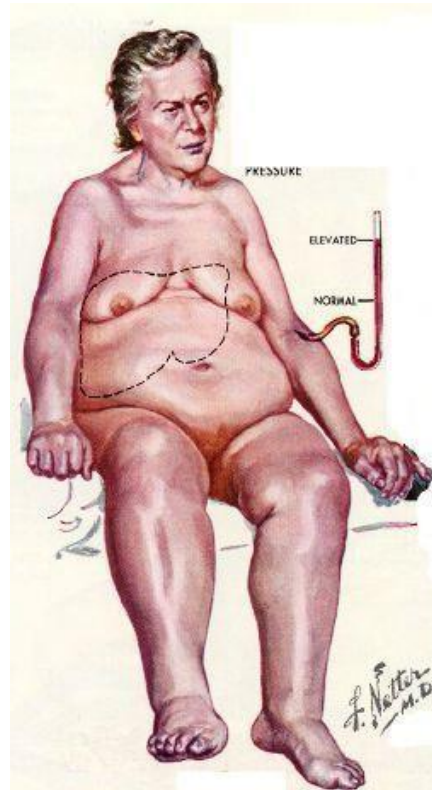


# Surgical treatment of severe heart failure: past, present and future

Dr. med. Anton Sabashnikov  
Nizhny Novgorod, 30. July 2015



## End stage heart failure



Roughly **1 000 000** people suffer from heart failure in Germany

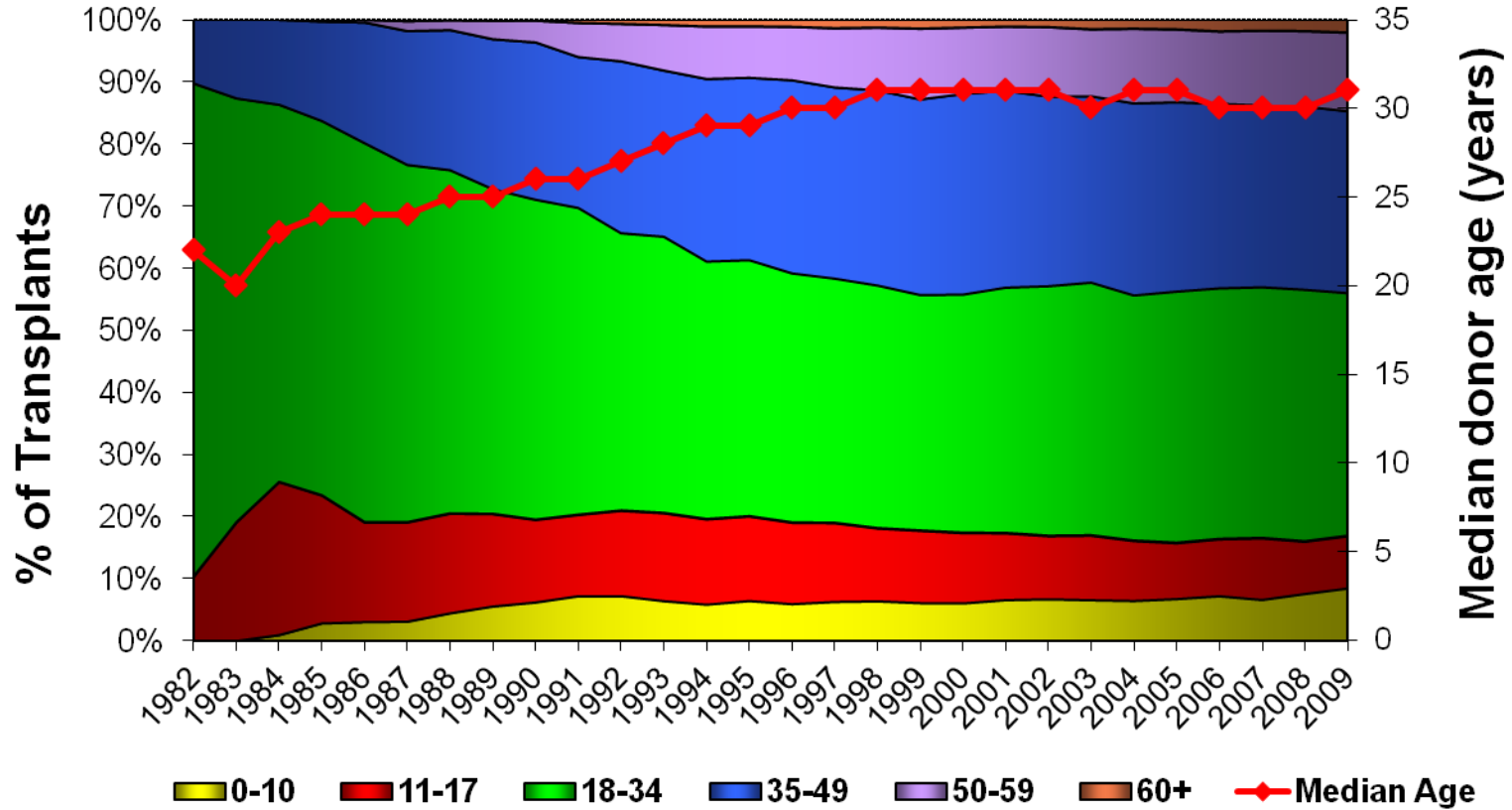
Ca. **200 000** people per year die

Ca. **2500** could be transplanted

However, only **300** donor organs per year are available

# Heart Transplants

## Donar age by year of transplant

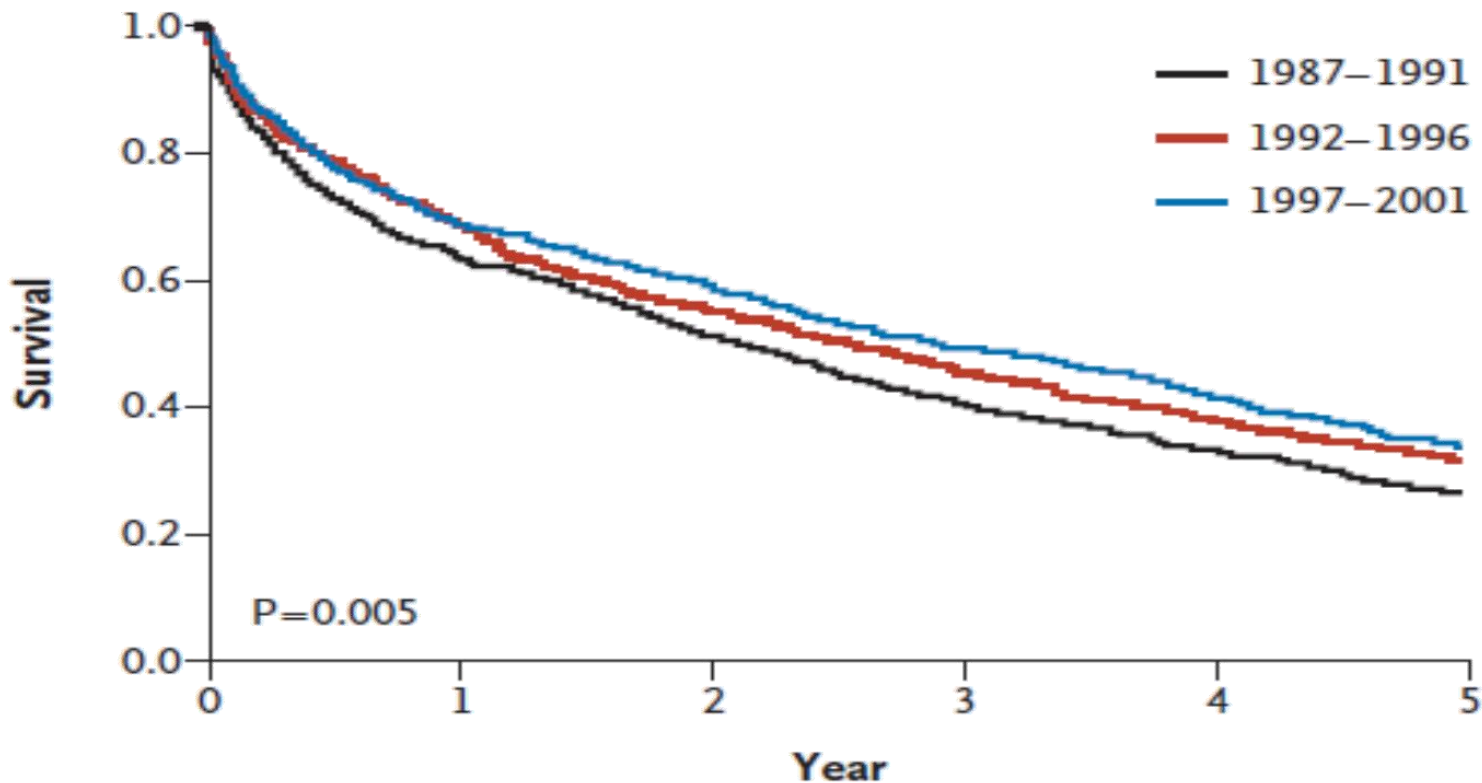


**ISHLT**

J Heart Lung Transplant. 2011 Oct; 30 (10): 1071-1132

