Current Therapies for Refractory Heart Failure: Heart Transplantation and Mechanical Circulatory Support

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Refractory Heart Failure

- Goals of Transplantation
- Stage D Heart Failure
- Heart Transplant Outcomes
- If Not Transplant … Then what?

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Goals of Transplantation

- Improve Quality of Life
- Improve Quantity of Life

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Heart Failure: Significant Clinical and Economic Burden

• Persons with HF in the US	4.9 million
• Overall prevalence	2.3%
• Incidence	550,000/year
• Mortality in 2001	52,828
• Cost	$27.9 billion

Reference: American Heart Association. Heart Disease and Stroke Statistics – 2005 Update.

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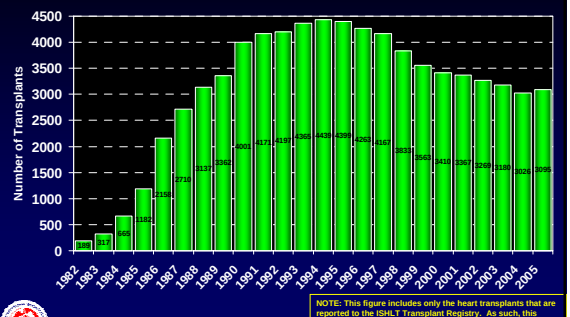
NUMBER OF HEART TRANSPLANTS REPORTED BY YEAR



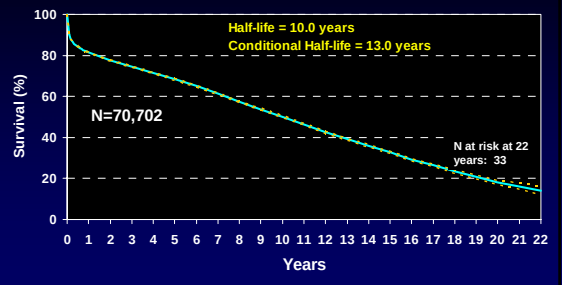
ISHLT 2007

NOTE: This figure includes only the heart transplants that are reported to the ISHLT Transplant Registry. As such, this should not be construed as evidence that the number of hearts transplanted worldwide has declined in recent years.

J Heart Lung Transplant 2007;26: 769-781

HEART TRANSPLANTATION

Kaplan-Meier Survival (1/1982-6/2005)



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Facts – Heart Failure

- 550,000 new cases of heart failure/year.
- 2500 donors for heart transplants/year 8-10% of those who may benefit from a transplant.
- **Thus, it is imperative to restrict transplantation for those with the greatest need and who are likely to derive the maximal benefit.**

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Heart Failure

- **First you need to determine who has the highest mortality with Heart Failure, then you need to determine who will live the longest with a Heart Transplant. That person will get the most benefit from a donated heart.**

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Refractory Heart Failure

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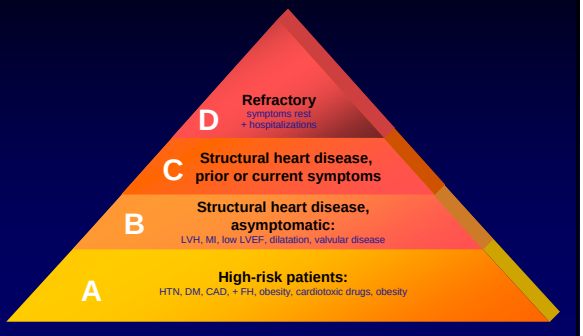
Stages of Heart Failure



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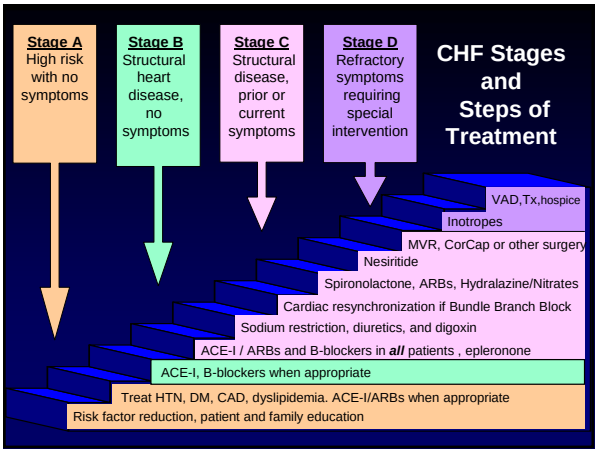
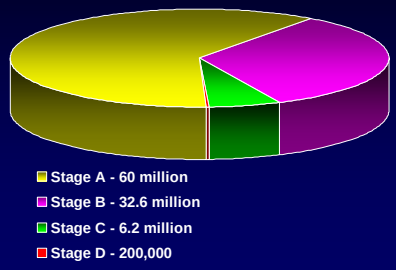
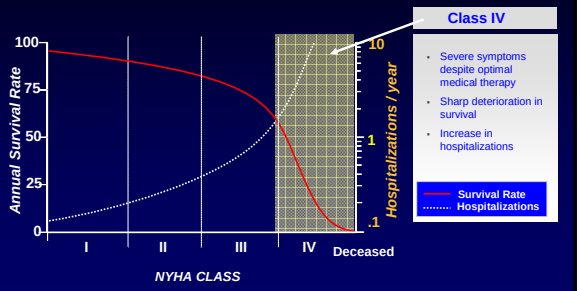


