

# **Predictors of Death and Transplant in Patients with a Mechanical Circulatory Support Device:**

## **A Multi-Institutional Study**

**Holman WL, Kormos RL, Miller MA, Pagani FD, Blume E,  
Cleeton T, Koenig SC, Naftel DC, Kirklin JK, and Edwards L**

University of Alabama at Birmingham, University of Pittsburgh, National Heart Lung and Blood Institute, University of Michigan, Childrens Hospital Boston, Shands Hospital/University of Florida, Jewish Hospital/University of Louisville, United Network for Organ Sharing

Interagency Registry for Mechanically Assisted Circulation  
ISHLT 2008

# Relevant Financial Relationship Disclosure Statement



## ***Predictors of Death and Transplant in Patients with a Mechanical Circulatory Support Device***

***William L. Holman, M.D.***

**I will not discuss off label use and/or investigational use of the following drugs/devices:**

**The following relevant financial relationships exist related to this presentation:**

**Author A: SAB Evaheart, Berlin Heart, Myotech; Speaker Abiomed**

**Author B: SAB Ventracor**

**Author C: None**

**Author D: Research grant support Thoratec**

**Author E: None**

**Author F: None**

**Author G: Consultant Abiomed; Research Grant Thoratec, Abiomed, SCR**

**Author H: None**

**Author I: None**

**Author J: None**

# Purpose

The **Interagency Registry for Mechanically Assisted Circulatory Support (*InterMACS*)** is a national registry for patients who receive a mechanical circulatory support device (MCSD) to treat advanced medically-refractory heart failure.

This study identifies predictors for death and transplantation among MCSD patients.

## InterMACS Devices

---

- FDA approved durable mechanical circulatory support devices (MCSDs)
- Devices approved as of March 1, 2008

AbioCor TAH

HeartMate IP

HeartMate VE

HeartMate XVE

MicroMed DeBakey

VAD-Child

Novacor PC

Novacor PCq

SynCardia CardioWest

Thoratec IVAD

Thoratec PVAD

## Methods and Materials

**From 6/23/2006 to 12/31/2007, 420 patients from 75 institutions were prospectively entered into the InterMACS database. Pre-implant data (demographics, hemodynamics, laboratory values), adverse events, and other outcomes were recorded.**

**Risk factors were identified for post-operative events including death and transplantation using competing outcomes methodology.**

# InterMACS Summary through December 2007 (n=420 pts)

---

**Gender:**

Males	328 (78%)
Females	92 (22%)

---

**Race:**

White	302 (72%)
African American	86 (20%)
Other	32 ( 8%)

---

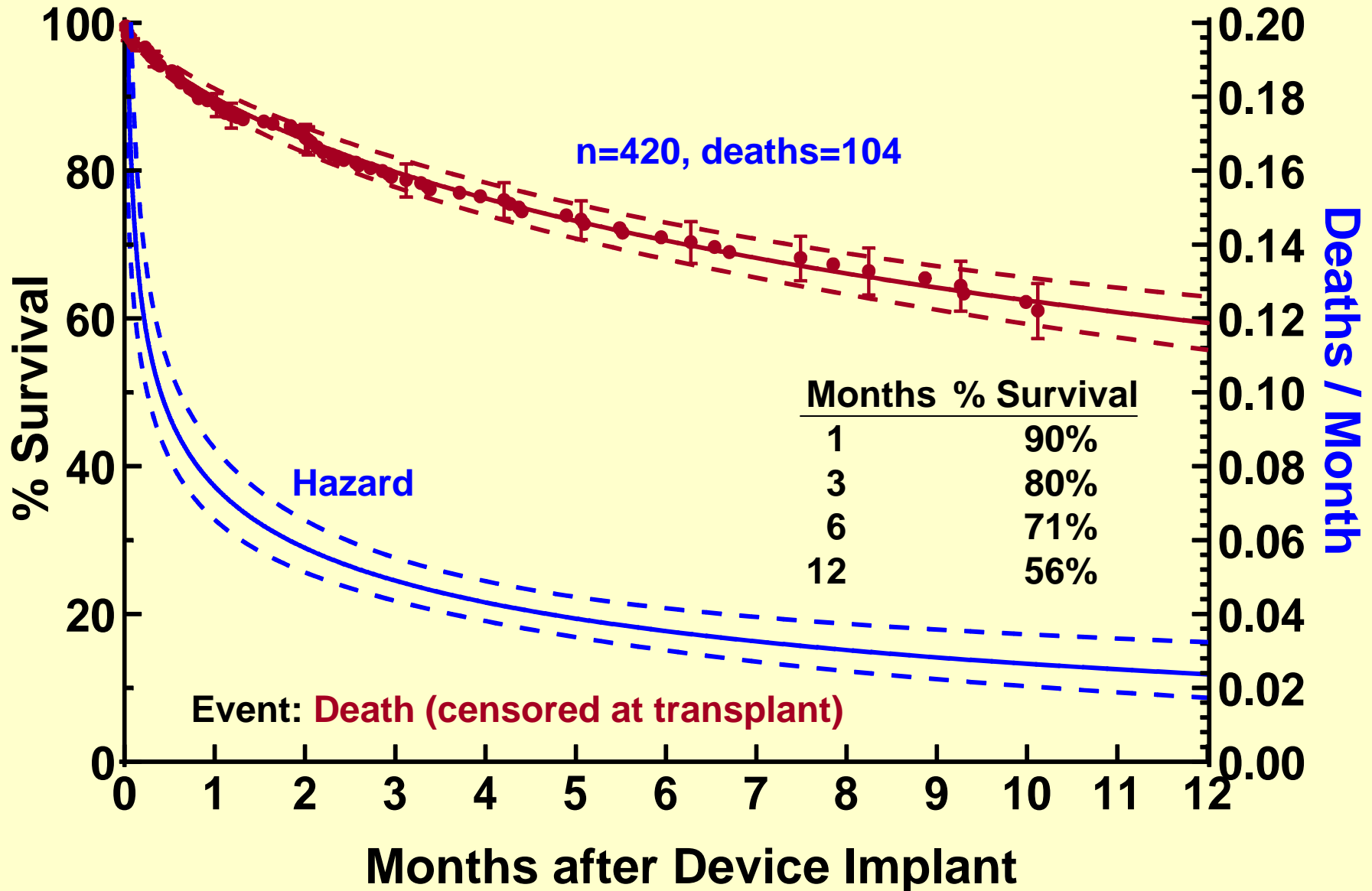
## **Age at Implant:**

Mean:	50.9 yrs
Range:	4.5 to 79.0 yrs
<19 yrs:	12 pts (3%)

## Overall Results:

Deaths (prior to transplant):	104 (24%)
Transplants:	156 (37%)
Recovery:	11 ( 3%)
Alive (device in place):	149 (36%)
<hr/>	
Total	420 (100%)

