

PATIENTS WITH MECHANICAL CIRCULATORY SUPPORT (MCSD): *IS IMPLANT STRATEGY STATIC OR DYNAMIC?*

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On behalf of the INTERMACS investigators.

Disclosure

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None

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Research and educational grant: Thoratec, Abiomed

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Travel: Thoratec

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None

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Background

- U.S. CMS allows 3 strategies for MCSD use:
- Post-cardiotomy (BTR: bridge to recovery, including rescue therapy)
 - Bridge to transplant (BTT:bridge to transplant)
 - Destination therapy (DT:destination therapy)

It is not clear whether these strategies describe different patient populations, or different outcomes, or even whether the strategies remain static throughout the patients' course.

Purpose

Evaluate the outcome of patients registered prospectively in INTERMACS with respect to their initial implant strategy and subsequent clinical course.

- * * BTT patients always includes 4 categories:
 - Listed
 - Likely to be listed
 - Moderately likely to be listed
 - Unlikely to be listed

Implant strategy

Implant Dates: June 23, 2006 – December 31, 2007

Follow-up Date: December 31, 2007

Total Hospitals Enrolled: 89

Hospitals that have contributed data: 75

Total Patients: 511

Retrospective: 91

Prospective: 420

FDA approved, as of March 1, 2008, durable mechanical circulatory support devices (MCSD)

AbioCor TAH

Novacor PC

HeartMate IP

Novacor PCq

HeartMate VE

SynCardia CardioWest

HeartMate XVE

Thoratec IVAD

MicroMed DeBakey

Thoratec PVAD

VAD-Child

| | | |
|----------------|----------------|------------------|
| 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 |
| below 19 yrs: | 12 (3%) |

Implants:

LVAD: 314 (75%)

RVAD: 5 (1%)

Bi-VAD: 77 (18%)

TAH: 24 (6%)

Total: 420 (100%)

| Device Strategy at Implant | n | % of 420 |
|-------------------------------------|------------|-----------------|
| Bridge to Recovery | 21 | 5% |
| Bridge to Transplant* | 336 | 80% |
| Listed | 179 | 43% |
| Likely to be listed | 83 | 20% |
| Moderate likely to be listed | 44 | 10% |
| Unlikely to be listed | 30 | 7% |
| Destination Therapy | 63 | 15% |
| Total | 420 | 100% |

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

| Device Strategy at Implant | n | NYHA = 4 | |
|-------------------------------|-------------|------------|------------|
| | | n | % |
| Bridge to Transplant | | | |
| Bridge to Transp: Listed | 168 | 150 | 89% |
| Bridge to Transp: Likely | 72 | 64 | 92% |
| Bridge to Transp: Moderately | 36 | 30 | 75% |
| Bridge to Transp: Unlikely | 28 | 23 | 93% |
| Destination Therapy | 58 | 49 | 85% |
| Bridge to Recovery | 20 | 15 | 75% |
| Total | 382* | 331 | 87% |

Age of patients initially in DT arm was somewhat older.

* 38 patients have unspecified NYHA class

| Device Strategy Level | n | Inotropes | |
|------------------------------|-------------|------------|------------|
| | | n | % |
| Bridge to Transplant | | | |
| Bridge to Transp: Listed | 176 | 158 | 90% |
| Bridge to Transp: Likely | 83 | 70 | 84% |
| Bridge to Transp: Moderately | 42 | 33 | 79% |
| Bridge to Transp: Unlikely | 29 | 25 | 86% |
| Destination Therapy | 61 | 52 | 85% |
| Bridge to Recovery | 20 | 18 | 90% |
| Total | 411* | 356 | 87% |

* 9 patients have unspecified inotropes use

| Device Strategy at Implant | n | Cardiac output at implant | | |
|-----------------------------------|------------|----------------------------------|-------------|--------------|
| | | mean | min | max |
| Bridge to Transplant | | | | |
| Bridge to Transplant: Listed | 117 | 4.34 | 1.50 | 8.50 |
| Bridge to Transplant: Likely | 51 | 4.28 | 1.60 | 8.40 |
| Bridge to Transplant: Moderate | 26 | 4.31 | 1.80 | 9.00 |
| Bridge to Transplant: Unlikely | 18 | 4.98 | 2.10 | 7.60 |
| Destination Therapy | 37 | 5.01 | 2.30 | 15.00 |
| Bridge to Recovery | 15 | 4.85 | 2.30 | 14.70 |
| Total | 264 | 4.49 | 1.50 | 15.00 |

156 patients are unspecified cardiac output at implant

Thus, the degree of HF signs and symptoms appear to be similar across the implant strategies.