The Scope and Burden of Heart Failure in the United States



Natural History of Heart Failure



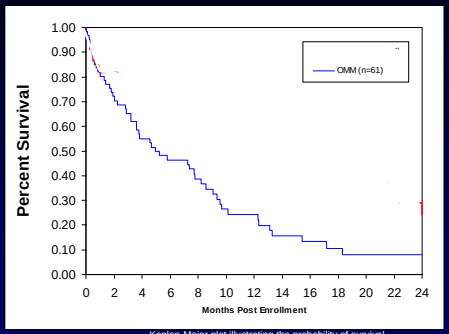
Adapted from Bristow, MR Management of Heart Failure, Heart Disease: A Textbook of Cardiovascular Medicine, 6th edition, ed. Braunwald et al.

Stage D Optimal Medical Management from REMATCH

1 year OMM 26.5%

2 year OMM 8.2%

3 year OMM 2%



Rose et al. *N Engl J Med* 2001;345:1435

Kaplan-Meier plot illustrating the probability of survival of LVAS versus OMM patients after 92 deaths. Logrank analysis: P=0.003

Diagnostic Predictors of Mortality

- Ischemic usually has a higher mortality than non-ischemic heart failure.
- Etiologies such as fulminant lymphocytic and peri-partum cardiomyopathy may resolve so should wait to decide if transplant is needed.
- Duration of CHF – The shorter the duration of HF, the more likely it is to recover

Echo Predictors of Mortality

- EF has failed to show consistent predictability in mortality.
- LVEDd (end-diastolic dimension – how large is the heart) well correlated to mortality.
- Change in EF appears to also be a predictor.

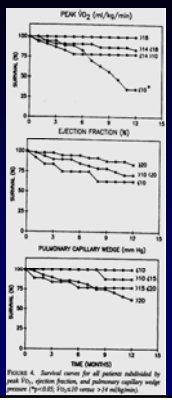
Hemodynamic Predictors of Mortality

- Hemos - worse outcome with low BP, high LVEDP, high RA pressure, low cardiac output, high PCWP (after medical Rx).
- Better prognostic info if these numbers are obtained while exercising.
- Cardiac Index < 2.0-2.5 l/min/m2
- PVR > 2 – 3 Wood Units

Exercise Predictors of Mortality

- Functional capacity - NYHA classification.
- Class IV 50-77% 1 year mortality.
- Class III 10-45%
- Class II 3-25%

Exercise Testing – Peak Exercise Oxygen Consumption



- Exercise VO2 is an objective way to measure exercise tolerance and perhaps the most frequently used way to predict mortality with heart failure.
- **VO2 < 14 ml/kg/min high predictor of mortality**. 1 yr survival (94% vs 47%) 2 yr survival (84% vs 32%) 1991 Circulation

Mancini et al. 1991

Neurohormonal Predictors of Mortality

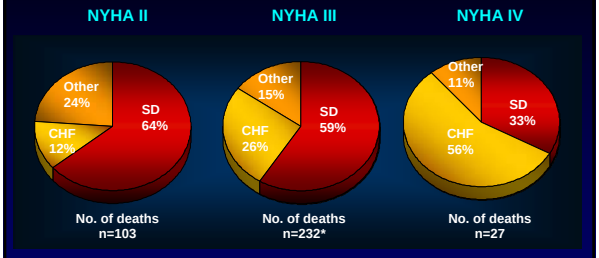
- Neurohormones - elevations norepi and others have all been associated with poor outcomes. Now BNP is being used commonly. ? Good enough predictor of mortality high enough to predict who needs a transplant?