Death in All MCSD Patients



## Primary Cause of Death, deaths=104

Primary Cause of Death	Early ( $\leq 1$ mo)		Later ( $> 1$ mo)		Total	
	n	% of 42	n	% of 62	n	% of 104
CNS Event	6	14.3%	13	21.0%	19	18.3%
Multi-Organ Failure	8	19.0%	9	14.5%	17	16.4%
Cardiac Failure*	10	23.8%	6	9.7%	16	15.4%
Infection	1	2.4%	7	11.3%	8	7.7%
Respiratory Failure	3	7.1%	5	8.1%	8	7.7%
Device Failure	1	2.4%	4	6.5%	5	4.8%
Hepatic Failure	4	9.5%	0	0%	4	3.8%
Pulmonary Embolism	2	4.8%	1	1.6%	3	2.9%
Surgical Bleeding	1	2.4%	2	3.2%	3	2.9%
GI Bleed	0	0%	2	3.2%	2	1.9%
Renal Failure	1	2.4%	1	1.6%	2	1.9%
Other	5	11.9%	12	19.4%	17	16.4%
<b>Total</b>	<b>42</b>	<b>100.0%</b>	<b>62</b>	<b>100.0%</b>	<b>104</b>	<b>100.0%</b>

\*Cardiac Failure includes RV Failure and VT/VF

---

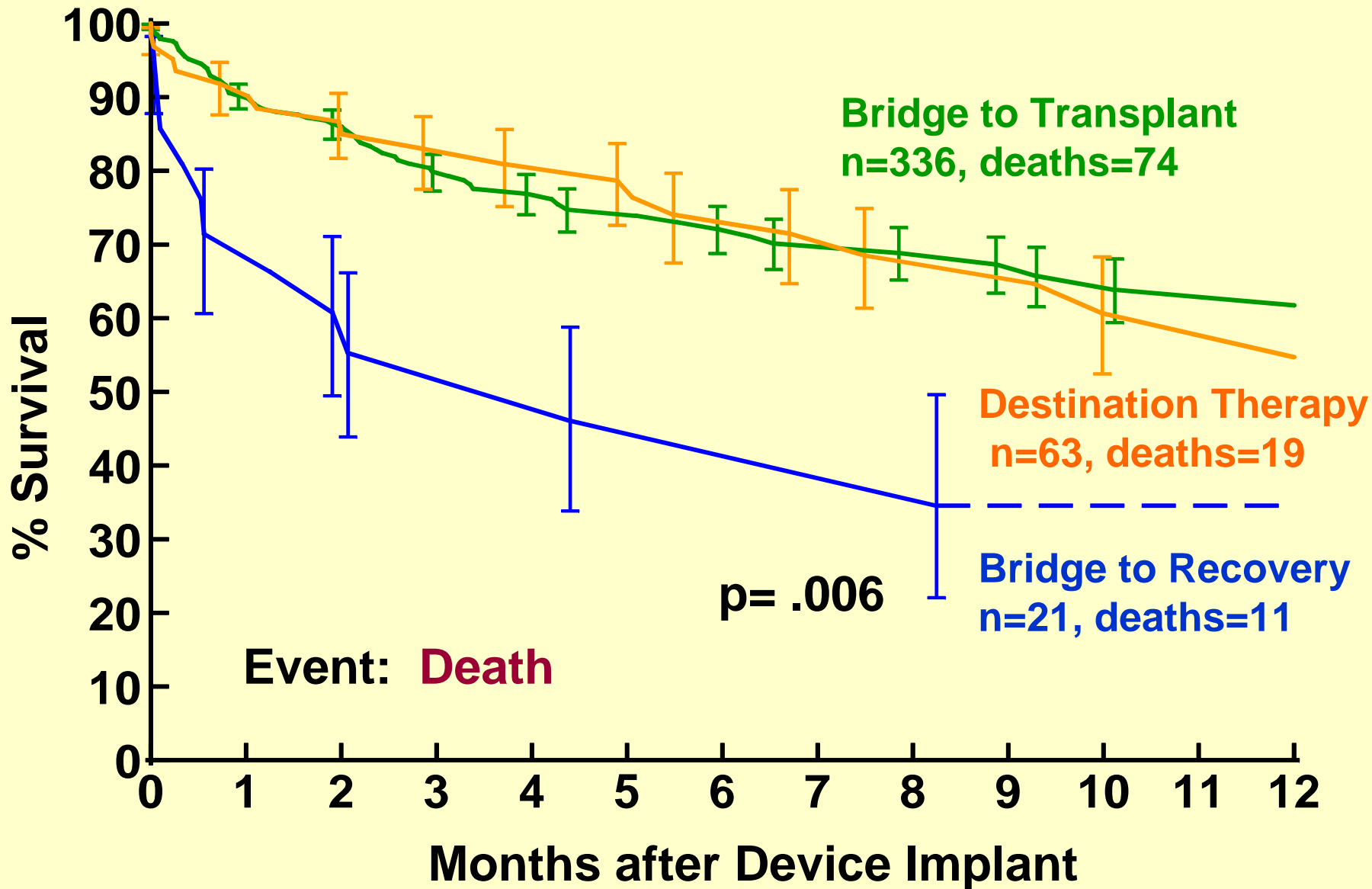
<b>Risk Factors for Death</b>	<b>Relative Risk</b>	<b>p-value</b>
<b>InterMACS Level 1</b>	<b>1.59</b>	<b>.02</b>
<b>Age (older)*</b>	<b>1.41</b>	<b>&lt; .001</b>
<b>Ascites</b>	<b>2.04</b>	<b>.003</b>
<b>Bilirubin (higher)**</b>	<b>1.49</b>	<b>.05</b>
<b>Bi-VAD Implant</b>	<b>2.12</b>	<b>.002</b>
<b>Total Artificial Heart</b>	<b>2.41</b>	<b>.03</b>

