

# Advanced heart failure Focus on LVAD therapy

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## Background on Heart Failure

Population Group	Prevalence	Incidence	Mortality	Hospital Discharges	Cost
Total Population	5,700,000	670,000	50% within 5.5 years	1,100,000	\$37 billion

- Over 1 million patients hospitalized this year; 12 million outpatient office visits
- HF hospitalizations one of largest expenses for CMS
- Mortality rates remain very high
- One of the few major cardiovascular diseases increasing in incidence

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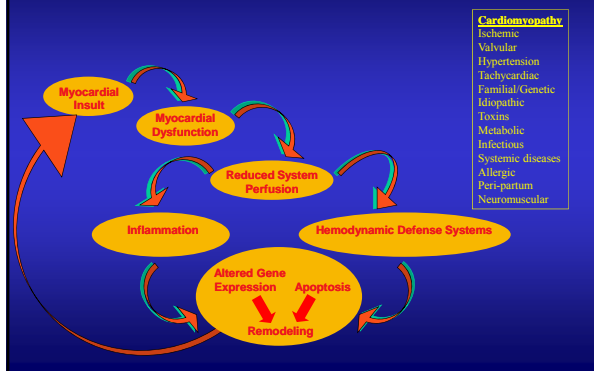
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## Pathophysiology (Downhill Cascade)




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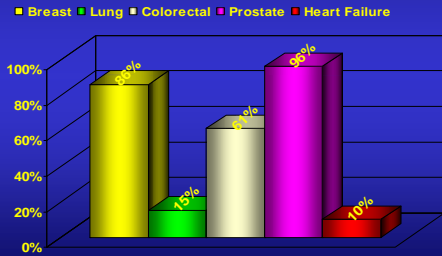
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## 7 year Survival of Cancer or Symptomatic Systolic Heart Failure



CDC/AHA Heart and Stroke Statistical Update 2001

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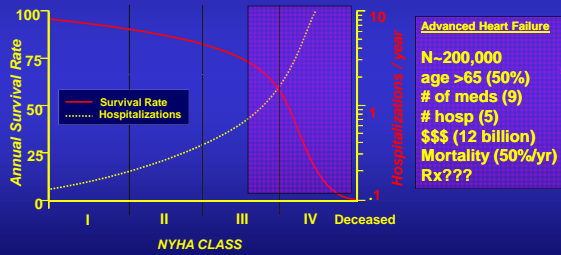
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## Un-Natural History of Heart Failure



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

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## Markers for Advanced CHF (EF<35%)

### Rapidly Assessable

- ✓ **Clinical Scenario**  
 Inotrop/pressor dependence (~50% 1-3 mos)  
 Acute myocardial Infarction (~50% 1-3 week)
- ✓ **Demographic**  
 Etiology (infiltrative>ischemic>non-ischemic>paripartum)  
 Age (>68)
- ✓ **Symptoms**  
 NYHA (PND)  
 Syncope
- ✓ **Signs**  
 Chronic S3  
 JVP

### Easily Available

- ✓ **12 lead ECG**  
 A-Fib QRS (>120ms)
- ✓ **Cardiopulmonary Testing**  
 VO2 max < 14 ml/kg/min
- ✓ **Blood Work**  
 Na (<130)  
 BUN/Cr (>40 / >2.3)  
 Hgb (<11 men, <10)  
 Cholesterol (<150)  
 BNP or nt-BNP
- ✓ **2 D Echo with Doppler**  
 LVEF (<25%) Depressed RV function  
 LVEDD (>6cm)  
 Restrictive Mitral Inflow Pattern (Doppler)  
 Pulmonary Hypertension (Doppler)