# Trends over time in heart failure overall survival

Patients with Reduced Ejection Fraction



2429 pts. CHF (EF<50%) ACE-I/ARB,  $\beta$ -blockers, ICD

Overall survival has improved only slightly since 1987



The NEW ENGLAND  
JOURNAL of MEDICINE

Owan et al. NEJM 2006

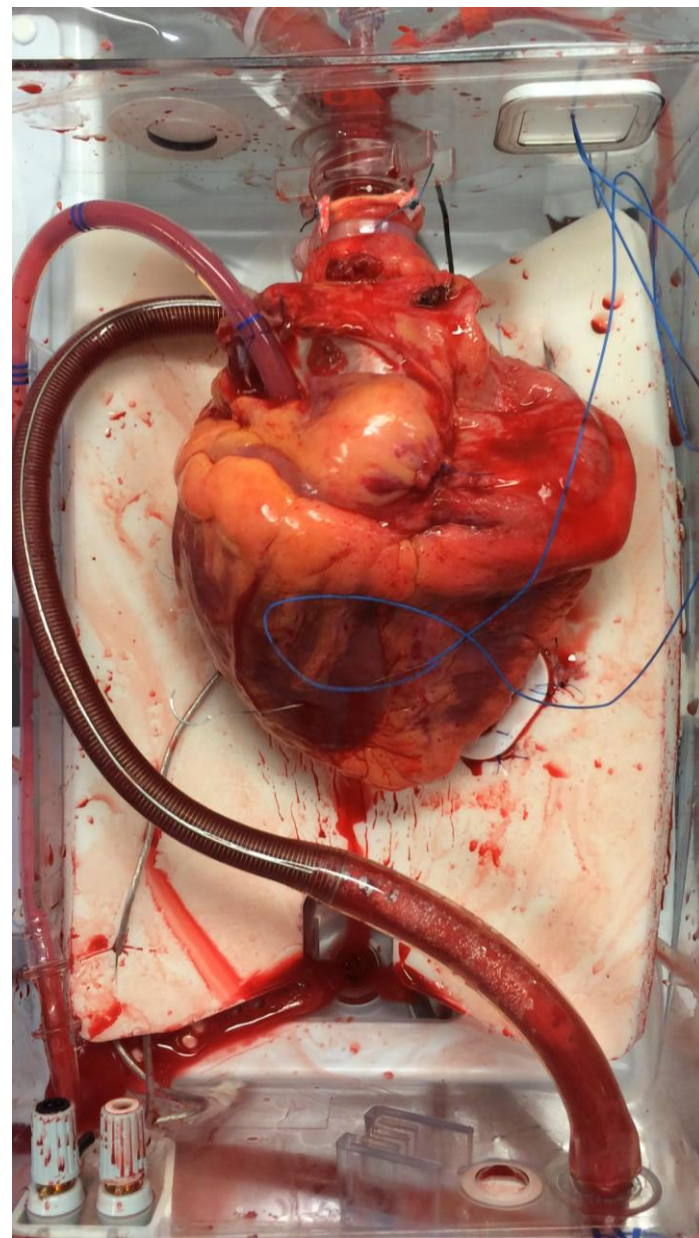
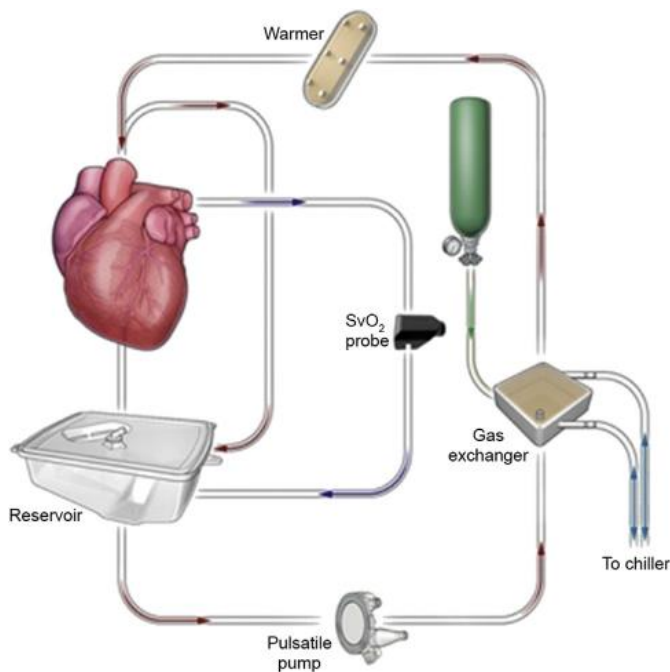
# Evaluation of the Organ Care System in Heart Transplantation With an Adverse Donor/Recipient Profile

Diana García Sáez, MD, Bartłomiej Zych, MD, Anton Sabashnikov, MD, Christopher T. Bowles, PhD, Fabio De Robertis, MD, Prashant N. Mohite, MD, Aron-Frederik Popov, MD, PhD, Olaf Maunz, CCP, Nikhil P. Patil, MRCS, MCh, Alexander Weymann, MD, Timothy Pitt, CCP, Louise McBrearty, CCP, Bradley Pates, CCP, Rachel Hards, RN, Mohamed Amrani, MD, PhD, Toufan Bahrami, MD, Nicholas R. Banner, MD, PhD, and Andre R. Simon, MD, PhD

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(Ann Thorac Surg 2014;98:2099–106)

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# Mechanical assistance as an alternative to heart transplantation



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Time for a paradigm shift?

