

Left Ventricular Assist Devices

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Goals

- Discussion of advanced heart failure
- Overview and definition of LVAD
- Basic function and components of the HeartMate II LVAD
- Patient selection for durable LVAD

A Modern Fairytale

Once upon a time there was a 53 year old man named Steve. He was living happily with his wife in the land of Stockton when he developed worsening fatigue and increased swelling. He found that he could perform fewer and fewer of his usual activities and was admitted to the hospital and told that he had heart failure.



Heart Failure Management

- Heart failure (HF) is a condition that is a result of various cardiac diseases including coronary artery disease and viral cardiomyopathy
- More than 5 million Americans have heart failure
- Medical management and lifestyle modification are the first line of therapy
 - Beta blockers, ACE inhibitors, ARBs, aldosterone antagonists, diuretics, digoxin, hydralazine...
 - Salt and fluid restriction
- Cardiac resynchronization therapy (CRT) has a role in patients with moderate to severe symptoms and a wide QRS on EKG
- Implantable defibrillators can be used to treat potentially fatal arrhythmias

A Modern Fairytale

Steve was told to start medications for his heart and did the best he could. He cut out salt and restricted his water and never missed any doses, but he never seemed to get any better. He was admitted to the hospital for heart failure exacerbations nine times in one year.

Heart Failure Management

- When a patient's symptoms progress despite medical management, lifestyle modification and CRT, advanced therapies must be considered for HF patients
- Estimated 300,000-800,000 Americans have Class IIIB-IV symptoms
 - Shortness of breath at rest or recent shortness of breath at rest
- Current advanced therapy options
 - Heart Transplantation (2000/year)
 - LVAD Therapy (HM II implants total 6000 and rising)

A Modern Fairytale

One day, when Steve was feeling quite low, his fairy godmother appeared to him and said, “Steve, I think there is something that might be able to help you, but you must travel to the Kingdom of Sacramento and confer with the good fairies at the VADican.”

What is a VAD?

- VAD = Ventricular Assist Device
 - Mechanical pump that assists the heart in pumping blood, but unlike transplant does not replace the heart
 - **RVAD** is a right sided VAD and supports the right heart.
 - Temporary only
 - **LVAD** is a left sided VAD and supports the left heart.
 - Temporary and durable types
- Durable LVADs are available at certain centers and now offer another surgical option for the management of advanced heart failure

A Modern Fairytale

His fairy godmother offered him safe passage to Sacramento. She even called the VADican and told her fairy friends to expect him and sent records.

When Steve arrived, he was greeted by the Cardiofairy who explained that he was welcome to their house of healing for as long as he needed to be there.

A Modern Fairytale

“You have been ill for a long time,” the Cardiofairy said to Steve. “Your heart is weak and weary and my good magic will probably not be strong enough to save you.”

“Cardiofairy, I am not ready to die. I am only 53 years old. Is there anything else?”

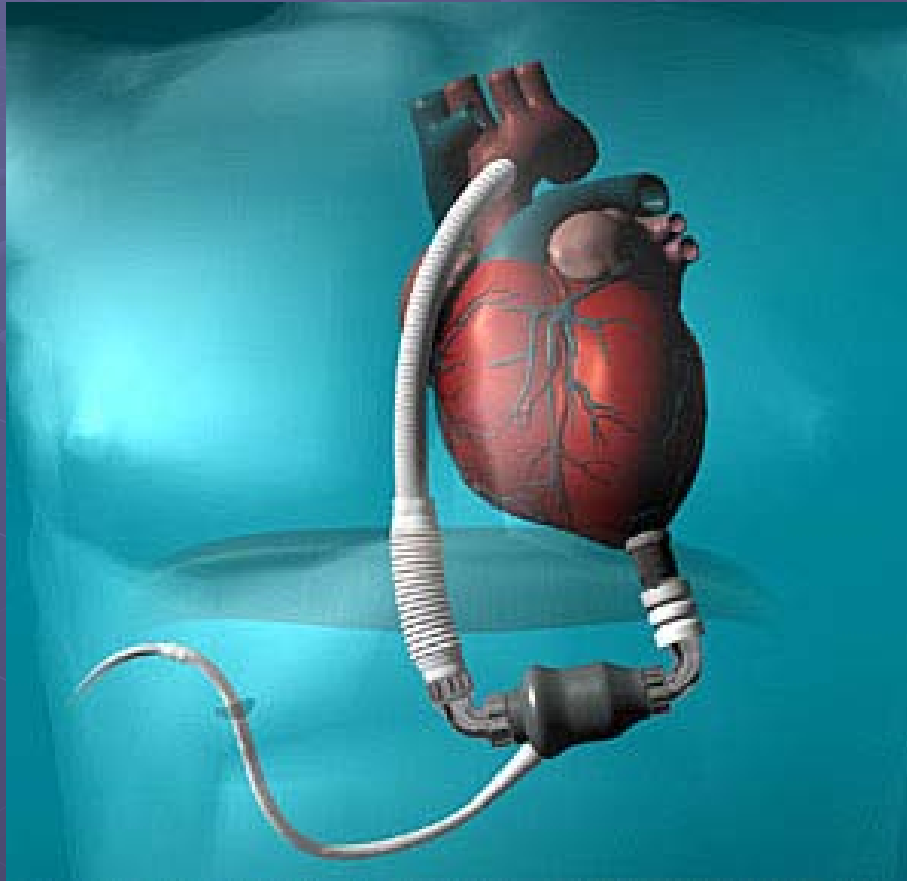
The Cardiofairy smiled and told him about a new device called a VAD.