---

**\*Compares increased risk from age 50 to 60 years**

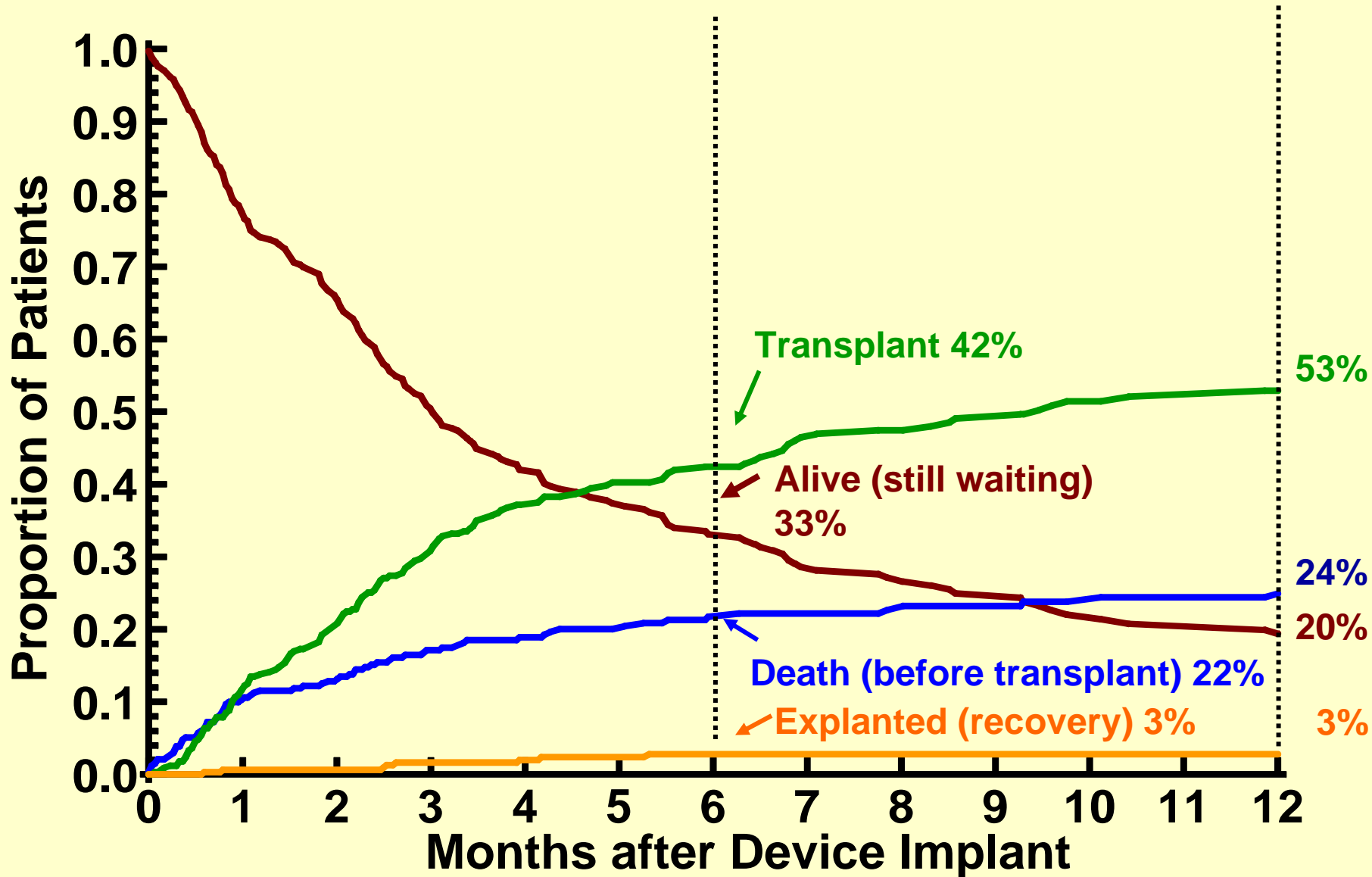
**\*\*Compares increased risk from bilirubin = 1 to 6(mg/dl)**

