - HF meds

Basic VAD parameters



- Speed (rpm)
 - Fixed, set by the clinician
 - HMIII 5000 \pm 1000
 - HMII 9000 \pm 1000
- Power (watt)
 - Direct measurement of pump motor energy use in Watts
 - 4 \pm 1.5
- Pump flow estimator (L/min)
 - Estimated CO thru pump
 - 4 \pm 1.5
- Pulsatility Index (PI)
 - The magnitude of flow pulses
 - 4 \pm 1.5

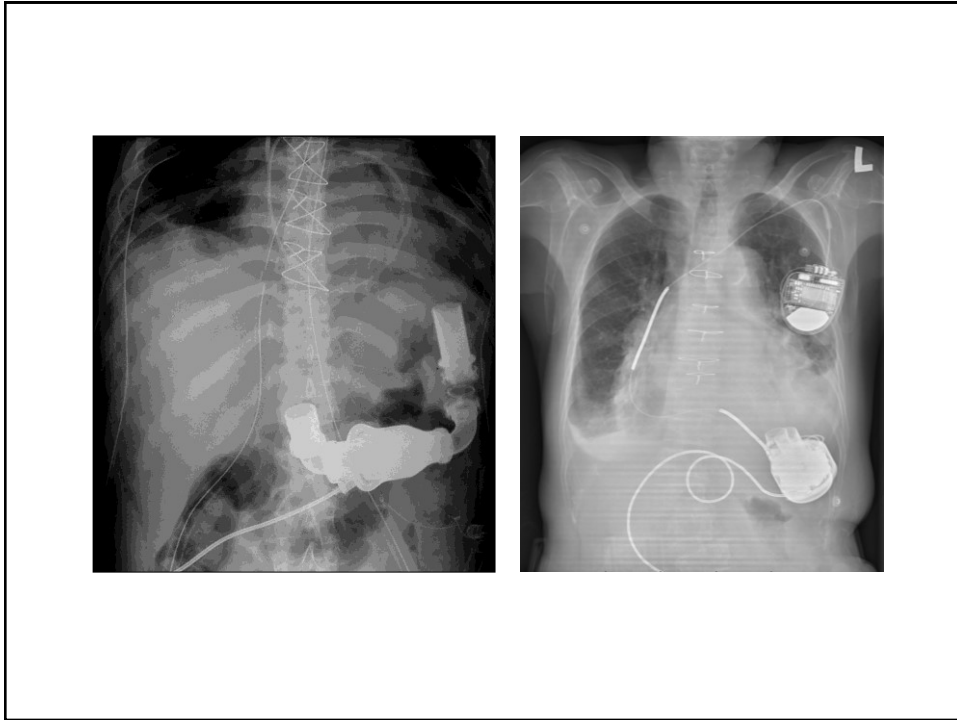
All parameters depend on patient condition and characteristics

HeartMate 3 System Overview

System Components



*New for HM 3



LVAD placement

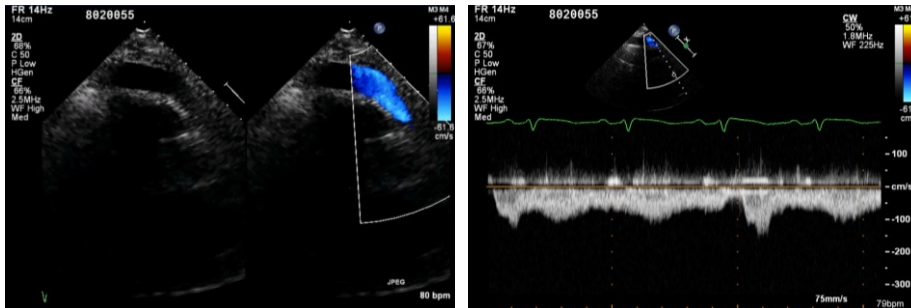
Pre VAD



Post VAD



Outflow cannula



Dos and Donts in VAD

Do

- TTE (always helpful)
- ECG
- Xray, USG, CT
- Defibrillation
- Cardiac cath
- Ablation

- Discuss with patients
- Switch to battery
- Contact pt's VAD coordinator
- Call me 091-879-6108

Don't

- No CPR
- Pregnant
- Stop treating HF

Recommendations for implantation of mechanical circulatory support in patients with refractory heart failure

Recommendations	Class ^a	Level ^b	Ref ^c
An LVAD should be considered in patients who have end-stage HFrEF despite optimal medical and device therapy and who are eligible for heart transplantation in order to improve symptoms, reduce the risk of HF hospitalization and the risk of premature death (Bridge to transplant indication).	IIa	C	
An LVAD should be considered in patients who have end-stage HFrEF despite optimal medical and device therapy and who are not eligible for heart transplantation to, reduce the risk of premature death.	IIa	B	605, 612, 613

HF = heart failure; HFrEF = heart failure with reduced ejection fraction; LVAD = left ventricular assist device.
^aClass of recommendation.
^bLevel of evidence.
^cReference(s) supporting levels of evidence.