“Tell me more.” Steve asked, “Is there good data?”

VAD

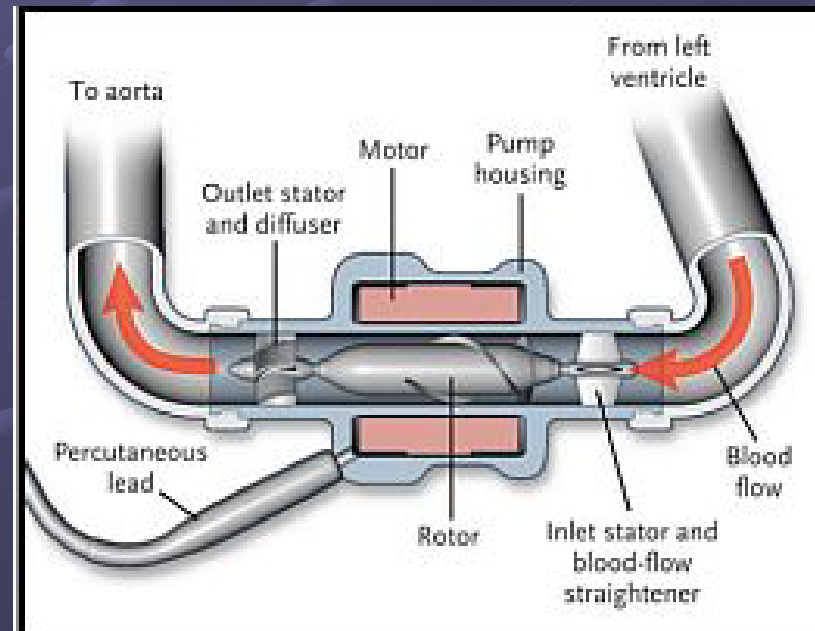
- The first VADs were developed decades ago and their use has been limited to heart transplant centers.
- Limitations of the early VADs
 - Large in size – small patients not candidates
 - Many moving parts - Something always broke
 - Pneumatic pumps - loud
 - Exclusively bridge to transplant
- Widespread use in the HF population has not been seen until recently

HeartMate II



HeartMate II

- Continuous flow (non-pulsatile)
- Rotating impellers with minimal bearings that are magnetically driven
- Left sided support only
- Weighs ~1 lb.
- Very durable
- Quiet



Categorizing LVAD Therapy by Intent

● Bridge to transplant (BTT)

- Intention is for patient to go to transplant
- May prevent death on the wait list

● Destination therapy (DT)