Overall Results:

Deaths (prior to transplant): 104 (24%)

Transplants: 156 (37%)

Recovery: 11 (3%)

Alive (device in place): 149 (36%)

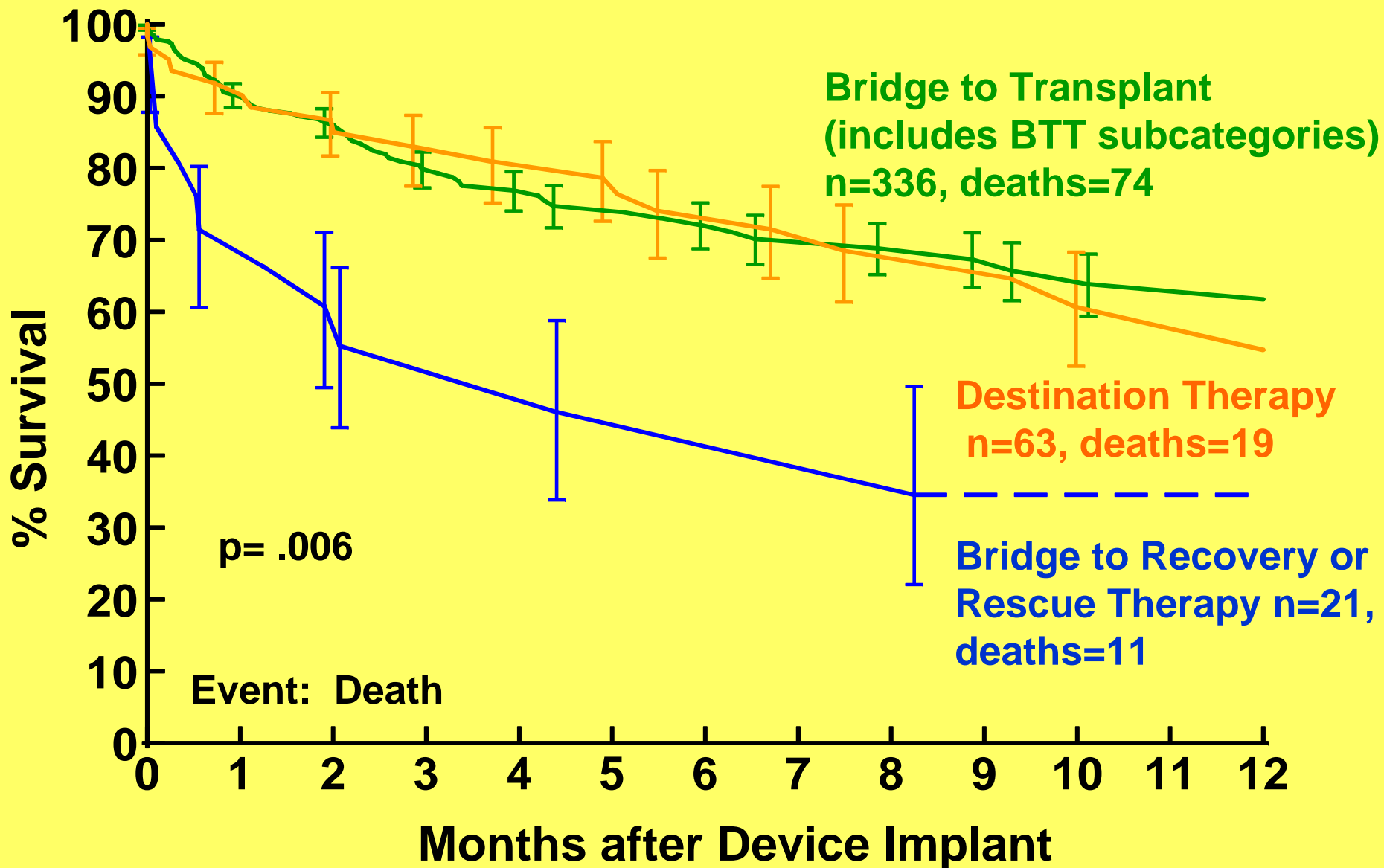
Total 420 (100%)