Other Predictors of Mortality

- Hyponatremia
- Elevated BUN
- Hypotension
- Elevated LFTs (T.Bili)
- Advanced Age
- Respiratory Rate (hospitalized)

- Heart Failure Survival Score
- Seattle Heart Failure Model

Mode of Death in HF Patients By Disease Severity



SD = Sudden death; CHF = mortality secondary to worsening heart failure

*One case unclassified
MERIT-HF Study Group. *Lancet.* 1999;353:2001–2007.

ACC/AHA Guidelines

Treatment of Stage D refractory heart failure

- Meticulous control of fluid retention
- Stage C treatment options, though often renal insufficiency and hypotension thwart attempts.
- Reverse reversible causes; ischemia
- Transplant
- Inotropes
- Assist devices
- Other

Hunt SA, et al. ACC/AHA practice guidelines. Chronic CHF in the adult. Circulation 2001;104:2996-3007

Treatment of Stage D refractory heart failure "trouble-shooting"

- Confirm medical adherence to diet, salt, meds
- Initiate multidisciplinary approach when available
- Look for reversible or contributing causes; ischemia, thyroid disease, anemia
- In patients with CRT, confirm appropriate function, LV lead placement and reevaluate AV optimization
- Right heart catheterization

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ACC/AHA Treatment Class I Recommendations: Stage D

- Referral to a HF program with expertise in the management of refractory HF (level of evidence A)
- Referral for heart transplant in eligible patients (level of evidence B)
- Stages A, B and C measures (levels of evidence vary)

Hunt et al. *JACC* 2001;38:2101.

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Refractory Heart Failure

- **Goals of Transplantation**
- **Stage D Heart Failure**
- **Heart Transplant Outcomes**
- **If Not Transplant … Then what?**

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Heart Transplant

Now that you have determined who has a high mortality with heart failure, you need to determine who will do poorly with transplant.

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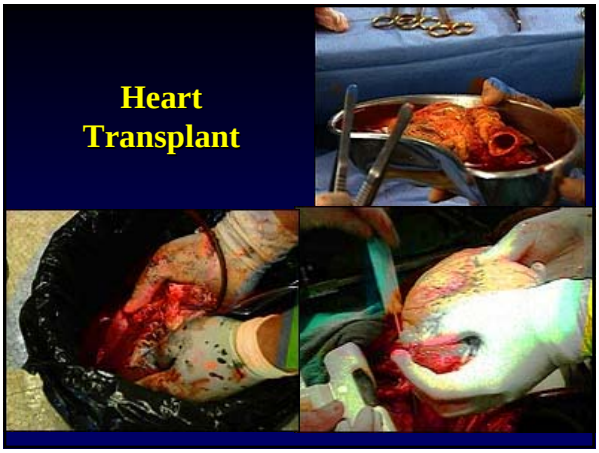
Heart Transplant



Predictors of Bad Outcomes with Heart Transplant

- Age - climbing 55 => 65 => 70 => ?
- Pulmonary Hypertension - PVR greater than 6 that does not reverse with inotropes is relative contraidication. One early study showed with PVR<2.5 on nitroprusside had 3.8% mortality at 3 mos after txp similar to those with PVR <2.5 at baseline. Those who could not get lower than 2.5 had a 40.6% mortality 3 month mortality. Strong predictor of early outcomes.
- Lung Disease - not less than 50% FEV1.
- Renal Dysfunction - Cr>2 predicts a worse outcome, actually it is a continuous variable.
- Hepatic Dysfunction

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Predictors of Bad Outcomes with Heart Transplant

- CNS disease
- Active ulcer disease
- Diabetes - relative. They do much worse with complications.
- Obesity
- Osteoporosis
- Active infection
- Malignancy - Only true contraindication.
- Systemic diseases with myocardial infiltration - sarcoid, amyloid, etc.

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Predictors of Bad Outcomes with Heart Transplant

- Poor social situation
- Psychologic problems
- Abuse of Cig, ETOH, Drugs in past or present.

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Indications for Cardiac Transplantation

- Refractory HF, age ≤ 65, with:
  - Stage D Heart Failure despite optimal medical therapy
  - Acceptable comorbidities
  - Adequate psychosocial support
  - Medical compliance
  - No substance abuse

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Contraindications to Cardiac Transplantation

- Active or recent malignancy
- Irreversible significant pulmonary disease
- Irreversible significant renal disease
- Irreversible hepatic dysfunction
- Severe vascular disease – peripheral or cerebral
- Irreversible pulmonary hypertension
- Severe osteoporosis
- Severe obesity
- Unstable psychiatric disease
- Active infection
- Coexistent systemic illness with poor prognosis
- HIV infection

(Adapted from Mudge, et. al.)