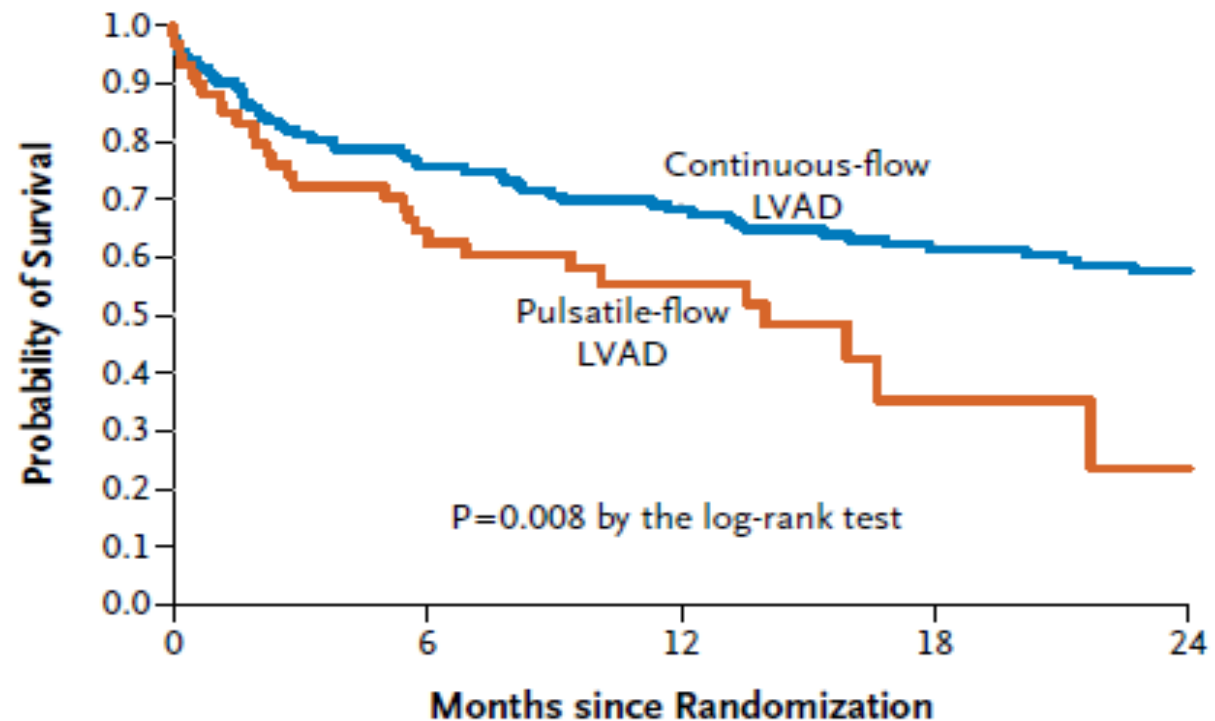
- HeartMate XVE and HeartMate II are the only LVADs approved for this purpose
- Intention is for LVAD therapy to be indefinite