| Device Strategy at Implant | n | Deaths | Txpl | Recov | Alive (device in place) | |
|------------------------------|------------|------------|------------|-----------|----------------------------|------------|
| | | | | | n | % |
| Bridge to Recovery* | 21 | 11 | 2 | 2 | 6 | 29% |
| Bridge to Transplant | | | | | | |
| Listed | 179 | 33 | 95 | 3 | 48 | 27% |
| Likely to be listed | 83 | 17 | 36 | 4 | 26 | 31% |
| Moderate likely to be listed | 44 | 14 | 13 | 1 | 16 | 36% |
| Unlikely to be listed | 30 | 10 | 5 | 0 | 15 | 50% |
| Destination | 63 | 19 | 5 | 1 | 38 | 60% |
| Total | 420 | 104 | 156 | 11 | 149 | 46% |

* Includes implants for Rescue Therapy

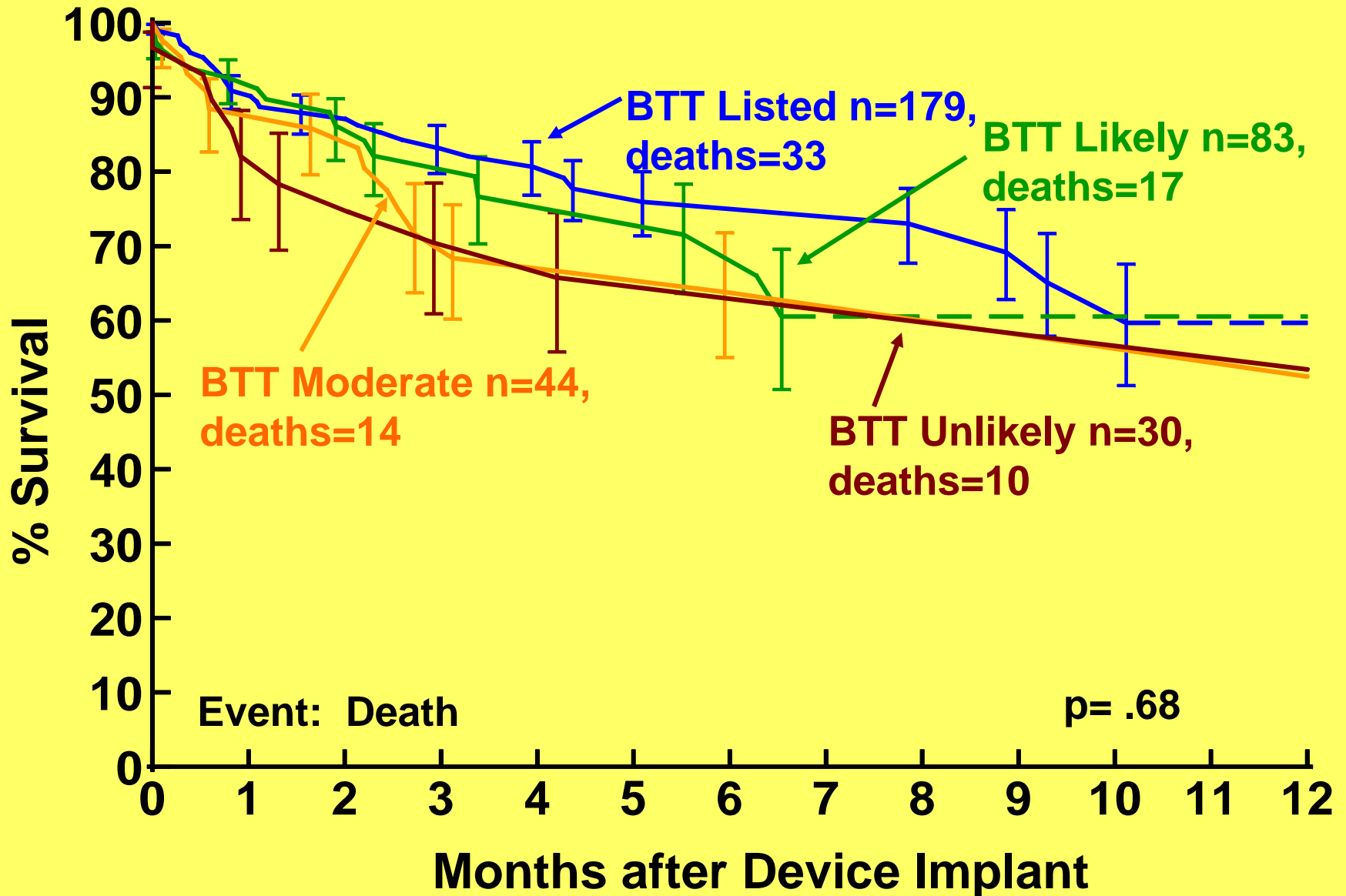
June 2006 – December 2007 (n=420)