# InterMACS Summary (n=420 pts) Device Strategy at Implant



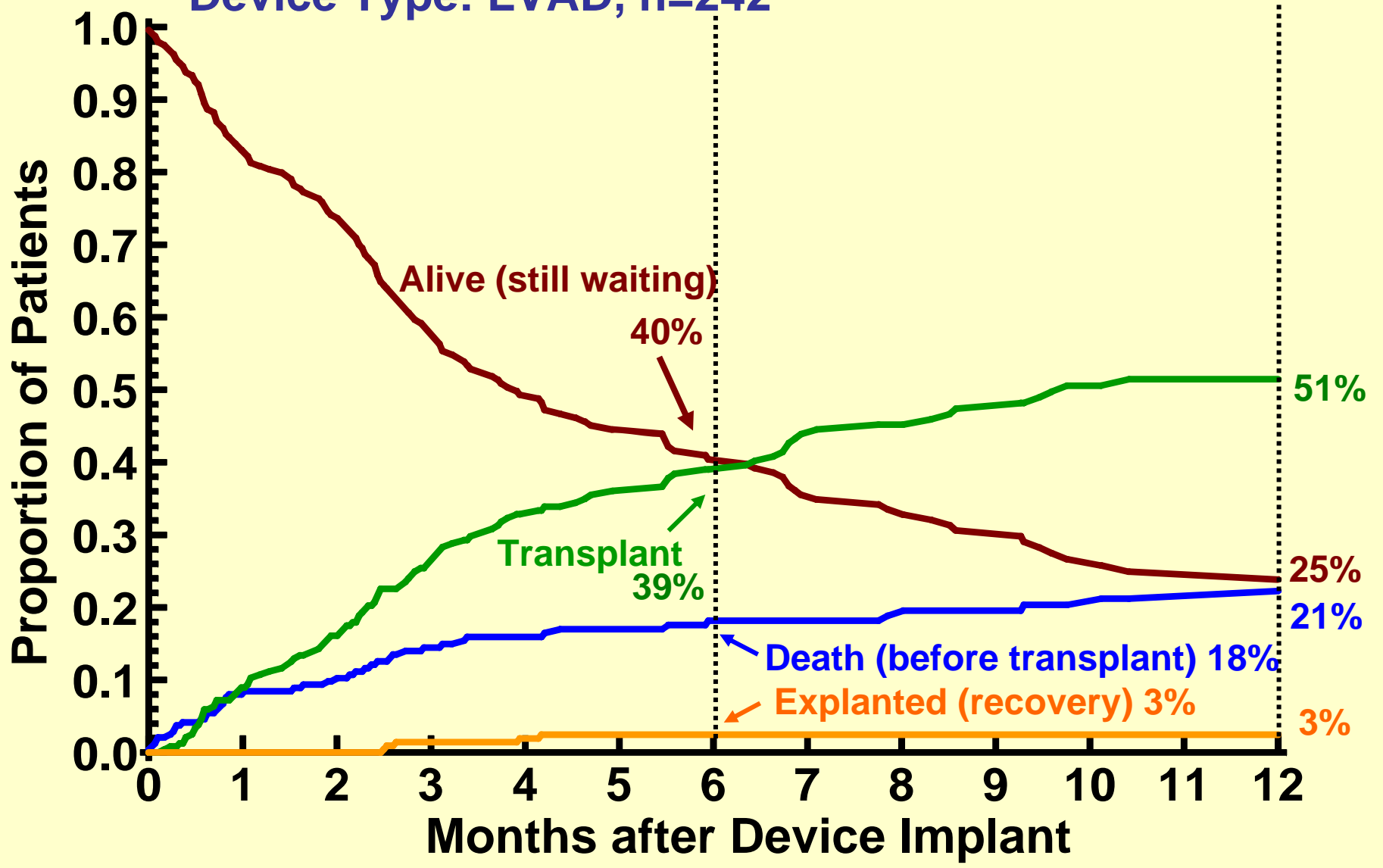
# InterMACS Competing Outcomes Analysis

## Device Strategy: Bridge to Transplant n=336 pts



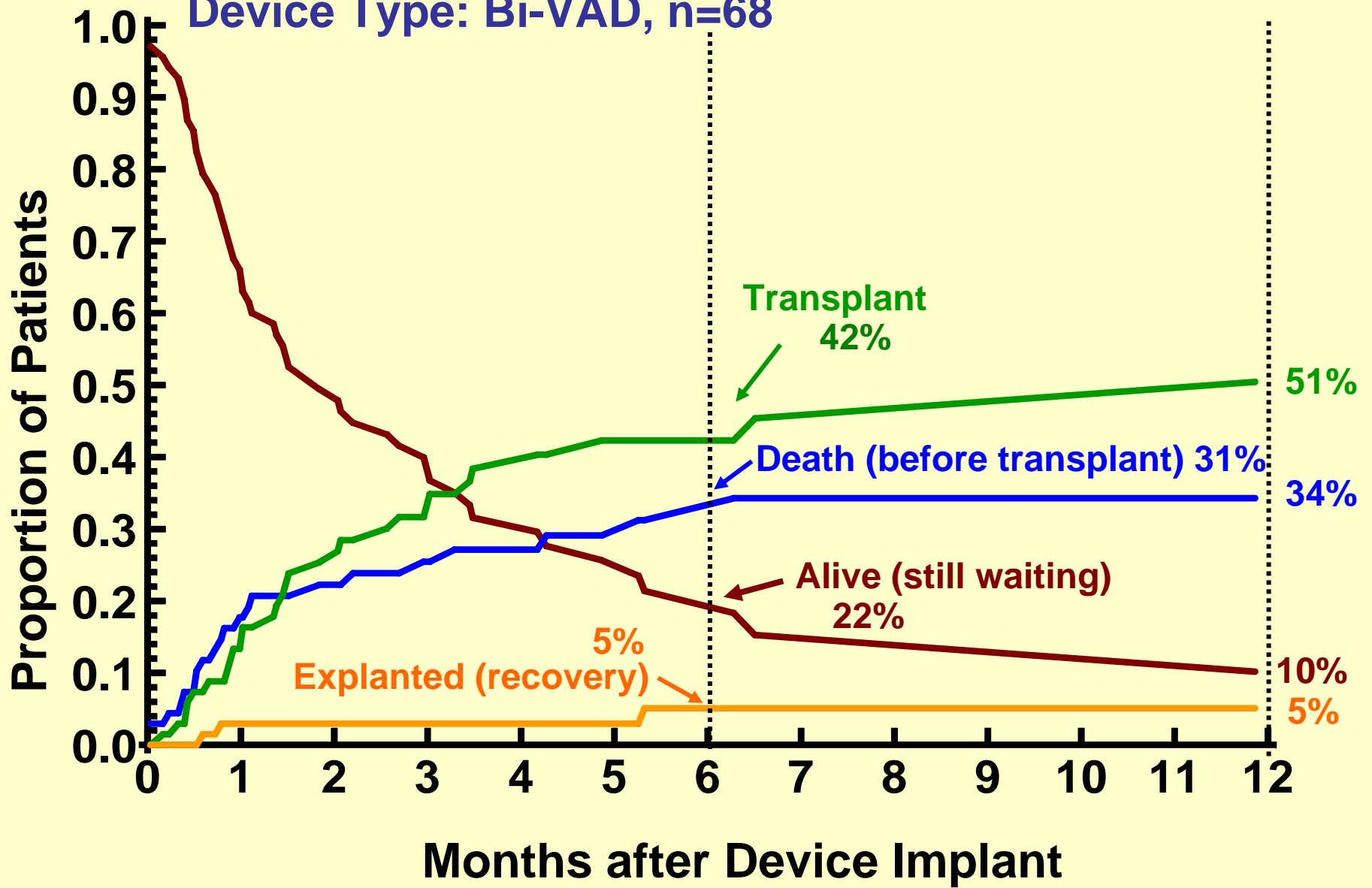
Device Strategy: Bridge to Transplant

Device Type: LVAD, n=242



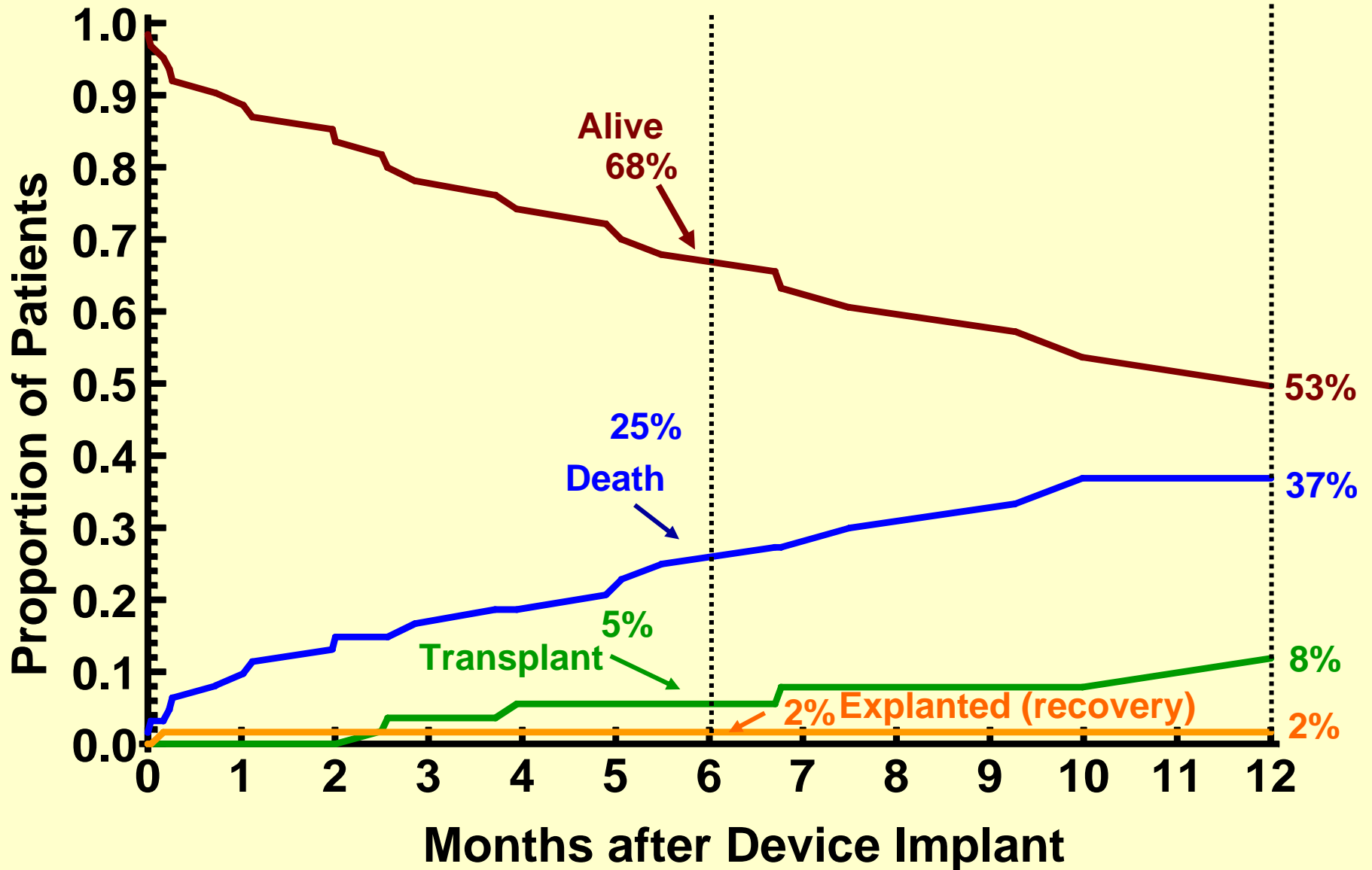
## Device Strategy: Bridge to Transplant