● Bridge to recovery

- Usually difficult to predict with certainty

● Bridge to decision

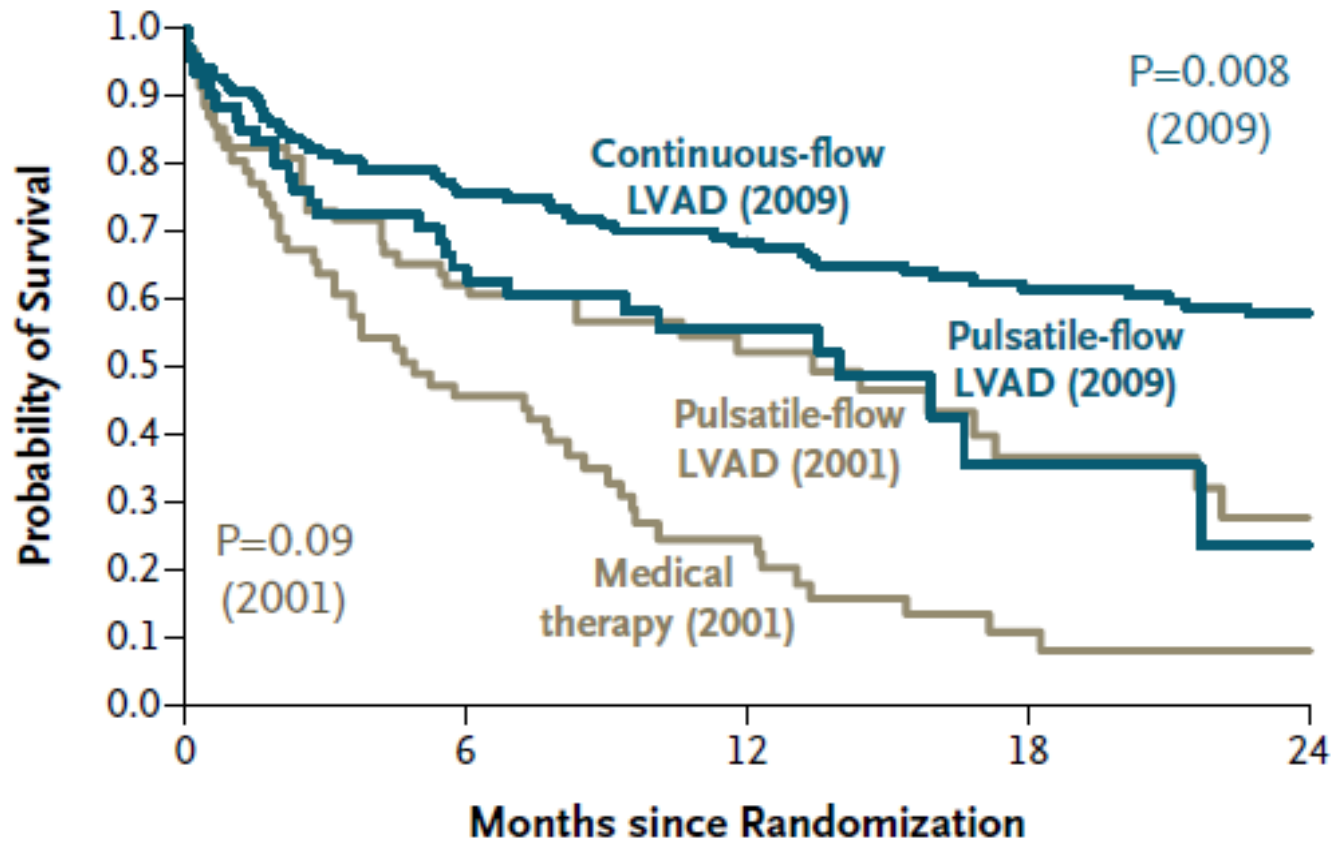
HMII Destination Therapy Trial



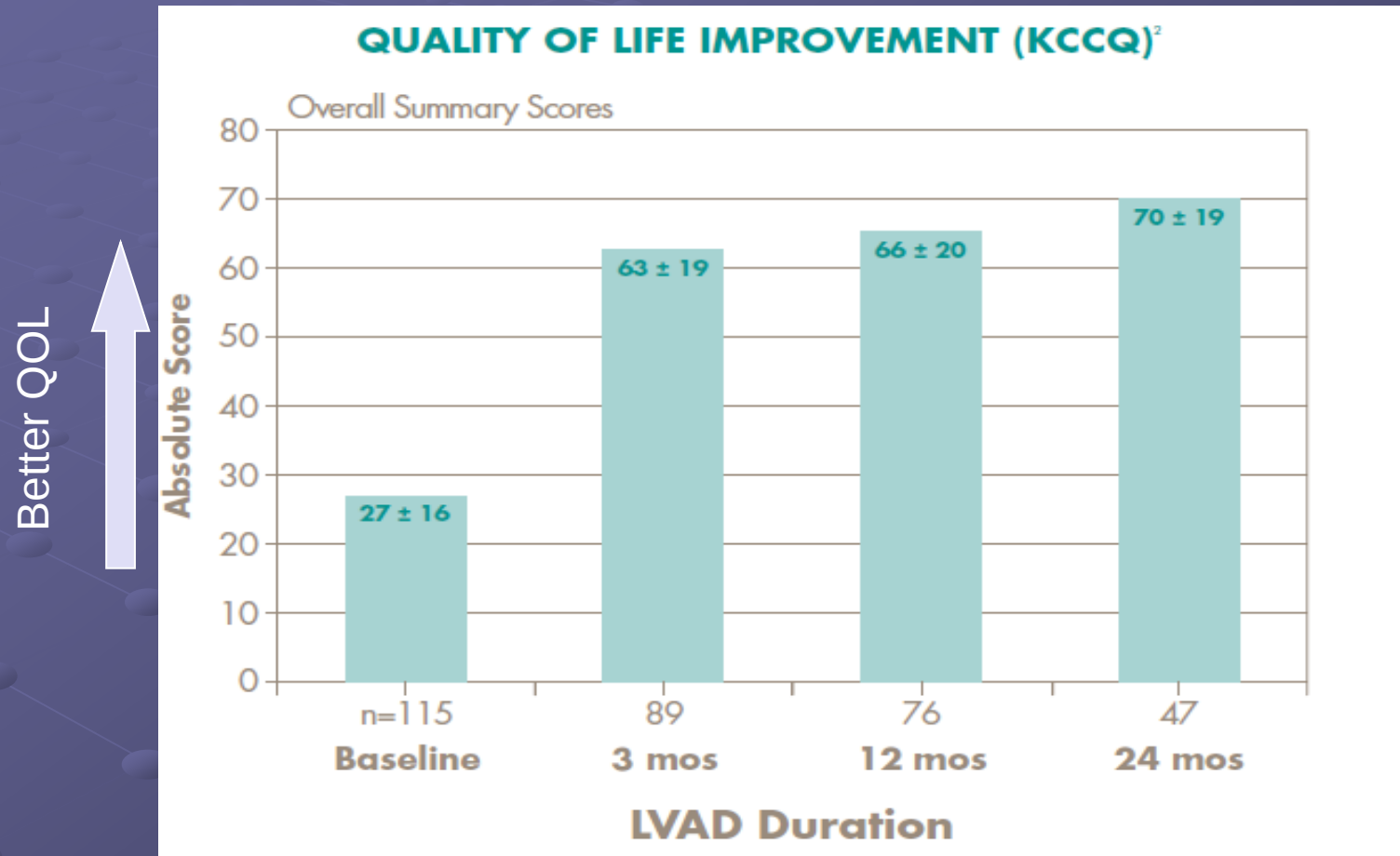
No. at Risk

Continuous-flow LVAD	133	95	82	69	62
Pulsatile-flow LVAD	59	32	19	5	2

DT Actuarial Survival vs REMATCH



Quality of Life



Increases of this magnitude have been shown to correlate closely with an improvement from NYHA Class IV heart failure to between Class I and II

Adverse Events

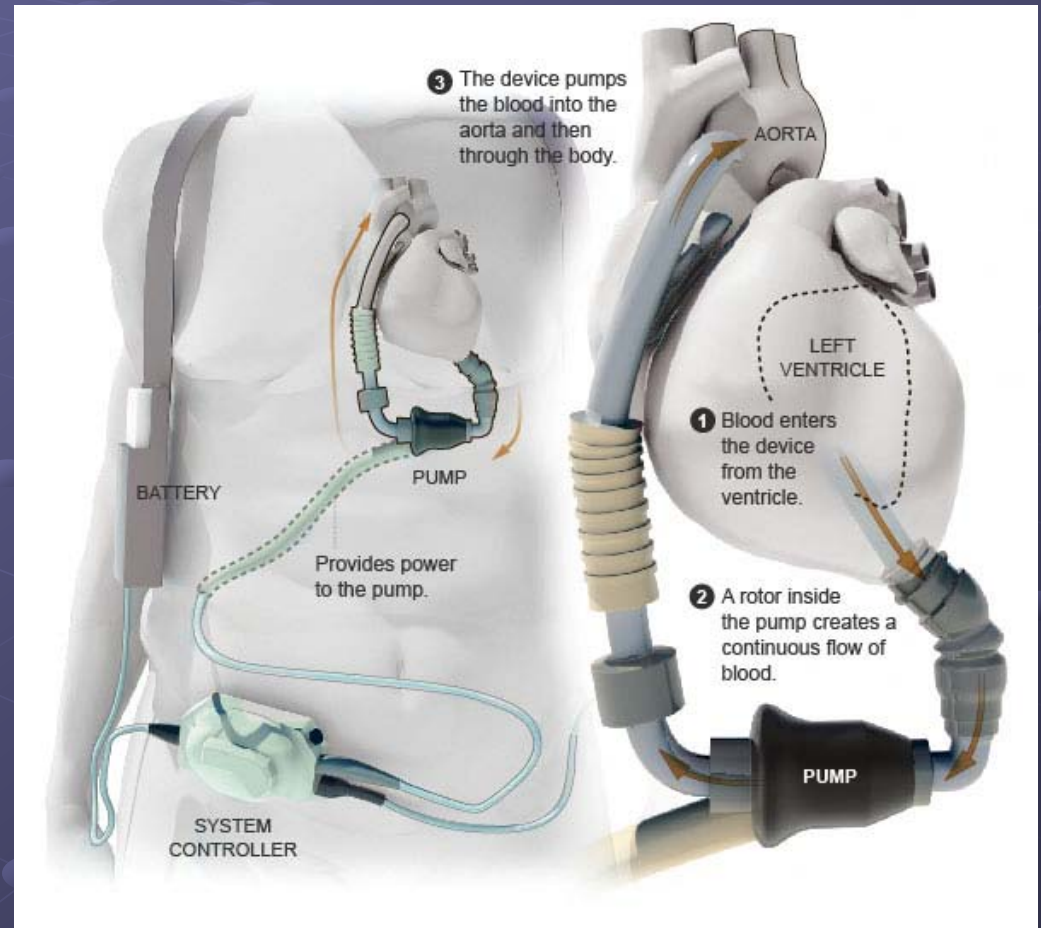
	CF LVAD (n=133) [211 pt-years]	PF LVAD (n=59) [41 pt-years]
	Events/pt yr	Events/pt yr
Pump Replacements	0.06	0.51
Stroke	0.13	0.22
Ischemic	0.06	0.10
Hemorrhagic	0.07	0.12
Device-related infection	0.48	0.90
Local non-device infection	0.76	1.33
Sepsis	0.39	1.11
Bleeding		
Bleeding requiring PRBC	1.66	2.45
Bleeding requiring surgery	0.24	0.29
Other Neurological	0.17	0.29
Right Heart Failure		
Extended Inotropes	0.14	0.46
RVAD	0.02	0.07
Cardiac Arrhythmias	0.69	1.31
Respiratory Failure	0.31	0.80
Renal Failure	0.10	0.34
Hepatic Dysfunction	0.01	0.00
Device Thrombosis	0.02	0.00
Re-hospitalizations	2.64	4.25