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Relative contraindications to Cardiac Transplantation

- Diabetes Mellitus
- Vascular disease
- Moderate obesity
- Peptic ulcer disease
- Age over 65 years
- Poor psychosocial support
- History of medical non-compliance
- Renal insufficiency
- Hepatitis C infection
- Active Hepatitis B infection
- Presence of anti-human antibodies (Positive panel reactive antibodies (PRA))

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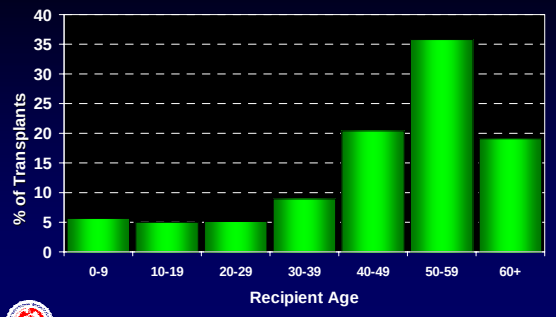
AGE DISTRIBUTION OF HEART RECIPIENTS (1/1982-6/2006)



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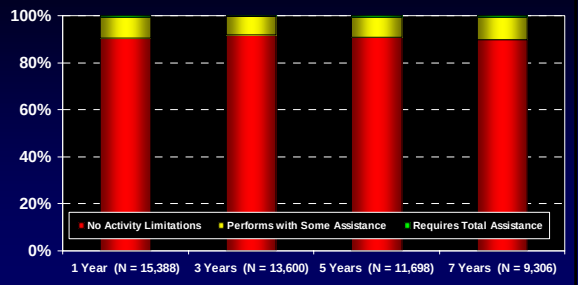
ADULT HEART RECIPIENTS

Functional Status of Surviving Recipients
(Follow-ups: 1995 - June 2006)



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POST-HEART TRANSPLANT MORBIDITY FOR ADULTS

Cumulative Prevalence in Survivors at 5 and 10 Years Post-Transplant (Follow-ups: April 1994 - June 2006)

Outcome	Within 5 Years	Total N with known response	Within 10 Years	Total N with known response
Hypertension	93.8%	(N = 8,266)	98.5%	(N = 1,586)
Renal Dysfunction	32.6%	(N = 8,859)	38.7%	(N = 1,829)
Abnormal Creatinine < 2.5 mg/dl	*21.2%*		*24.4%*	
Creatinine > 2.5 mg/dl	*8.4%*		*8.2%*	
Chronic Dialysis	*2.5%*		*4.9%*	
Renal Transplant	*0.5%*		*1.2%*	
Hyperlipidemia	87.1%	(N = 9,237)	93.3%	(N = 1,890)
Diabetes	34.8%	(N = 8,219)	36.7%	(N = 1,601)
Cardiac Allograft Vasculopathy	31.5%	(N = 5,944)	52.7%	(N = 896)

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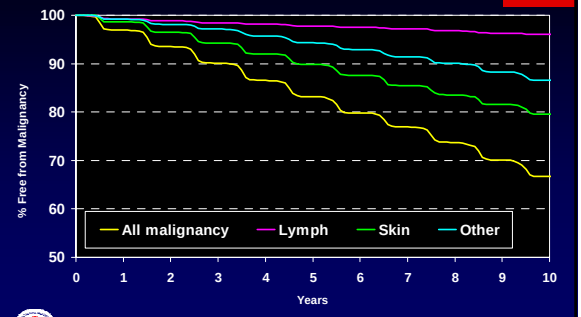
FREEDOM FROM MALIGNANCY

For Adult Heart Recipients (Follow-ups: April 1994 - June 2006)



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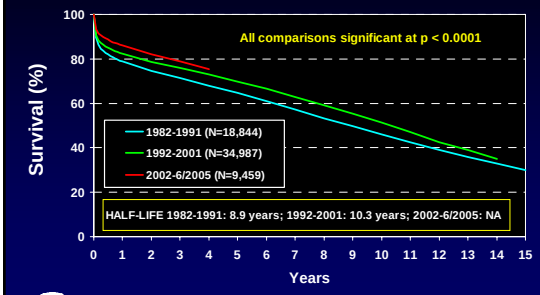
ADULT HEART TRANSPLANTATION

Kaplan-Meier Survival by Era (Transplants: 1/1982 – 6/2005)