Device Strategy at Implant



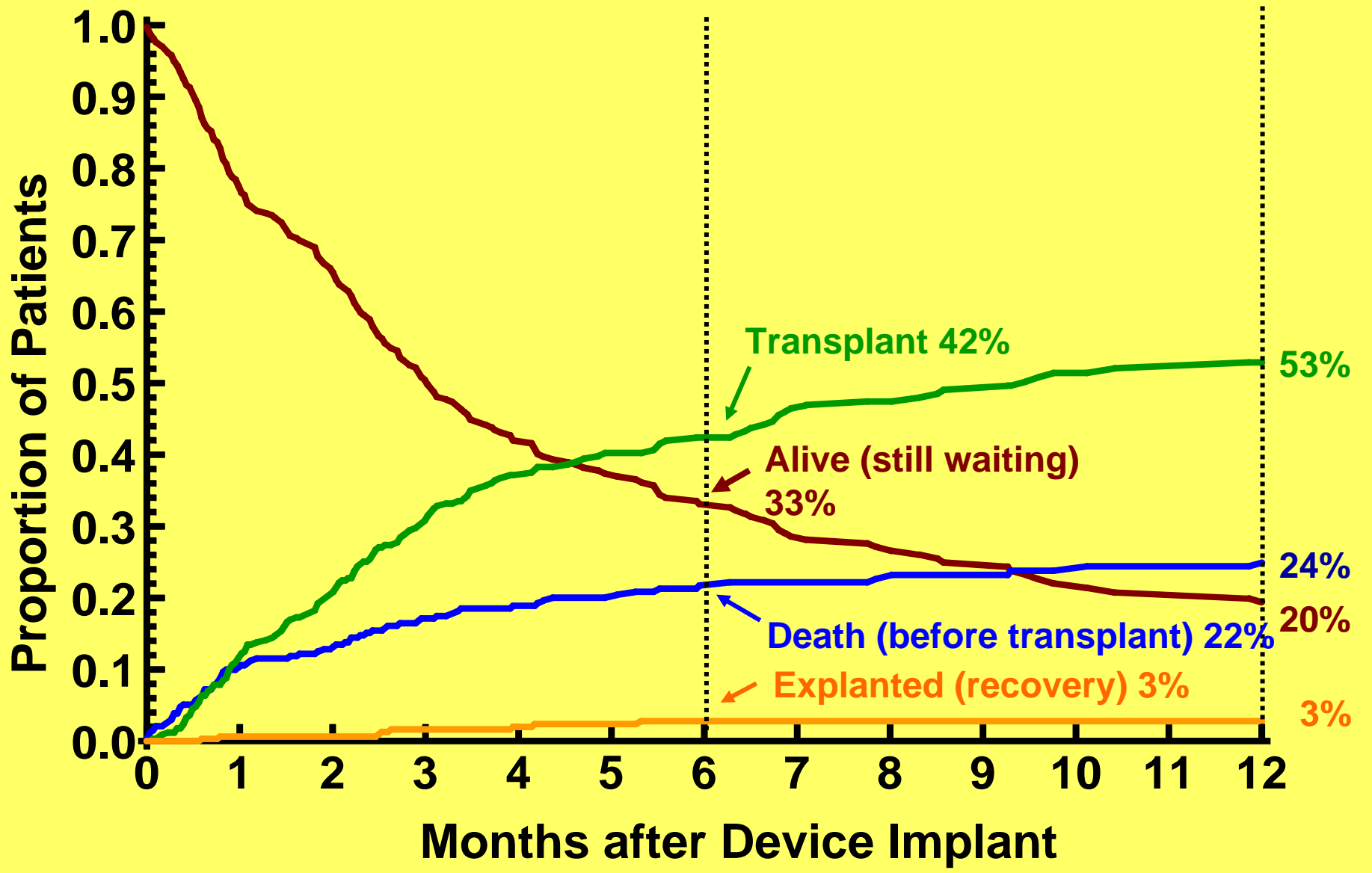
June 2006 – December 2007 (n=420)