ESC 2016:
Class: IIa

AHA/ACC 2013:
Class IIa

MCS	IIa	B
MCS is beneficial in carefully selected* patients with stage D HF in whom definitive management (eg, cardiac transplantation) is anticipated or planned	IIa	B
Nondurable MCS is reasonable as a "bridge to recovery" or "bridge to decision" for carefully selected* patients with HF and acute profound disease	IIa	B
Durable MCS is reasonable to prolong survival for carefully selected* patients with stage D HF/EF	IIa	B

End-Stage Heart Failure - Recommendation

Recommendation	COR	LOE
Heart transplant In carefully selected patients who are transplant candidates, heart transplants are recommended to improve survival, symptoms and quality of life.	I	C
Mechanical circulatory support (MCS) include LVAD In carefully selected patients, a short-term MCS should be considered in patients with severe cardiogenic shock to improve hemodynamic in between evaluation ("bridge to decision").	IIa	B
In carefully selected patients, a short-term or long-term MCS should be considered in patients with advanced HF who are transplant candidates to improve survival, symptoms and quality of life while awaiting suitable donors ("bridge to transplant")	IIa	B
In carefully selected patients, a long-term MCS should be considered in patients with advanced HF who are not transplant candidates to improve survival, symptoms and quality of life. ("destination therapy")	IIa	B
Palliative care Integration of palliative care as an adjunctive treatment in combination with other curative treatments is recommended for patients with advanced HF to improve quality of life.	I	B
In patients whose prognosis are weeks to months, an end-of-life or specialized hospice care service should be considered.	IIa	B



Available online at www.sciencedirect.com
 ScienceDirect
 Journal homepage: www.elsevier.com/locate/ijhe

Durable left ventricular assist device therapy in advanced heart failure: Patient selection and clinical outcomes

Sachin P. Shah ^{a,b,c,d}, Manday R. Mohan ^{b,c,d}

^aCenter for Advanced Heart Failure, Brigham and Women's Hospital Heart and Vascular Center, Boston, MA, United States
^bHarvard Medical School, Boston, MA, United States
^cDivision of Cardiovascular Medicine, Tufts Hospital and Medical Center, Burlington, MA, United States
^dTufts University School of Medicine, Boston, MA, United States

ARTICLE INFO

Article history:
 Accepted 14 January 2016
 Accepted 20 January 2016
 Available online 15 February 2016

Keywords:
 Heart failure
 Mechanical circulatory support
 End-stage heart failure

Abstract
 The increasing adoption of left ventricular assist devices (LVADs) into clinical practice is limited by a combination of engineering challenges to pump technology and improvements in understanding the appropriate clinical use of these devices in the management of patients with advanced heart failure. This review attempts to assess the clinical evidence identifying candidates for LVAD implantation, to describe long-term outcomes and provide an overview of the consensus recommendations related to use of these devices.

© 2016 Elsevier Inc. All rights reserved.

The increasing adoption of left ventricular assist devices (LVADs) into clinical practice is limited by a combination of engineering challenges to pump technology and improvements in understanding the appropriate clinical use of these devices in the management of patients with advanced heart failure. This review attempts to assess the clinical evidence identifying candidates for LVAD implantation, to describe long-term outcomes and provide an overview of the consensus recommendations related to use of these devices.

Indian Heart Journal 2016; 68:s45–s51.

© 2016 Indian Heart Journal. Published by Elsevier, a division of Reed Elsevier India, Pvt. Ltd. This is an open access article under the CC BY-NC-ND license (<http://creativecommons.org/licenses/by-nc-nd/4.0/>).

CONTRIVERSIES IN CARDIOVASCULAR MEDICINE

Is Left Ventricular Assist Device Therapy Underutilized in the Treatment of Heart Failure?