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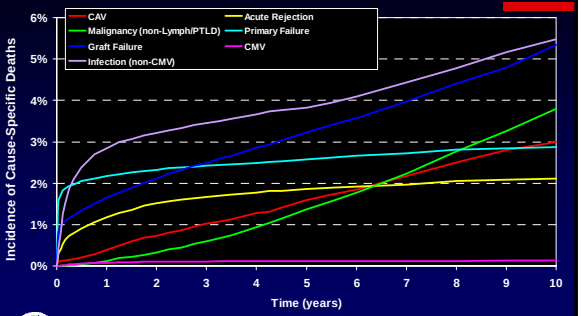
ADULT HEART TRANSPLANT RECIPIENTS: Cumulative Incidence of Leading Causes of Death

(Transplants: January 1992 - June 2005)



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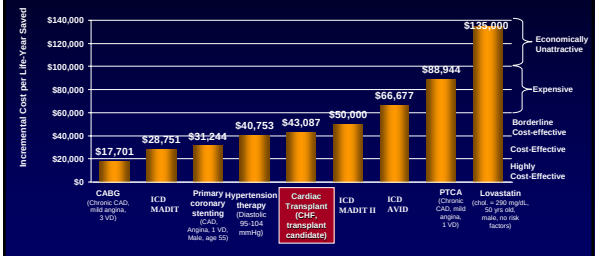
Incremental Cost-Effectiveness of Cardiovascular Interventions

Total Cost A – Total Cost B
Life Expectancy A – Life Expectancy B



*Moss AJ. Presentation at Satellite Symposium, "Cost-Effectiveness of Device Therapy in the Heart Failure Population", Heart Failure Society of America Annual Meeting September 23, 2003.

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Societal Spending on Other Life-Saving Interventions [1]

Intervention	Cost/Life-Year Saved in 1993
Flashing lights at railroad crossings	$42,000
Flammability standard for upholstered furniture	$68,000
Airbags (vs. manual lap belts) in cars	$120,000
Annual mammography for women age 40-49	$190,000
Smoke detectors in homes	$210,000
Front disk (vs. drum) brakes in cars	$240,000
Strengthen buildings in earthquake-prone areas	$18,000,000
Ground fault circuit interrupters	$1,200,000

1. Tengs TO, et al. *Five-Hundred Life-Saving Interventions and Their Cost-Effectiveness. Risk Analysis*, Vol. 15, No. 3

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Refractory Heart Failure

- Goals of Transplantation
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- **If Not Transplant … Then what?**

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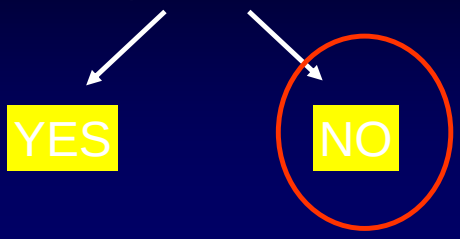
"Truly" Refractory Heart Failure

Question #1

Transplant candidate ?



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"Truly" Refractory Heart Failure Contraindications to transplant

- Advanced age
- Fixed pulmonary hypertension
- Unstable psychosocial situation
- Serious co-morbidity
  - Cancer
  - Diabetes
  - Vascular disease
  - Renal failure
  - Systemic disorder
  - Stroke
  - Extreme obesity
  - etc.

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ACC/AHA Heart Failure Guidelines: Therapeutic Options in Stage D

- All measures under stages A, B, and C
- Cardiac transplantation
- Continuous (not intermittent) IV inotropic infusions for palliation
- Mechanical assist devices
- Hospice care

Hunt et al. *JACC* 2001;38:2101.

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Inotropes

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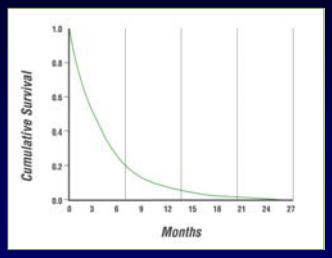
Limitations of Current Therapies for Acute CHF: Positive Inotropes

- **Increased mortality**
  - Milrinone [1,2]
  - Enoximone [3]
  - Imazodan [4]
  - Vesnarinone [5]
  - Dobutamine [6,7]
  - Xamoterol [8]
  - Ibopamine [9]
- **Increased risk of hospitalization** [1]
- **Aggravation and induction of arrhythmias (need telemetry)**
  - Milrinone [10,11]
  - Dobutamine [12]
  - Dopamine [13]
- **Tachycardia** [14]
- **Tachyphylaxis** (dobutamine)[15]
- **Neurohormonal activation and/or lack of suppression** [16]
- **Physiologic effects antagonized by b-blockade** (dobutamine, dopamine)