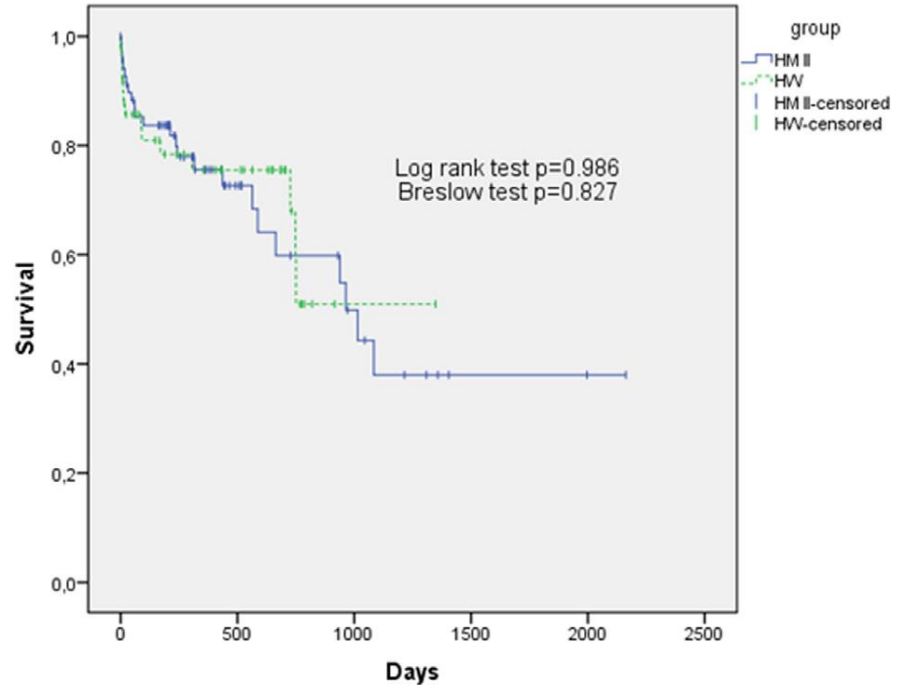






# Outcomes in Patients Receiving HeartMate II Versus HVAD Left Ventricular Assist Device as a Bridge to Transplantation

A. Sabashnikov<sup>a,b,\*</sup>, P.N. Mohite<sup>a</sup>, B. Zych<sup>a</sup>, A.-F. Popov<sup>a</sup>, J. Fatullayev<sup>a,b</sup>, M. Zeriuoh<sup>b</sup>, R. Hards<sup>a</sup>, D. García Sáez<sup>a</sup>, M. Capoccia<sup>a</sup>, Y.-H. Choi<sup>b</sup>, T. Wahlers<sup>b</sup>, F. De Robertis<sup>a</sup>, T. Bahrami<sup>a</sup>, M. Amrani<sup>a</sup>, and A.R. Simon<sup>a</sup>



Patients were censored for transplantation and VAD explantation due to myocardial recovery

## Long-term outcomes

Support duration (d)	448.8 (175–529.3)	385.1 (50–686)	.655
Died on support	23 (32.9%)	14 (27.5%)	.524
Transplanted	7 (10%)	5 (9.8%)	.972
Explanted for recovery	17 (24.3%)	2 (3.9%)	.020*
Changed for device failure	6 (8.6%)	5 (9.8%)	1.000
Stroke	13 (18.6%)	9 (18%)	.936

# First Ventricular Assist Device

## Left Ventricular Bypass Pump for Cardiac Assistance

Clinical Experience

MICHAEL É. DeBAKEY, MD, FACC  
*Houston, Texas*

- Product of Total Artificial Heart Program (Est. 1963)
- Temporizing Measure Only