Device Strategy at Implant: Bridge to Transplant



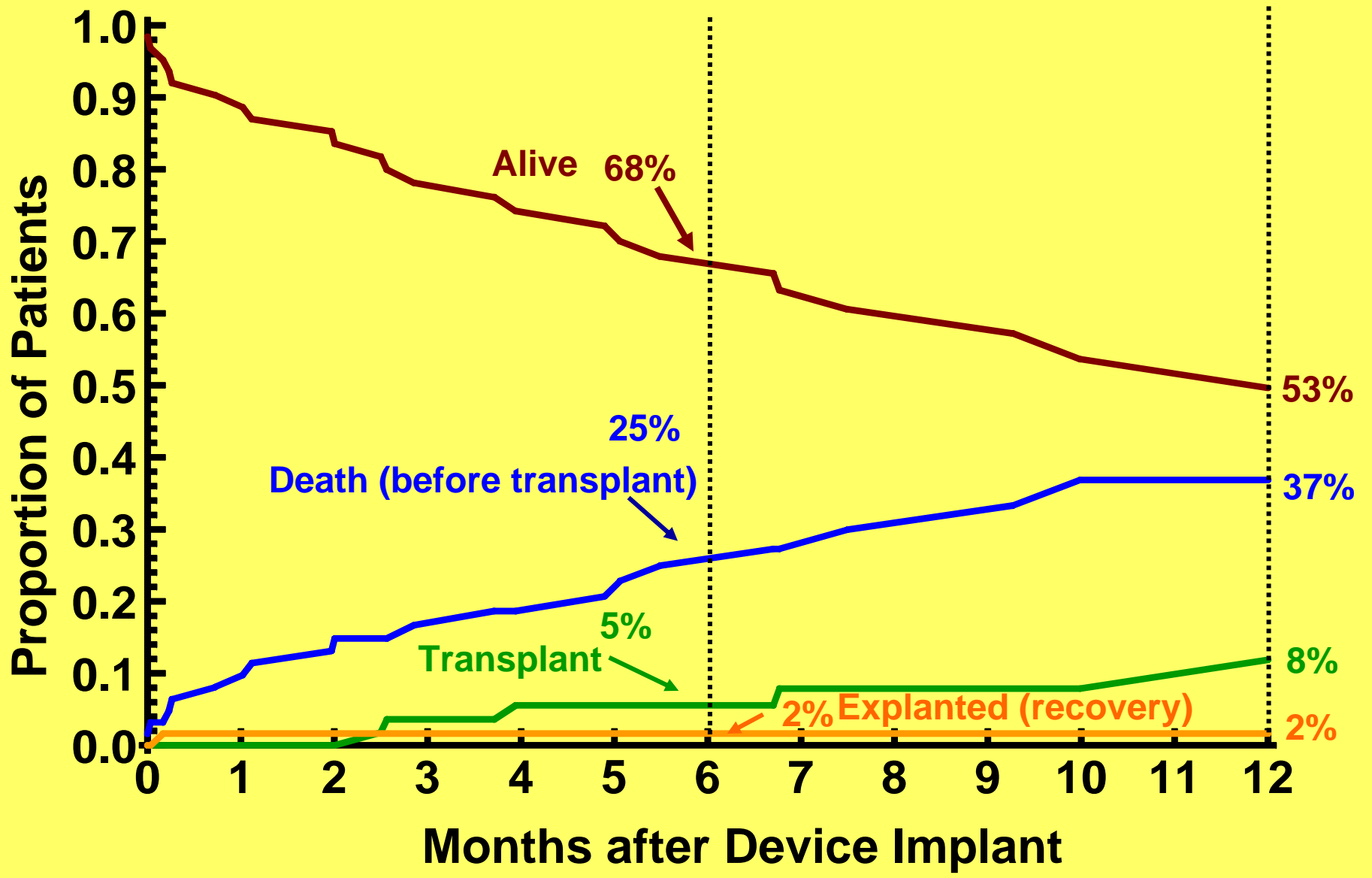
June 2006 – December 2007

Device Strategy: Bridge to Transplant, n=336



June 2006 – December 2007

Device Strategy: Destination Therapy, n=63



BTT Listed at Implant (n=179)

Strategy at:

| | <u>3mths</u> | | <u>6mths</u> | | <u>1yr</u> | |
|--------------------|--------------|------|--------------|------|------------|------|
| | n | % | n | % | n | % |
| BTR | 1 | 1% | 0 | 0% | 0 | 0% |
| BTT | 72 | 95% | 30 | 94% | 7 | 100% |
| Listed | 59 | | 24 | | 7 | |
| Likely | 6 | | 3 | | 0 | |
| Moderate | 4 | | 1 | | 0 | |
| Unlikely | 3 | | 2 | | 0 | |
| Destination | 0 | 0% | 0 | 0% | 0 | 0% |
| Other | 3 | 4% | 2 | 6% | 0 | 0% |
| Total | 76 | 100% | 32 | 100% | 7 | 100% |

Destination at Implant (n=63)**Strategy at:**

| | <u>3mths</u> | | <u>6mths</u> | | <u>1yr</u> | |
|--------------------|--------------|-------------|--------------|-------------|------------|-------------|
| | n | % | n | % | n | % |
| BTR | 0 | 0% | 0 | 0% | 0 | 0% |
| BTT | 11 | 29% | 6 | 30% | 3 | 50% |
| Listed | 1 | | 2 | | 2 | |
| Likely | 5 | | 1 | | 1 | |
| Moderate | 3 | | 0 | | 0 | |
| Unlikely | 2 | | 3 | | 0 | |
| Destination | 26 | 68% | 14 | 70% | 3 | 50% |
| Other | 1 | 3% | 0 | 0% | 0 | 0% |