Left Ventricular Assist Devices Are Underutilized

Leslie W. Miller, MD

Heart failure has become one of the leading causes of cardiovascular diagnosis, with estimates as high as 10.6 million new cases per year.¹ This growth is in part a result of improved survival with acute cardiovascular interventions, which has led to this continued increase in the number of patients who develop progressive heart failure (HF). The estimated number of people in the United States with the diagnosis of HF may exceed 1 million based on the estimated average prevalence of 2.2%² and a census of 300 million patients (Figure 1).³ HF is clearly an ailment with a high prevalence as low as 0.3% in those <50 years of age, but it can affect nearly 10% of people 70 years of age.⁴ This is an important demographic, because it is estimated that the number of people >65 years of age will double in the next 20 to 30 years.⁵ HF is not a homogeneous condition. Based primarily on data from recent hospital registries⁶ and other studies,⁷ nearly half of all patients have HF with preserved systolic function, and the other half have varying degrees of severity of HF with reduced systolic function. Although the prevalence of HF is higher in males at <70 years of age, overall HF is equally common in men and women. Furthermore, the average survival of patients with either preserved or reduced systolic function is only 60% at 1 year after diagnosis.⁸ Survival in the high-risk HF cohort is much less in advanced stages.⁹ One study of 3000 patients in Medicare registries reported that nearly 50% mortality in 1-year time.¹⁰ The rapid increase in patients with reduced systolic function has beyond current therapeutic options and for whom new and effective therapies must be identified.

Keywords: Heart failure and Mechanical circulatory support

The actual number of patients receiving HF therapy who have advanced to guideline-based medical management for HF is controversial,¹¹ with estimates ranging between 0.6%¹² and 1%¹³ to the actual prevalence of increasing HF. This wide range is in part due to varying survey techniques and population. In most (National Cancer Registry,¹⁴ etc.), survey data are higher. Patients with the advanced stage not only have a very advanced disease, but require frequent hospitalization and quality of life. This evidence is typically characterized by an increasing frequency of hospitalizations for both men and women (Figure 2). In fact, more hospital days are spent in the care of patients with HF than any other diagnosis, and one-third of all Medicare expenditures for the care of HF patients is for hospital care. Importantly, such data are further reflective in survival (Figure 3).¹⁵ One study of nearly 6000 patients hospitalized for HF showed a mortality of 13% at 1 year after a single HF admission.¹⁶ This identified patients with more than one hospitalization or general medical therapy, and reflects those thought to be potential candidates for evaluation for mechanical circulatory support (MCS) therapy, which likely include several advanced HF patients. One study of 3000 patients in Medicare registries reported that nearly 50% mortality in 1-year time.¹⁰ The rapid increase in patients with reduced systolic function HF also has the highest morbidity rate of any diagnosis.

Circulation 2011;123:1552-1558

© 2011 American Heart Association, Inc.

Circulation is available at ahajournals.org.

Thank you



จุฬาลงกรณ์
 ภาวะหัวใจล้มเหลว
 และอายุรศาสตร์การปลูกถ่ายหัวใจ



ศูนย์โรคหัวใจ
 โรงพยาบาลจุฬาลงกรณ์
 สภากาชาดไทย



Back up slide

Quality of life



TABLE 6 Adverse Events			
	OMM (n = 103)	LVAD (n = 94)	DT Trial§ (EPPY)
Bleeding	1 (1) [0.02]	44 (47) [1.22]‡	1.13
GI bleeding	1 (1) [0.02]	29 (31) [0.76]‡	—
Driveline infection	—	9 (9.6) [0.14]‡	0.22
Pump thrombus	—	6 (6.4) [0.08]†	0.07¶
Within 90 days	—	1 (1.1)	—
Pump exchange yr 1	—	4 (4.3)	2.1%
Stroke	2 (2) [0.02]	8 (8.5) [0.09]*	0.08
Ischemic	1 (1) [0.01]	5 (5.3) [0.06]*	0.05
Hemorrhagic	1 (1) [0.01]	4 (4.3) [0.03] ^{NS}	0.03
Arrhythmias VT/VF	6 (5.8) [0.12]	17 (18.1) [0.23]*	0.46
Worsening HF#	36 (35) [0.68]	10 (10.6) [0.12]‡	—
Rehospitalizations	64 (62) [1.43]	75 (79.8) [2.49]‡	2.64**
Composite event rate††	39 (38) [0.83]	62 (66) [1.89]‡	2.09
Relative risk (95% CI)	OMM/LVAD: 0.44 (0.35-0.56)‡		—

No Chest Compression

- Ok to cardioversion/defib