[1]Packer M, et al. *New Engl J Med* 1991; 325: 1468-75.
[2]DiBianco R, et al. *New Engl J Med* 1989; 320: 677-83.
[3]Uretsky BF, et al. *Circulation* 1990; 82: 774-80.
[4]Goldberg AD, et al. *Circulation* 1990; 82: Suppl III: III-673.
[5]Cohn JN, et al. *New Engl J Med* 1998; 339: 1810-16.
[6]Dies F, et al. *Circulation* 1986;74: Suppl II: II-38.
[7]O'Connor CM, et al. *Am Heart J* 1999; 138: 78-86.
[8]The Xamoterol in Severe Heart Failure Group. *Lancet* 1990; 336: 1-6.
[9]Hampton JR, et al. *Lancet* 1997; 349: 971-7.
[10]Kleiman NS, et al. *J Am Coll Cardiol* 2000; 36: 310-25
[11]Thackray S, et al. *Eur J Heart Fail* 2000; 2: 209-212
[12]Burger AJ, et al. *Am J Cardiol* 2001 Jul 1;88(1):35-9
[13]Chiolero, et al, *Cardiovasc Surgeon* 1991; 39: 81-84
[14] Colucci WS. *J Card Fail* 2001;7(1):92-100.
[15] B. Hoffman and R. Lefkowitz. Chapter 10, The Pharmacologic Basis of Therapeutics, Goodman and Gilman, Eds, 9th. Edition (CD-ROM) 1996.
[16]Aronson D, et al. J Card Fail 2001; 7 (No. 3 Suppl 2): 2

Continuous Inotropic Infusions - COSI



Source
Ray E. Hershberger MD;
Oregon Health and Science University

n = 26

Hershberger RE et al. J Cardiac Failure 2003;9:180

Left Ventricular Assist Devices (LVAD)

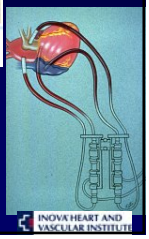
Current MCS Definitions

- **Bridge To Recovery**
- **Bridge To Transplant**
- **Destination Therapy**
- **?? Salvage / Bridge To Decision ??**

Left Ventricular Assist Devices "First-generation" Positive Displacement Devices

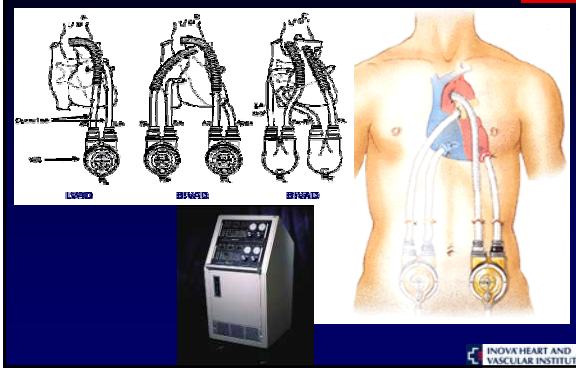
Abiomed BVS 5000

BVS 5000 Blood Pump



Can pump up to 5 l/min
Right or left ventricular support
Dual pumping chambers on each side similar to natural heart.

Thoratec BiVAD



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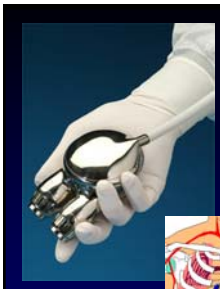
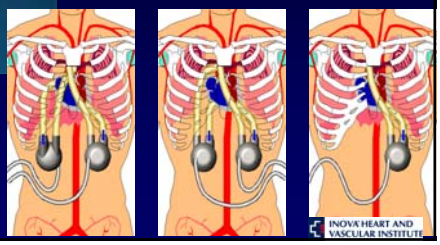
Thoratec IVAD





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HeartMate XVE

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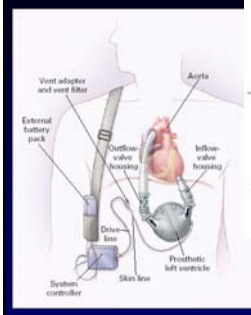


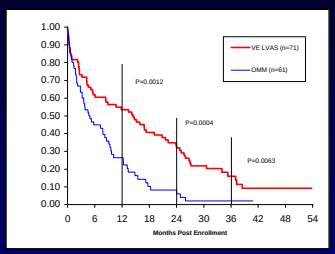

The New England Journal of Medicine

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

REMATCH

1st study for Destination Therapy which got FDA approval for HeartMate XVE

LVADs as Destination Therapy REMATCH Update



- 1 year LVAD vs. OMM survival = 53.5% vs. 26.5%
- 2 year LVAD vs. OMM survival = 32% vs. 8.2%
- 3 year LVAD vs. OMM survival = 15.9% vs. 2%