| Total | 38 | 100% | 20 | 100% | 6 | 100% |

Prospective Patients with the opportunity for 3 mth Followup (n = 351)

| Device Strategy at Implant | n | Deaths | Txpl | Recovery | Strategy Change* |
|------------------------------|------------|----------------|----------------|--------------|------------------|
| Bridge to Recovery | 18 | 7 | 1 | 2 | 5 (28%) |
| Bridge to Transplant | | | | | |
| Listed | 148 | 23 | 55 | 2 | 15 (10%) |
| Likely to be listed | 68 | 13 | 28 | 1 | 18 (26%) |
| Moderate likely to be listed | 40 | 11 | 8 | 1 | 14 (35%) |
| Unlikely to be listed | 23 | 4 | 2 | 0 | 8 (35%) |
| Destination | 54 | 10 | 2 | 1 | 9 (17%) |
| Total | 351 | 68(19%) | 96(27%) | 7(2%) | 69(20%) |

* Status change is any change in the strategy including changes within the bridge to transplant subcategories.

Conclusions:

- HF signs and symptoms are similar across implant strategies.
- Outcome appears similar for DT and BTT strategies.
- MCS is a dynamic state during which recipients undergo frequent re-evaluation.

Implications:

- Newer indications for MCSD might include long term mechanical support rather than the premature assignment to transplant with uncertain eligibility.
- Less reliance on terminology for implant intent might improve patient care and reimbursement.