### Device Type: Bi-VAD, n=68



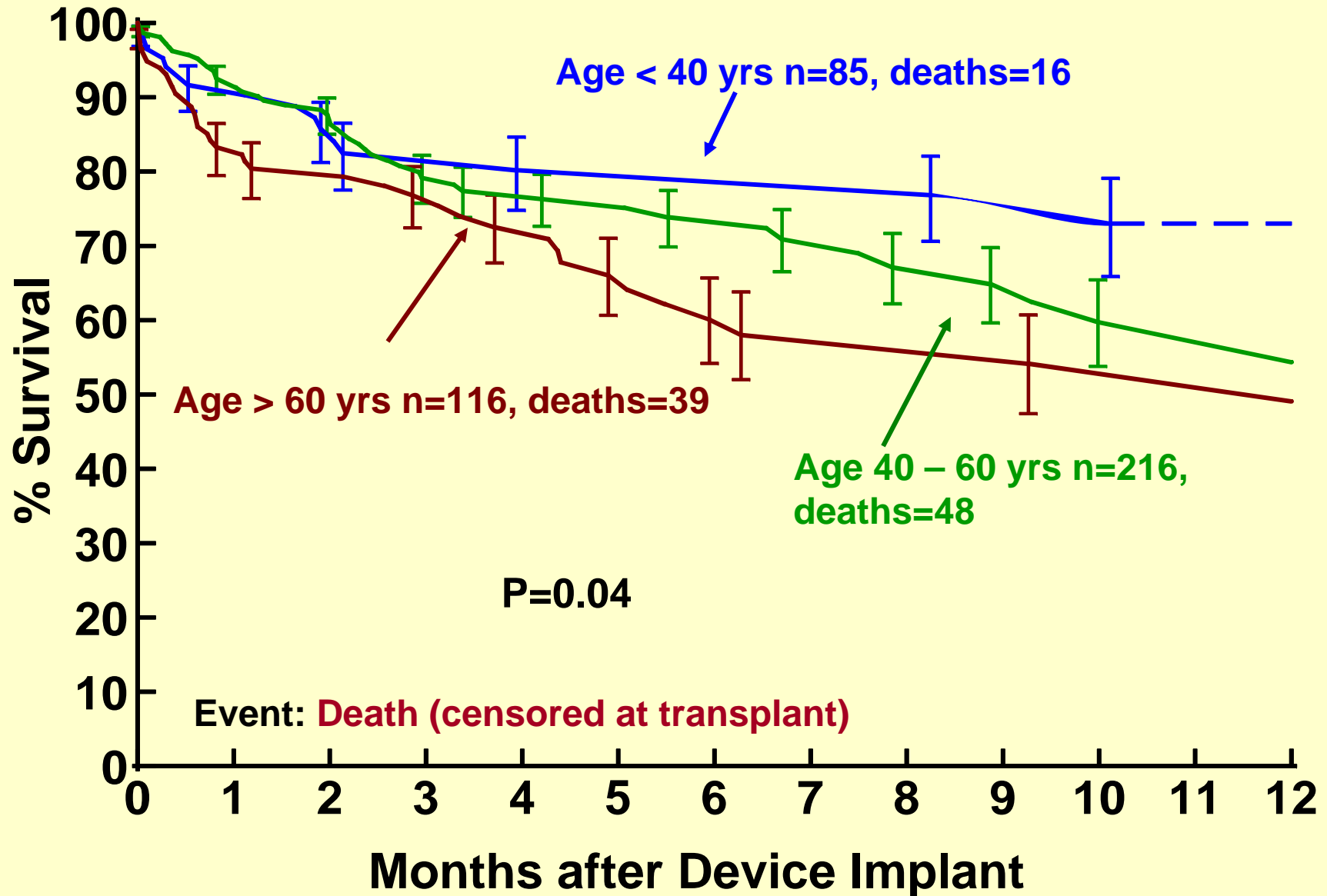
# InterMACS Competing Outcomes Analysis

## Device Strategy: Destination Therapy, n=63



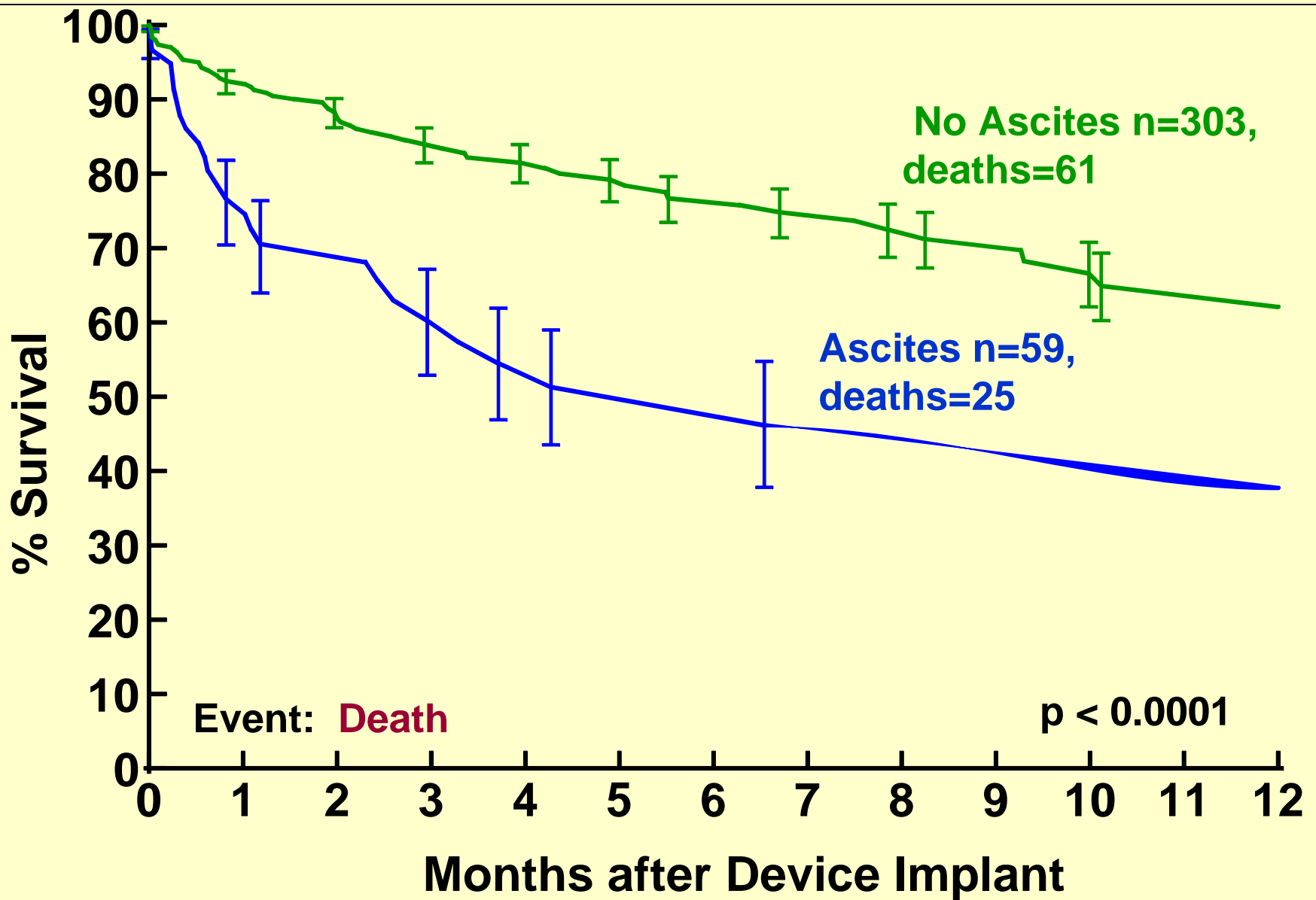
# InterMACS Age and Survival on MCSD

June 2006 - December 2007 (n=420 pts)