REMATCH Update (as of April 2004) – Source Thoratec Registry

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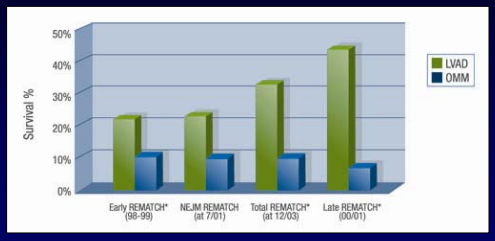
Improved Outcomes in 2-Year LVAD Survival



REMATCH Update (as of April 2004) – Source Thoratec Registry

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FDA/CMS Criteria for Destination Therapy

- Not a candidate for heart transplant
- NYHA class IV end-stage LV failure
- Life expectancy < 2 years
- Symptoms failed to respond despite optimal medical management for ≥ 60 of past 90 days
- LVEF < 25%
- Peak VO_2 < 12 ml/kg/min or inotrope dependence
- BSA ≥ 1.5 m^2

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Destination LVAD Therapy

Inclusion criteria:

Refractory heart failure with Class IV symptoms on optimized oral medical therapy and who are inotrope dependent.
Patient who has refractory ventricular arrhythmias
Patient not a transplant candidate.
Insurance evaluated by finance coordinator
Age < 75 years
If ambulatory, measured peak VO2 of <12 ml/kg/min or 6-minute walk < 150 meters.
Has at least three of the four hemodynamic criteria:
- Measured cardiac index of < 2.0 l/min/m2
- Measured pulmonary capillary wedge pressure of > 20 mm Hg
- Measured pulmonary vascular resistance of < 6 Wood units
- Measured right atrial pressure of < 20 mm Hg

Adequate psychosocial support system, including designated caretaker(s)
Demonstrates ability to manage LVAD equipment as evaluated by LVAD nurse after teaching sessions.

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Destination LVAD Therapy

- ***Exclusion criteria:***
- Active infection
- Any co-morbid disease that may impact on two-year survival
- BMI <20 or >40, or BSA < 1.5 m2
- Multiorgan failure
- Chronic renal disease with high likelihood of dialysis within the next year or on dialysis.
- Diabetes mellitus with severe end organ damage, or uncontrolled
- Uncorrectable aortic regurgitation or mitral stenosis
- Prosthetic mechanical aortic or mitral valve
- Evidence of significant cerebrovascular or peripheral vascular disease.
- Aortic aneurysm, thoracic or abdominal, unless cleared by vascular surgery
- Serum creatinine > 2.5 mg/dl
- Serum transaminases > 3 times normal
- Total bilirubin of > 2 mg/dl
- Ventilator-dependent
- Chronic narcotic use
- Alcohol or substance/tobacco abuse
- FEV1 < 1.2 l/min
- Any medical condition that would have a negative impact on rehabilitation
- Chronic psychiatric disorder that would impact on ability to care for the device
- Coagulopathy or significant thrombocytopenia
- Malnutrition
- Any co-morbidity that, in the opinion of team, would make home management dif

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Left Ventricular Assist Devices "Second generation" axial flow pumps

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Rotary blades of an Axial Flow Device

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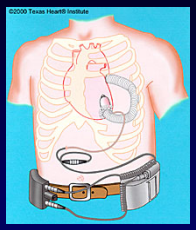
Jarvik 2000



Axial blood flow pump
Vaned impeller of neodymium-iron-boron magnet inside titanium
Supported by ceramic bearings.
2.5 cm x 5.5cm wt 85 grams.
8000-12,000 RPM to provide 5 l/min

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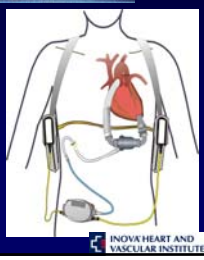
HeartMate® II LVAD



BTT and DT
Axial flow, rotary blood pump.
12 oz, 1.5 in x 2.5 in.
Potential use in small adults or children.
Internal titanium.
6,000-15,000 RPM up to 10 l/min