Warnings & Restrictions

- No excessive jumping or contact sports
- No swimming/bathing
 - Special equipment and training required for them to shower
- No exposure to MRI
- No pregnancy
- No chest compressions
- Many patients return to work
- Driving is controversial
- Travel needs to be well planned
- Patients may be pulseless. This is okay.
- Blood pressure best taken with a doppler probe

Components of an LVAD

- Cannula
- Pump
 - Internal
- Controller (computer)
- Power source
 - Always external
 - Batteries
 - Wall unit



Components of an LVAD

- Power Module
 - Plugs into wall
- Battery charger
 - Batteries



A Modern Fairytale

“This sounds wonderful,” Steve exclaimed.

“Not so quickly” said the Cardiofairy. “Before you can have this device, you will have to endure many trials. If you pass these trials, I will present you to Surgeonfairy and rest of the multidisciplinary team to discuss implantation of the LVAD.”

Patient Selection

- **Overriding principle is to select patients who will have a survival benefit from the device**
 - Identifying the appropriate window for therapy
 - Cannot be so sick that they will not do well after surgery
 - “Crash and Burn”
 - Cannot be so well that risk of complication or morbidity of the surgery will leave them worse than they were before surgery
 - Right heart must have adequate function

Patient Selection: Clinical Features

- Consider LVAD in heart failure patients with **NYHA III or IV** plus one of the following:
 - Inability to walk < 1 block without dyspnea
 - Serum sodium < 136 mmol/L
 - Worsening renal function (BUN>40)
 - Intolerant or refractory to ACE-I / ARB / BB
 - Diuretic dose > 1.5mg/kg/d (Lasix equivalent)
 - Multiple CHF related hospital admissions within 6 months
 - Refractory to Cardiac Resynchronization Therapy
 - Inotrope dependent

Other Factors

● Psychosocial factors

- Support person
- Transportation
- Some money for dressing supplies, hotel stays if from out of town
- Insurance
- Substance abuse?