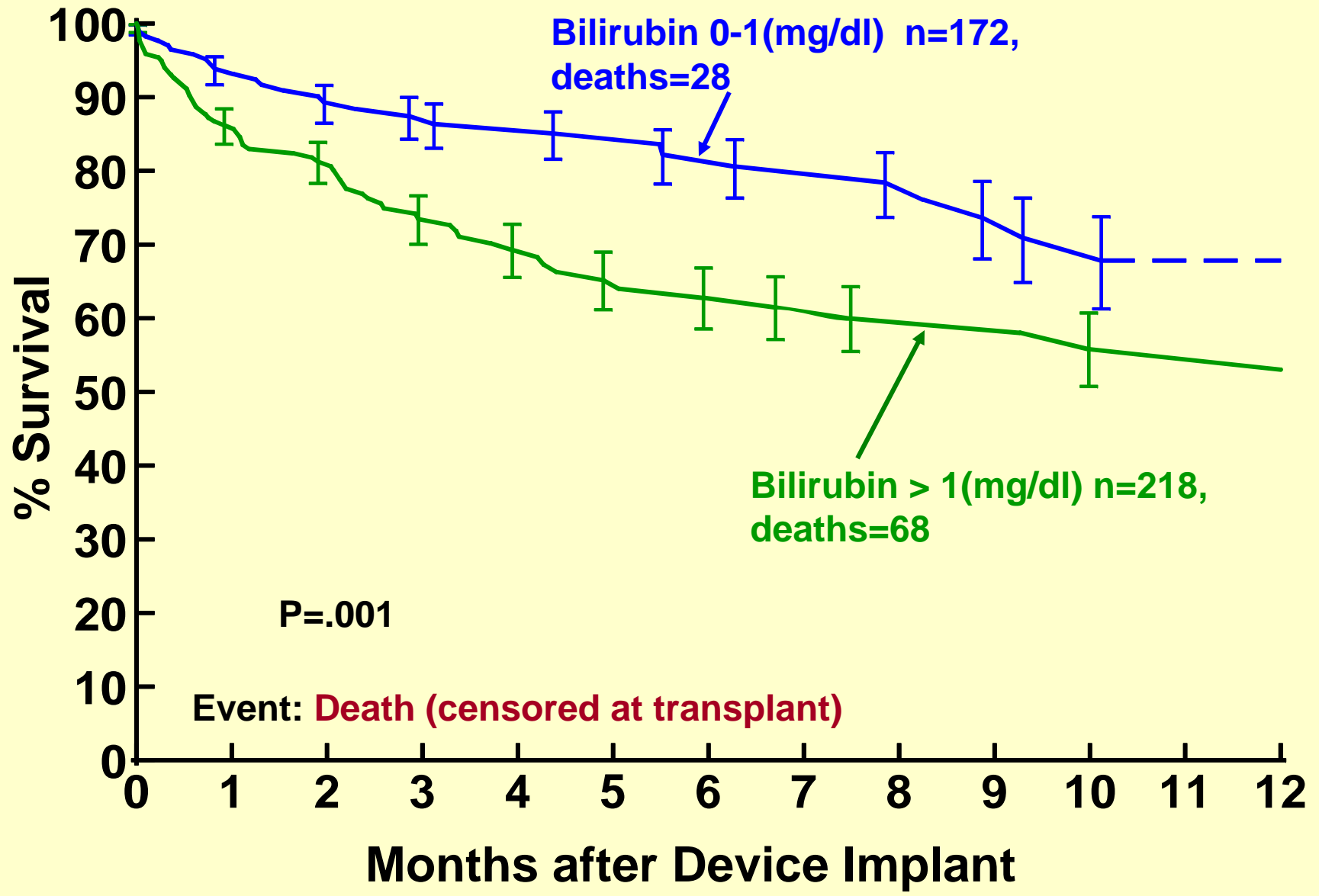


# InterMACS Survival

## Ascites at implant



Note: 58 patients have unspecified Ascites at implant



## Summary

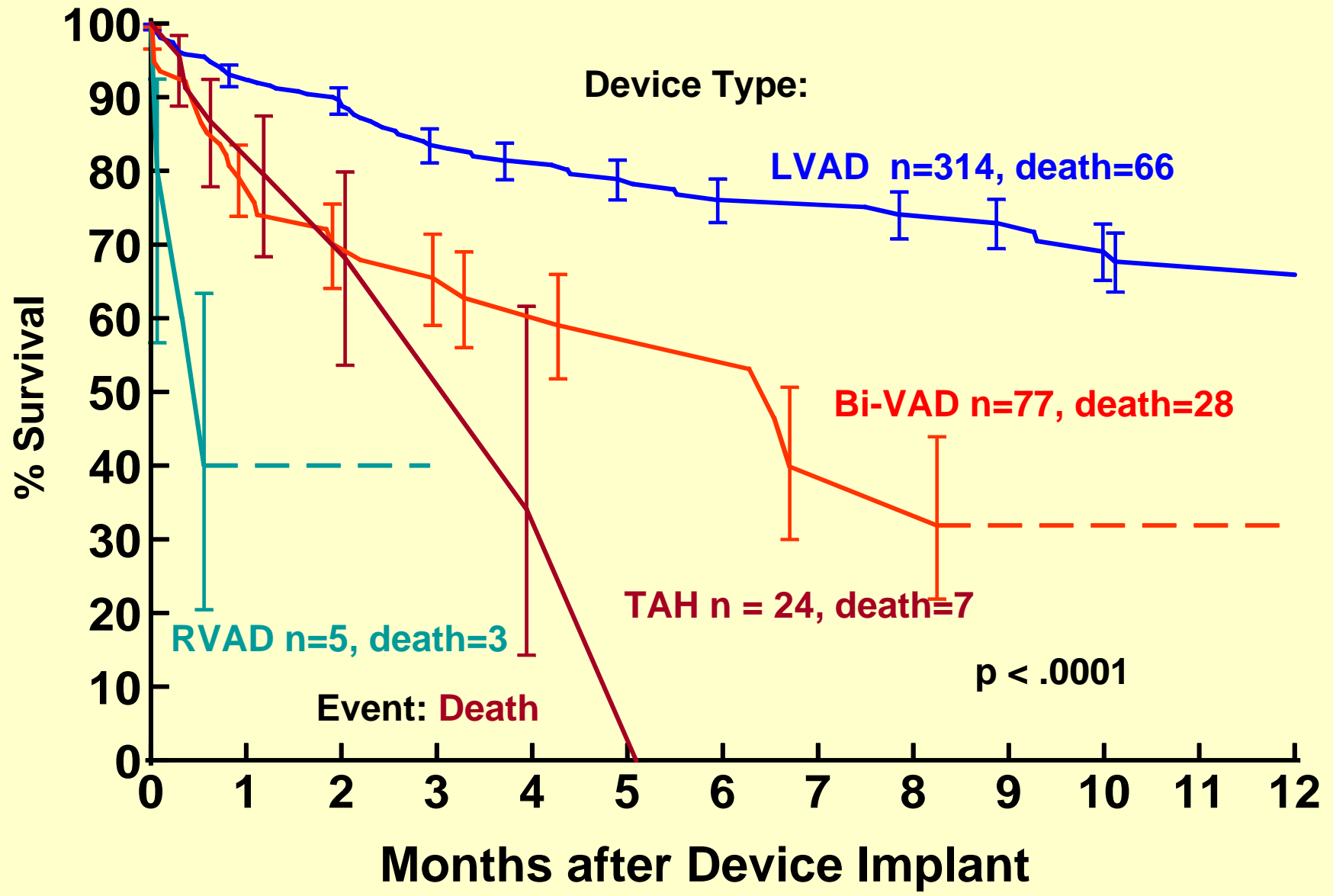
InterMACS level 1, advanced age, and severe right heart failure (ascites, bilirubin, bi-VAD) are risk factors for death in all patients with MCS therapy.