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Heart Mate II

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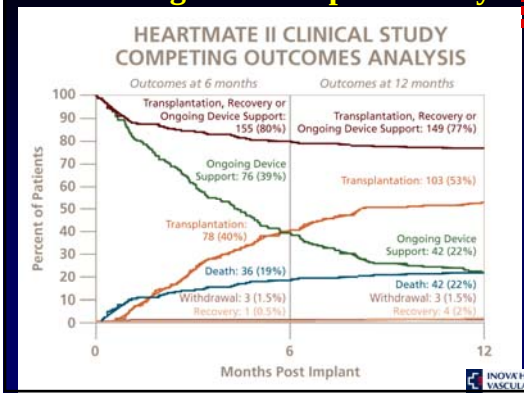
Bridge to Transplant Study



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Impella – In the Cath Lab

Either directly into LV or percutaneously into LV
Provides 2.5 l/min blood flow at 33,000 RPM
21Fr pump at the end of a 9Fr catheter
5 l/min catheter also available
Designed for up to 7 days of support.

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Left Ventricular Assist Devices
"Third generation"
Magnetically Driven

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Thoratec (Levitronix) CentriMag LVAS

Short-term – up to 14 days.
Operates without mechanical bearings or seals.
Magnetically levitated impeller contacting only blood.
1500-5500 RPM up to 9 l/min.

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TandemHeart pVAD

Short-term support – up to 14 days.
Percutaneous implantation.
Magnetically driven 6 blade impeller.
4 l/min.

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Levacor

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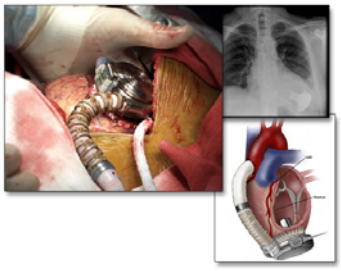
HeartWare

HeartWare HVAD
Implanted in Pericardial Space



Potential Benefits

- No pump pocket or abd surgery
- Shorter implant time
- Reduced procedural invasiveness and complexity
- Reduced recovery time

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Total Artificial Heart

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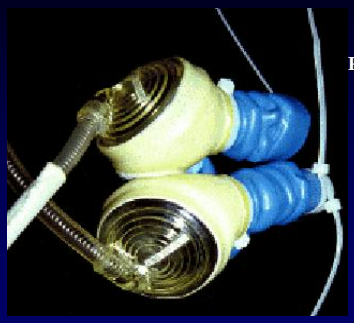
Cardiowest® TAH



FDA approved for biventricular support as a bridge to transplantation

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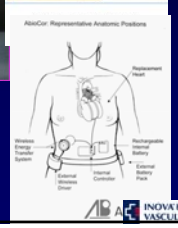
Abiomed's Abiocor Total Artificial Heart



Artificial ventricles and valves.
2 lb motor driven hydraulic pump
Internal rechargeable battery
Charged across the skin.

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Must categorize patients when considering MCS

- **Salvage –**
  - **Rescue in failure to wean from CPB in OR**
  - **Acute MI in shock**
- **Bridge to transplant -**
  - **Progressive class IV failure with maximal pharmacologic support**
  - **Acute cardiogenic shock**
- **Bridge to recovery –**
  - **fulminant myocarditis with shock**
- **Destination therapy –**
  - **outpatient class IV HF.**

A Case of Cardiogenic Shock

History

- 65 yo Ischemic CM, CABG 1992, stent, afib, known EF of 30%.
- Infarct in Oct 2008 with troponin of 26 developed worsening symptoms of heart failure since then of SOB, decreasing exercise tolerance, and orthopnea.
- Jan 2009 upgrade to BiV pacer with 1 month improvement, then continued to fail.

History

- Anorexia, 30 lb weight loss, and confusion.
- Feb 2009 increasing nausea with negative GI evaluation. Na 138, TBili 1.1, Cr 1.2, prealbumin 15.
- Presented to OSH and urgently transferred to Fairfax.

Admit

- Na 126, TBili 2.5, ALT 523, AST 603, Bun 81, Cr 3.0, INR > 9.9.
- On physical – BP 88/61, P 80, cachectic in distress, drowsy with decreased mentation, elevated JVP, parasternal heave, systolic murmur, and S3. Ascites and frank hepatomegaly. Cool extremities.

Decision Making

- RHC
- IABP
- Impella
- Tandem Heart
- VAD
- ECMO

ECMO

- ECMO implanted emergently in OR.
- Implant on 3/19.
- Extubation and weaning off inotropes
- Improvement of labs with Na 142, BUN 21, Cr 0.8, TBili 2.1.
- Explanted and upgrade to HMII LVAD on 3/24.

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LVAD

- Heart Mate II LVAD implanted 3/24/09.
- Listed for transplant and discharged home with a very good quality of life.
- Underwent subsequent heart transplantation several months later.
- Doing very well.

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