## Technical development

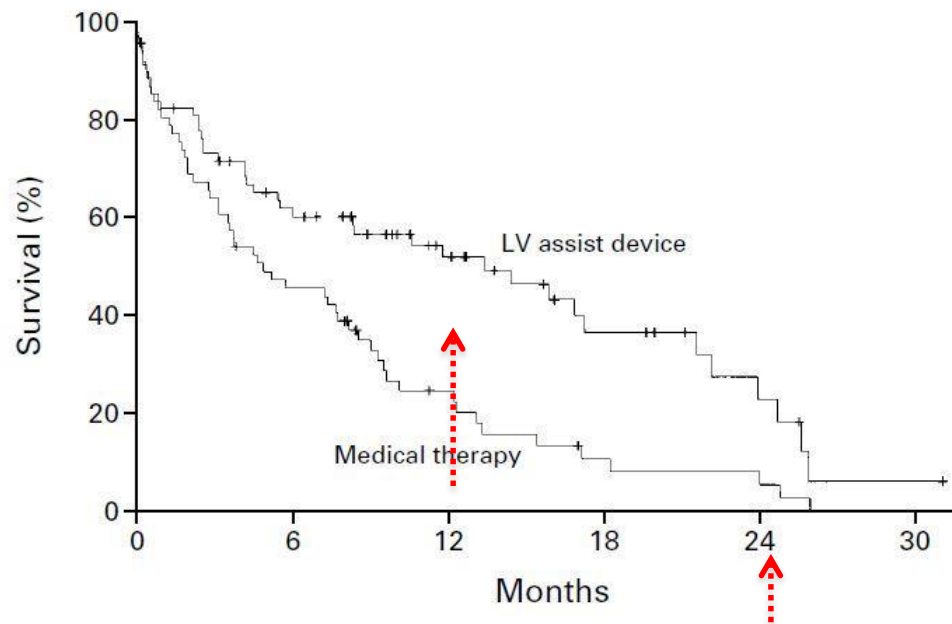


1. Generation: pulsatile VAD (Thoratec HeartMate I)
2. Generation: non-pulsatile axial pump (Thoratec HeartMate II)
3. Generation: non-pulsatile centrifugal pump (HeartWare HVAD)
4. Generation: partial support VAD (CircuLite Synergy)



ORIGINAL ARTICLE

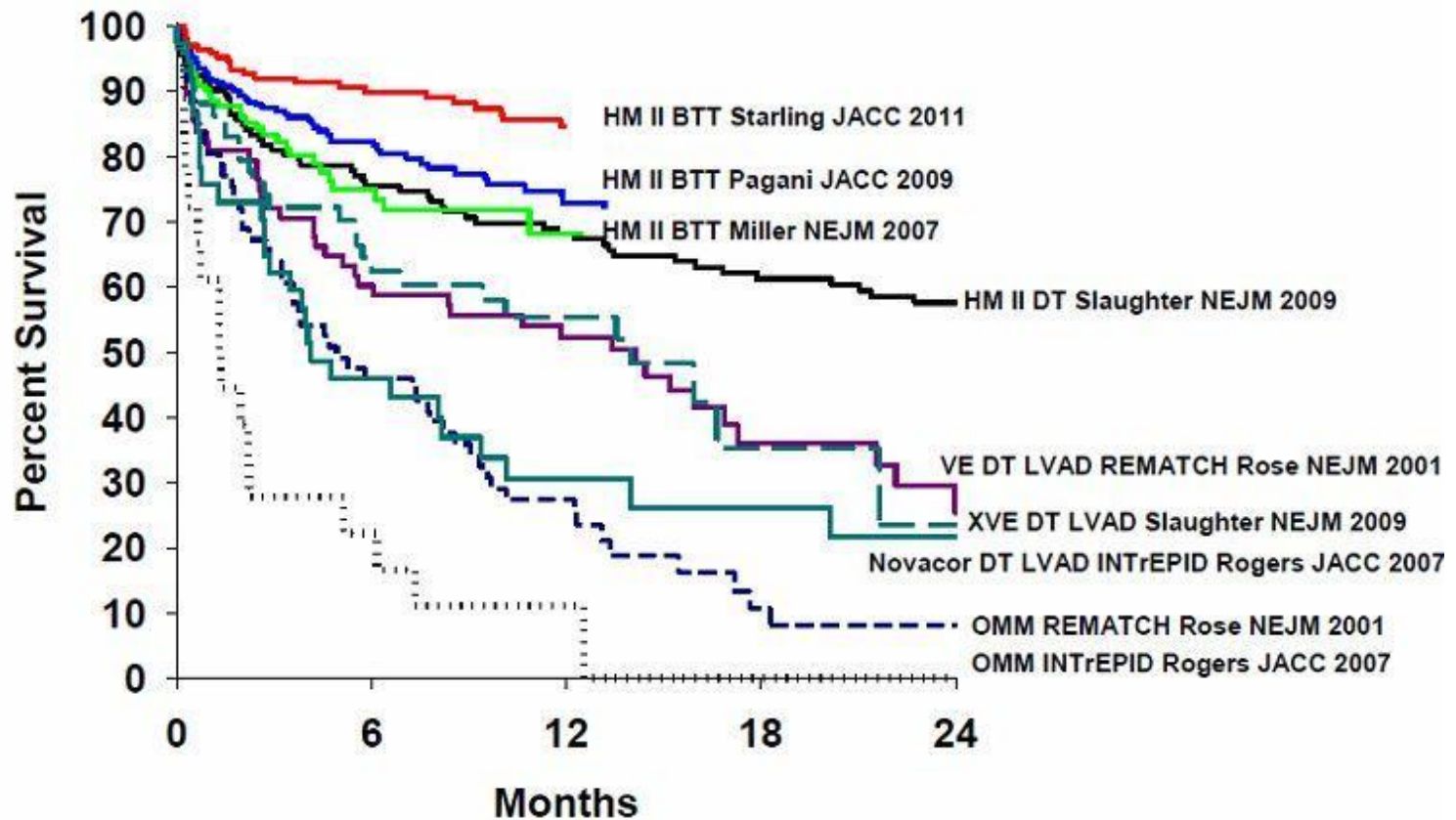
# Long-Term Use of a Left Ventricular Assist Device for End-Stage Heart Failure