BTT patients who require bi-VAD support have a transplant rate similar to LVAD-only patients, but their mortality at 6 and 12 months exceeds that of LVAD-only patients.

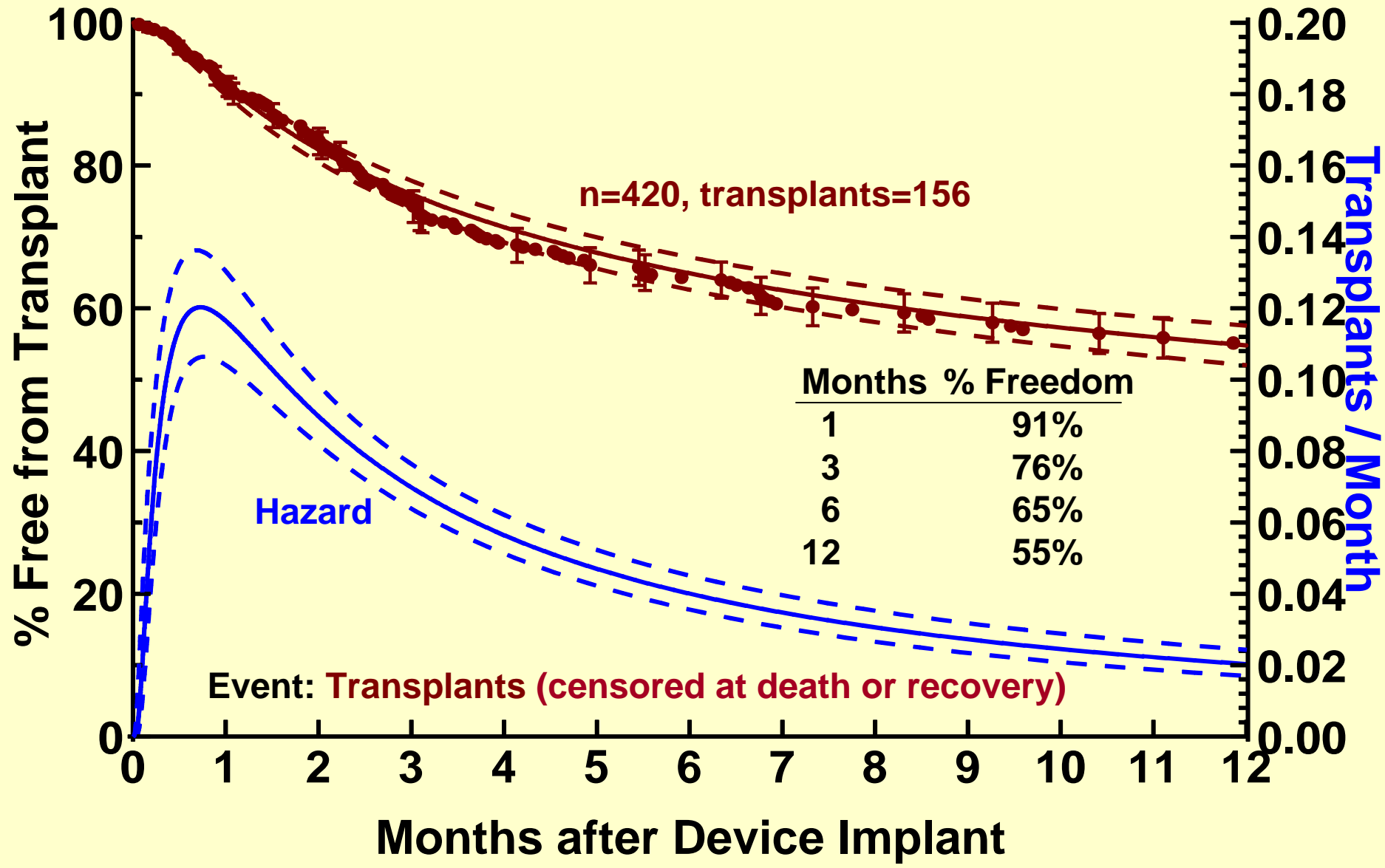
Consideration should be given to MCS referral before the sequelae of right ventricular failure dominate the heart failure syndrome.

Device Side	n	<u>Ascites</u>	
		n	%
LVAD	270	36	13.3%
RVAD	5	2	40.0%
Bi-VAD	64	16	25.0%
TAH	23	5	21.7%