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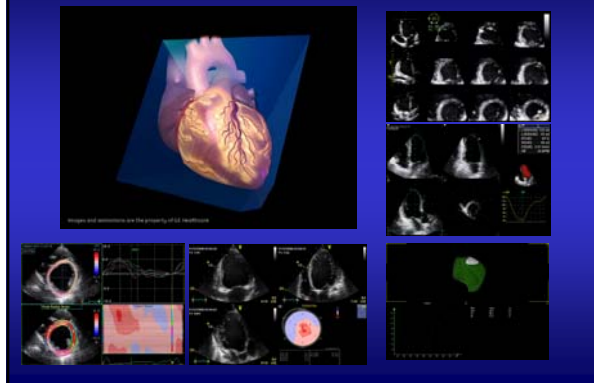
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### 3D the future of heart failure imaging



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### Are there any better options

#### What if a therapy could improve??

- ✓ Functional capacity
  - Mobility/independence
  - Improve QOL
- ✓ End-organ dysfunction
  - Kidney, Lungs and Liver
- ✓ Low complication rate
- ✓ Survival

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### Mechanical Assist Applications 21st Century

General

- Cardiogenic
- Refractory
- Pulmonary

HEMODYNAMIC → → →

INVASIVE → → →

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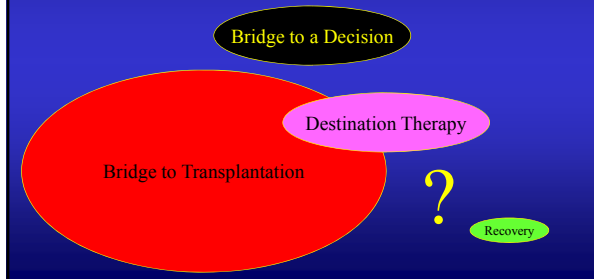
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## VAD Applications 21<sup>st</sup> Century



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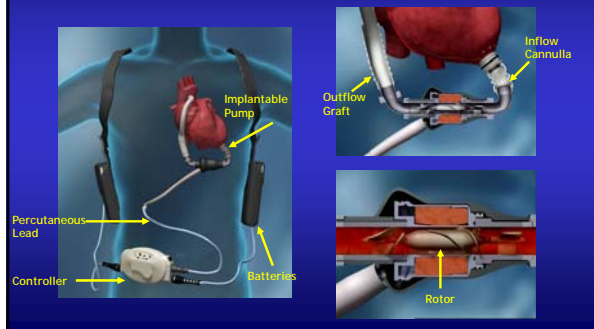
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## Surgically implanted HeartMate II



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## Worldwide Clinical Experience\*

*More than 7,000 patients worldwide have now been implanted with the HeartMate II LVAS.*

- Patients supported  $\geq 1$  year: 2439
- Patients supported  $\geq 2$  years: 851
- Patients supported  $\geq 3$  years: 269
- Patients supported  $\geq 4$  years: 83
- Patients supported  $\geq 5$  years: 20
- Patients supported  $\geq 6$  years: 1

As of March 2011

\*Based on clinical trial and device tracking data (Thoratec Corporation)

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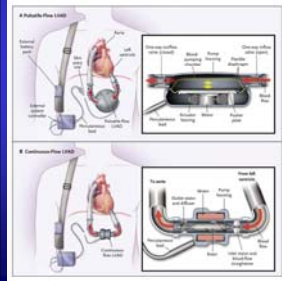
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## Advanced Heart Failure Treated with Continuous-Flow Left Ventricular Assist Device

Mark S. Slaughter, M.D., Joseph G. Rogers, M.D., Carmelo A. Milano, M.D., Stuart D. Russell, M.D., John V. Conte, M.D., David Feldman, M.D., Ph.D., Benjamin Sun, M.D., Antone J. Tatroles, M.D., Reynolds M. Delgado, III, M.D., James W. Long, M.D., Ph.D., Thomas C. Wozniak, M.D., Waqas Ghumman, M.D., David J. Farrar, Ph.D., and O. Howard Frazier, M.D.