No. AT Risk

LV assist device	68	38	22	11	5	1
Medical therapy	61	27	11	4	3	0

# Improved Survival in LVAD Trial



## HeartMate II BTT outcomes

Reference	Study	Enrollment period	n	One-Year Survival
Miller, Pagani, Russell et al NEJM 357:885-896, 2007	HM II Pivotal Trial	3/05 - 5/06	133	68%
Pagani, Miller, Russell et al JACC 54:312-321, 2009	HM II Pivotal Trial	3/05 - 3/07	281	74%
Starling, Naka, Boyle et al JACC 57:1890-8; 2011	Post Approval Study	4/08 - 8/08	169	85%
John, Naka, Smedira et al Ann Thor Surg 92:1406-13; 2011	Commercial vs. Trial	4/08 - 9/10	1469	85%

### Baseline INTERMACS Profiles

INTERMACS Profile	HeartMate II (n=169)
1	41 (24%)
2	63 (37%)
3	33 (20%)
4	21 (12%)
5-7	11 (7%)

61% of patients in the study were in profile 1 or 2.

# **INTERMACS PATIENT PROFILE/STATUS**

## **& Timeframe Initiating Mechanical Circulatory Support**

**(Interagency Registry for Mechanical Assisted Circulatory Support)**

<b>Profile</b>	<b>Description</b>	<b>Time to MCS</b>
<b>1</b>	<b>„Crashing and burning“ – critical cardiogenic shock</b>	<b>Within hours</b>
<b>2</b>	<b>„Progressive decline“ – inotropes dependence with continuing deterioration</b>	<b>Within few days</b>
<b>3</b>	<b>“Stable but inotrope dependent” –describes clinical stability on mild-moderate</b>	<b>Within few weeks</b>
<b>4</b>	<b>“Recurrent advanced heart failure” “recurrent” rather than “refractory” decompensation</b>	<b>Within weeks to months</b>
<b>5</b>	<b>“Exertion intolerant” – describes patients who are comfortable at rest but are exercise intolerant</b>	<b>Variable</b>
<b>6</b>	<b>„Exertion limited“ – a patient who is able to do some mild activity but fatigue results a few minutes or any meaningful physical exertion</b>	<b>Variable</b>
<b>7</b>	<b>„Advanced“ describes patients who are clinically stable with reasonable level of comfortably activity, despite history of previous decompensation that is not recent</b>	<b>Not a candidate for MCS</b>

## **Target Population for VAD Therapy**

- **Motivated**
- **Refractory to guideline-based medical management**
- **Able to understand pro and contra**
- **Excellent social support**
- **Excellent compliance**
- **No comorbidities with significant impact on survival, functional capacity and quality of life**



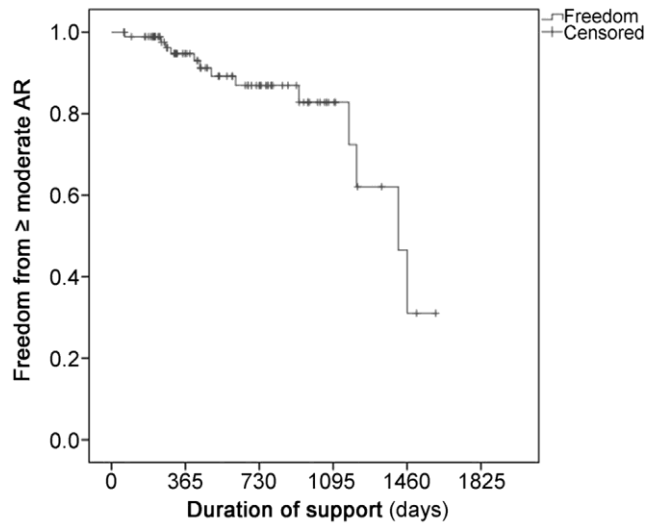
## Relative contraindications

- Age > 70 years, unless minimal or no clinical risk factors
- Chronic kidney disease with serum creatinine level > 3mg/dl
- Severe malnutrition (BMI < 21kg/m<sup>2</sup> in males and < 19kg/m<sup>2</sup> in females)
- Morbid obesity (BMI > 40 kg/m<sup>2</sup> )
- Severe mitral stenosis or moderate aortic insufficiency, or uncorrectable mitral insufficiency