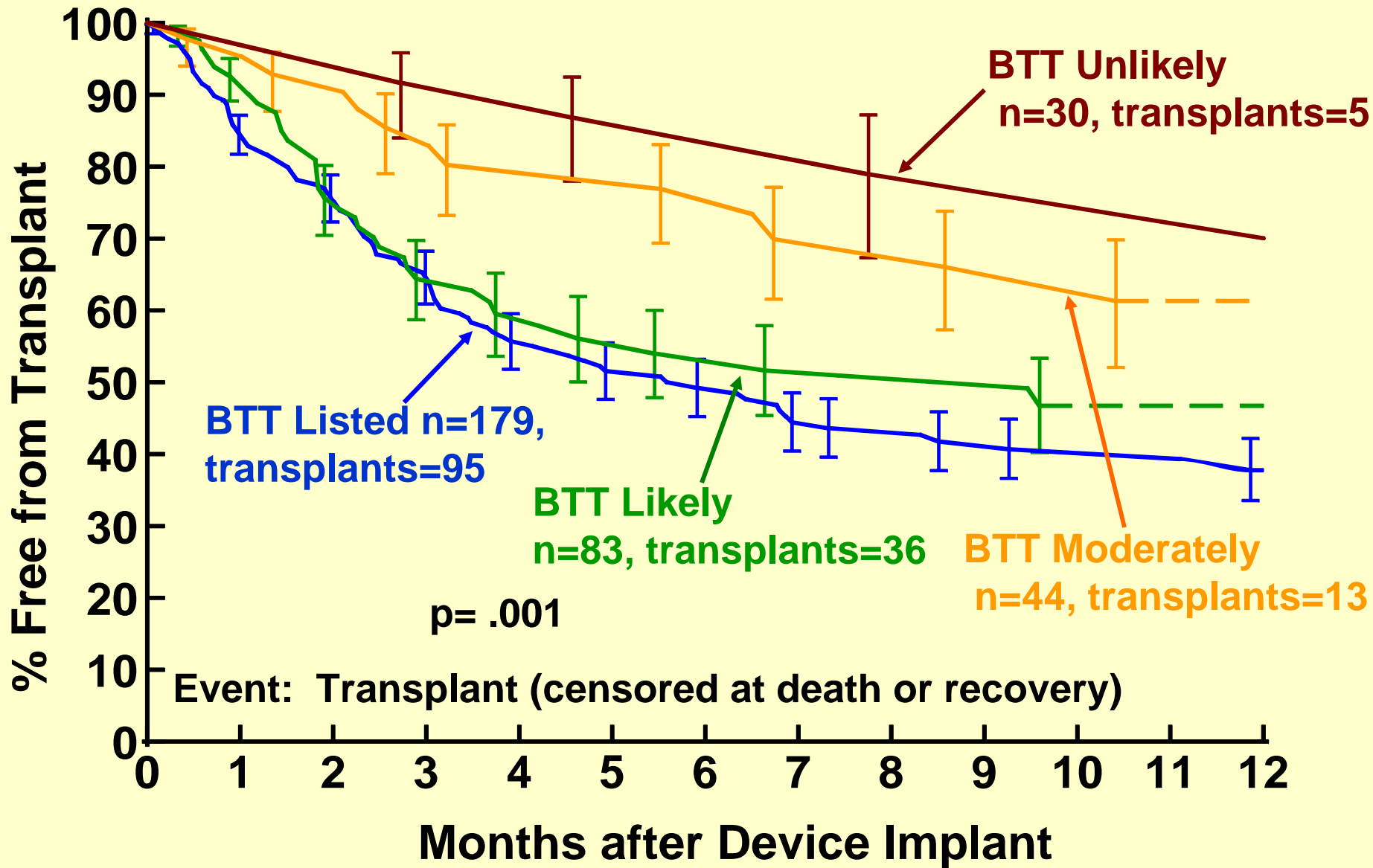
**p=.05**



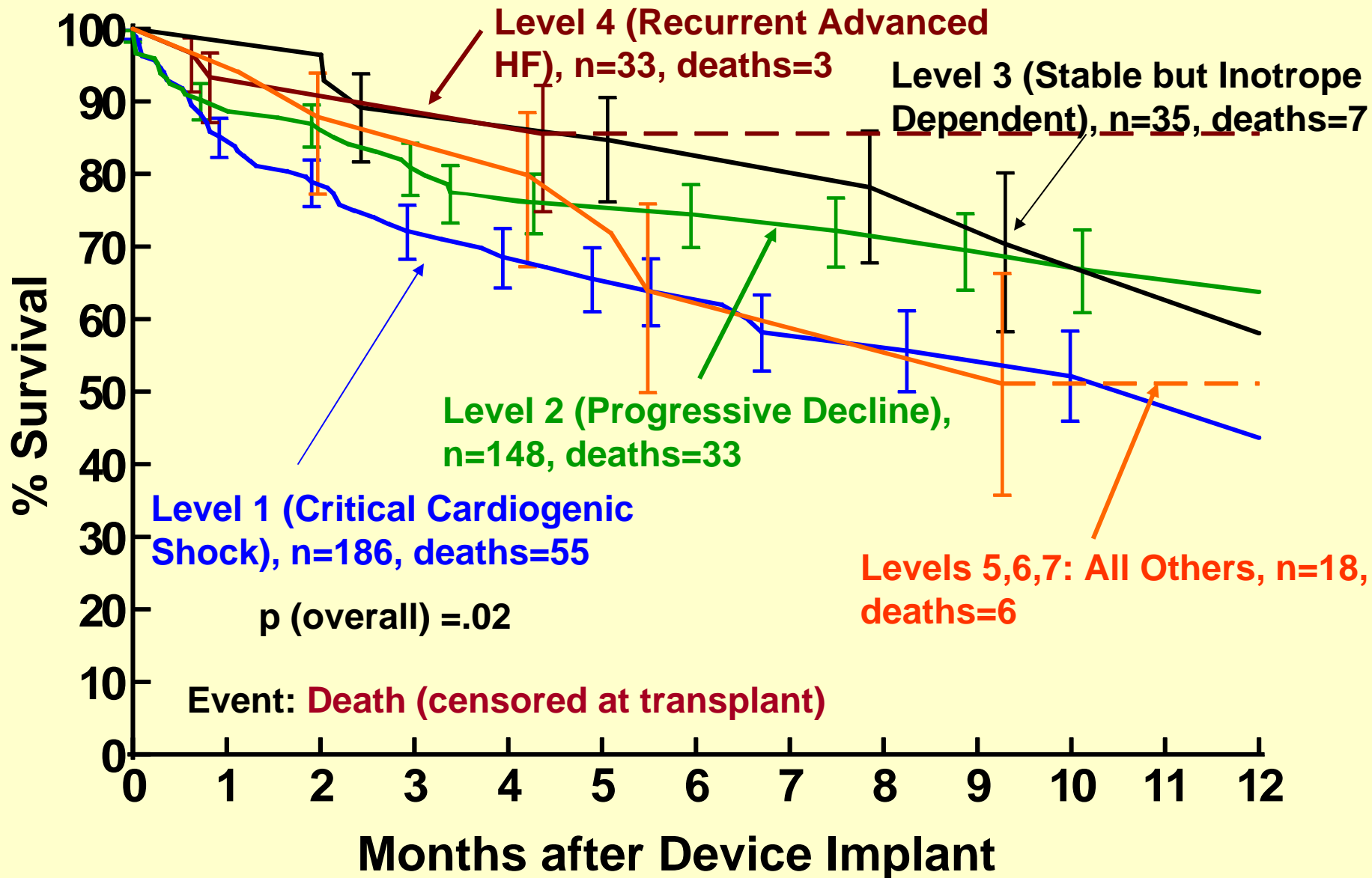
<b>INTERMACS LEVEL (<i>PRE-IMPLANT</i>)</b>	<b>BTR</b>	<b>BTT: Listed</b>	<b>BTT: Likely</b>	<b>BTT: Mod</b>	<b>BTT: Unlikely</b>	<b>DT</b>
<b>1. Critical Cardio Shock</b>	<b>17</b>	<b>68</b>	<b>50</b>	<b>23</b>	<b>11</b>	<b>17</b>
<b>2. Progressive Decline</b>	<b>1</b>	<b>74</b>	<b>25</b>	<b>15</b>	<b>11</b>	<b>22</b>
<b>3. Stable but Inotrope Dep.</b>	<b>1</b>	<b>15</b>	<b>3</b>	<b>2</b>	<b>5</b>	<b>9</b>
<b>4. Recurrent Advanced HF</b>	<b>2</b>	<b>15</b>	<b>5</b>	<b>2</b>	<b>1</b>	<b>8</b>
<b>5. Exertion Intolerant</b>	<b>0</b>	<b>3</b>	<b>0</b>	<b>1</b>	<b>0</b>	<b>1</b>
<b>6. Exertion Limited</b>	<b>0</b>	<b>1</b>	<b>0</b>	<b>1</b>	<b>1</b>	<b>3</b>
<b>7. Advanced NYHA Class III</b>	<b>0</b>	<b>3</b>	<b>0</b>	<b>0</b>	<b>1</b>	<b>3</b>
<b>Total</b>	<b>21</b>	<b>179</b>	<b>83</b>	<b>44</b>	<b>30</b>	<b>63</b>



# Device Strategy at Implant



Patient Profile at Implant



# InterMACS Survival with VAD (n=420 pts)