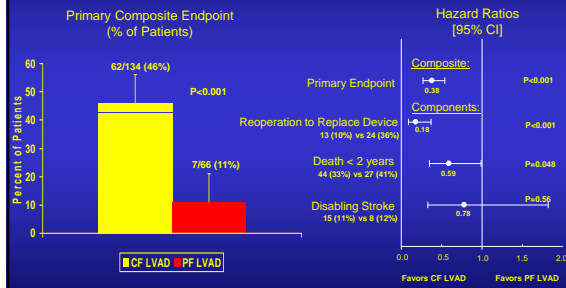


n=200 (134 HMIL, 66 XVE)  
**Primary endpoint: 2 yr survival free from disabling stroke or pump repair/replacement**

	Continuous	Pulsatile
AGE	62±12	63±12
LVEF	17±5.5	16.8±5.4
SBP	104±14	104±18
PCWP	24±8	24±9
CI	2.0±0.6	2.1±0.6
Na	134.7±4.3	133.9±6.0
Cr	1.6±0.6	1.8±0.7
Inotropic	103(77%)	55(83%)

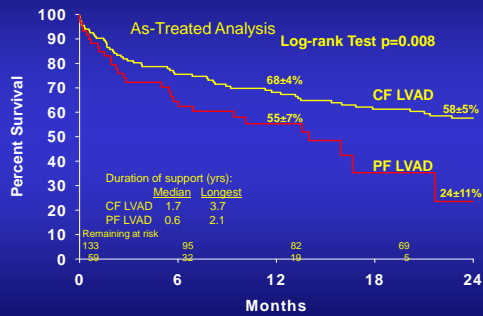
## Primary Endpoint

Survival at 24 months, free from disabling stroke or re-operation for device replacement (intention-to-treat)



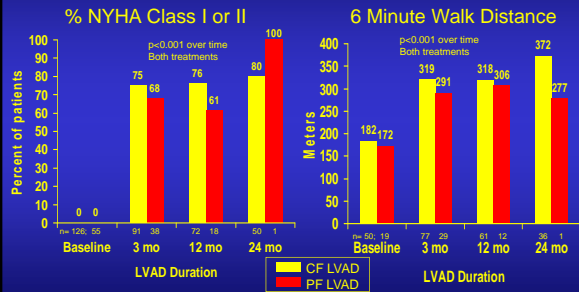
NEJM 2009;361(23):2241-51.

## Actuarial Survival



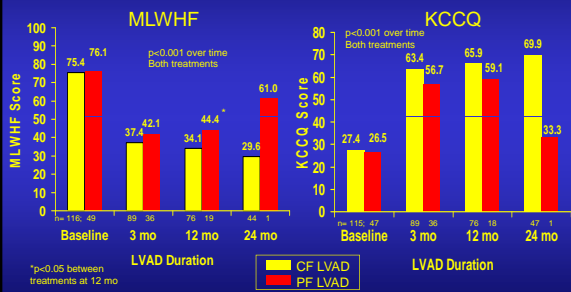
NEJM 2009;361(23):2241-51.

## Functional Status



NEJM 2009;361(23):2241-51

## Quality of Life



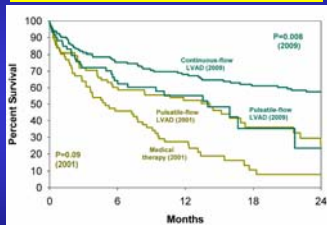
NEJM 2009;361(23):2241-51

## DT Trial CAP: Background

### Background

- Initial HeartMate II Destination Therapy (DT) trial demonstrated significant improvements in outcomes compared to randomized patients with pulsatile LVADs<sup>1</sup>
  - 68% survival at 1 year
  - 58% survival at 2 years
- Over 500 additional DT patients have been enrolled under continued access protocol (CAP)

### Survival in Destination Therapy Trials<sup>2</sup>



<sup>1</sup> Staiger M, Rogers JG, Milano CA et al. Advanced heart failure treated with continuous-flow left ventricular assist device. *N Engl J Med*. 2009 Dec 3;361(23):2241-51.  
<sup>2</sup> Fang JC, Ross H, Mahoney J. Left Ventricular Assist Devices as Permanent Therapy for Advanced Heart Failure. *N Engl J Med*. 2009 Dec 3;361(23):2250-64.

Source: Park SJ, AHA 2010