# De Novo Aortic Regurgitation After Continuous-Flow Left Ventricular Assist Device Implantation

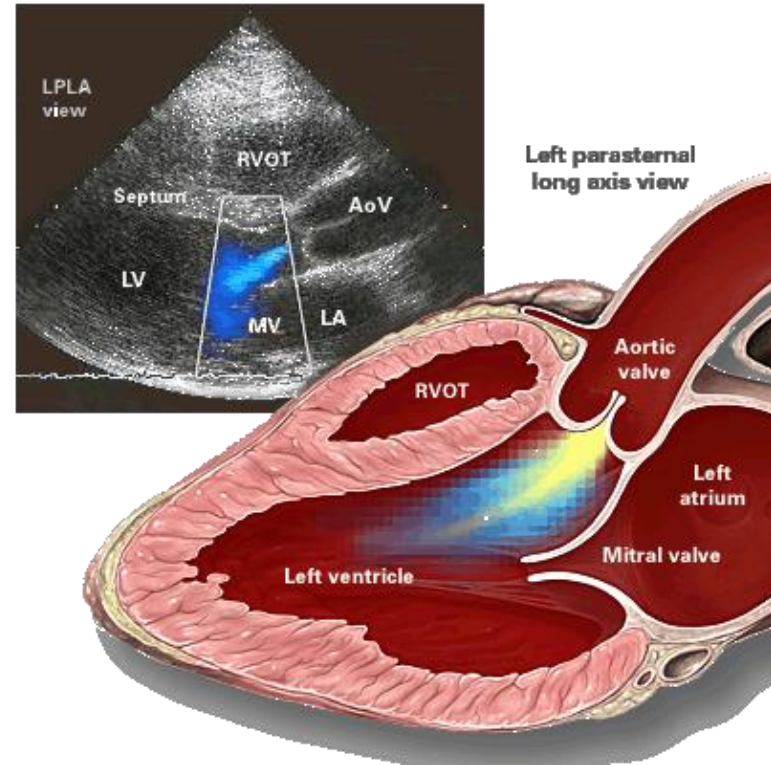
Nikhil Prakash Patil, MRCS, MCh, Anton Sabashnikov, MD,  
 Prashant N. Mohite, MRCS, MCh, Diana Garcia, MD, Alexander Weymann, MD,  
 Bartłomiej Zych, MD, Christopher T. Bowles, PhD, Rachel Hards, RGN,  
 Michael Hedger, RGN, Aron F. Popov, MD, Fabio De Robertis, MD, Ajay Moza, MD,  
 Toufan Bahrami, MD, Mohamed Amrani, MD, PhD, Shelley Rahman-Haley, MD,  
 Nicholas R. Banner, FRCP, FESC, and André Rüdiger Simon, MD, PhD

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NS	6 month	1 year	2 years	3 years	4 years
Freedom (%)	98.9	94.7	86.9	82.8	46.6
Patients at risk	85	57	32	10	3

Fig 1. Kaplan-Meier survival estimate (solid line) for freedom from moderate or greater aortic regurgitation (AR). Patients were censored (tick mark) for cardiac transplantation, device explantation for myocardial recovery, and device exchange, such as for device failure. (NS = not significant.)



# Contraindications

- **Recent or evolving stroke**
- **Neurological deficits impairing the ability to manage device**
- **Biventricular failure in patients older than 65 years**
- **Active systemic infections or major chronic risk for infection**
- **Severe pulmonary dysfunction (FEV1 < 1 l)**
- **Impending renal or hepatic failure**
- **Multisystem organ failure**
- **Inability to tolerate anticoagulation**
- **Significant underlying psychiatric illness**

## Ventricular Assist Devices

- LVAD/RVAD
- BiVAD (Biventricular Assist Device)
- TAH (Total Artificial Heart)

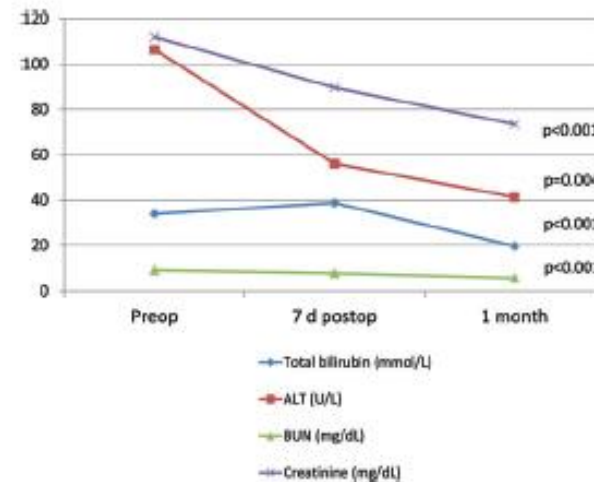
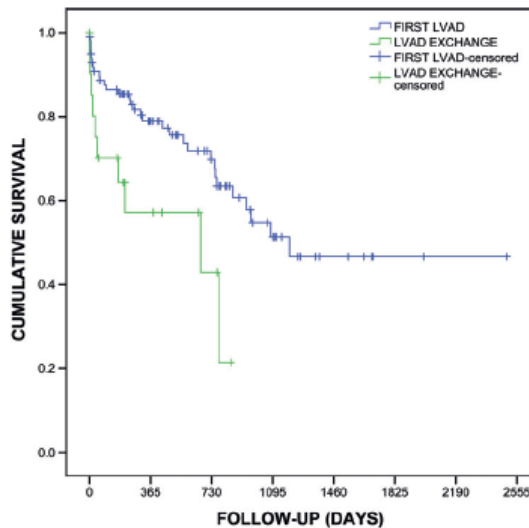
## Therapeutische Strategien