● Co-morbidities

LVAD vs. Transplant

- Malignancy is typically a contraindication for heart transplantation, but LVAD may be a consideration
- No strict age limit for LVAD
- No immunosuppressive therapy for LVAD
- If there are psychosocial factors that make the patient ineligible for transplant, it is unlikely that the patient will be an LVAD candidate

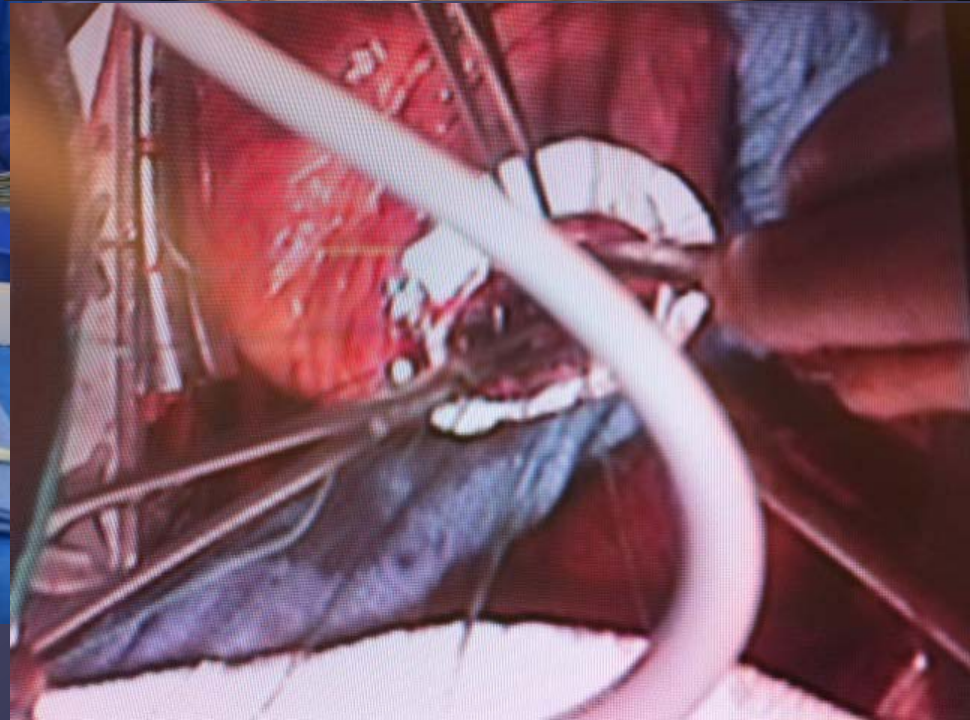
A Modern Fairytale

Steve's first trial was to wean him off of dopamine which the fairies were unable to do which actually meant he passed that test.

He then underwent imaging studies, blood tests, heart catheterization, and a psychosocial evaluation and was told that he had no contraindications.

A Modern Fairytale

Steve met the Surgeonfairy. She noted that he had passed all of his trials and said she would think about it. He anxiously awaited her answer. She went to the highest tower of the VADican and pondered his case. She and the Cardiofairy ate chocolate and decided that the LVAD could be bestowed upon him.





His faithful wife stayed
by his side during the
entire journey.
And they lived....

Summary

- Advances in VAD technology have made durable mechanical assist therapy available for select severely symptomatic heart failure patients
- These pumps are surgically implanted at some tertiary care centers
- Demonstrate mortality and QOL benefit
- Patients must undergo selection similar to heart transplant evaluation

LVADs Save Lives



Ally Smith sees herself in her taffeta gown, staring back in the mirror—and tears up. “I thought,” she says, “this was never going to happen.”

Just last year Ally, 22, was planning her funeral: A strep throat had led to a broader infection that left the Richmond, Texas, student in advanced heart failure. In an eight-hour surgery, doctors implanted a revolutionary new version of a life-saving heart pump. Miniaturized with a lightweight and extra-long-lasting battery pack, it has helped some 4,000 patients like Ally resume their lives; otherwise she might at best have been on a heart-transplant waiting list for years. “Without this,” says Ally’s physician Dr. Roberta Bogaev, “Ally would be dead. Now she has a great life.”

While the former competitive swimmer can’t go back in the pool (the tubing leading to the battery pack can’t be submerged), Ally can do just about everything else—most important, march down the aisle June 26 in her gown and leather cowboy boots. “No one,” says fiancé Mike Babineaux, 24, “can replace her.”

By Alicia Dennis and Darla Atlas

Thanks to a powerful new heart pump, Ally Smith has a second lease on life—and big plans for her wedding day

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Photographs by MATTHEW MAHON