- Bridge to transplant
- Destination therapy
- Myocardial recovery

# Outcomes after implantation of 139 full-support continuous-flow left ventricular assist devices as a bridge to transplantation

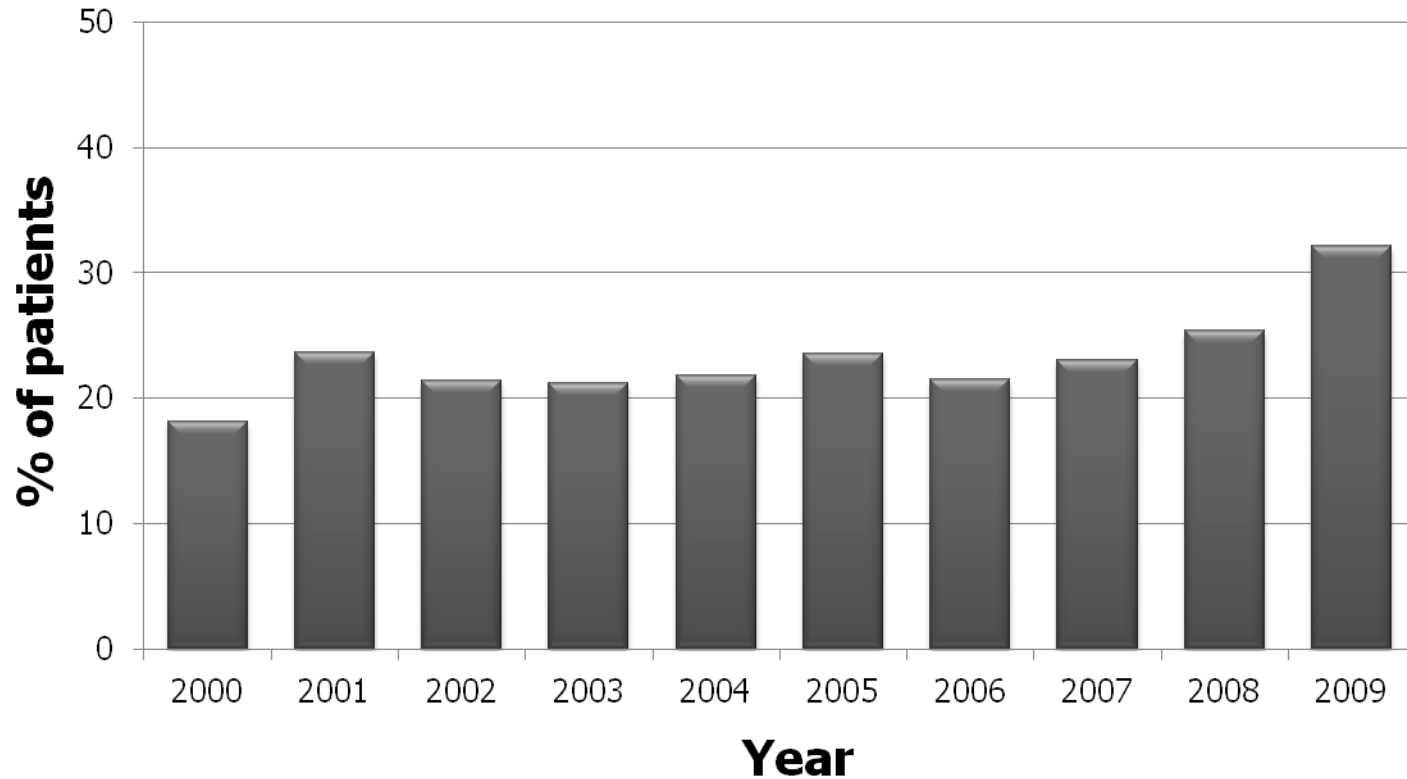
Anton Sabashnikov<sup>a,b,\*</sup>, Prashant N. Mohite<sup>a</sup>, Alexander Weymann<sup>a</sup>, Nikhil P. Patil<sup>a</sup>, Mike Hedger<sup>a</sup>, Diana García Sáez<sup>a</sup>, Bartłomiej Zych<sup>a</sup>, Thorsten Wahlers<sup>b</sup>, Jens Wippermann<sup>b</sup>, Fabio De Robertis<sup>a</sup>, Toufan Bahrami<sup>a</sup>, Mohamed Amrani<sup>a</sup>, André R. Simon<sup>a</sup> and Aron-Frederik Popov<sup>a</sup>

<sup>a</sup> Department of Cardiothoracic Transplantation and Mechanical Circulatory Support, Royal Brompton & Harefield NHS Foundation Trust, Harefield Hospital, Harefield, UK  
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# ADULT HEART TRANSPLANTATION

% OF PATIENTS BRIDGED WITH MECHANICAL CIRCULATORY SUPPORT\*  
(Transplants: 1/2000 – 12/2009)



**ISHLT** J Heart Lung Transplant. 2011 Oct; 30 (10): 1071-1132

\* LVAD, RVAD, TAH

**Are you too old for an LVAD?**



**Thank you for your attention!**

