The Impact of Age, Sex, Therapeutic Intent, Race, and Severity of Advanced Heart Failure On Outcomes in the MOMENTUM 3 Pivotal Trial

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#Drs. Mehra, Uriel, Goldstein, Cleveland served as Study Oversight Committee and contributed equally to the trial conduct and oversight; All author disclosures provided to ISHLT

Relevant Financial Relationship Disclosure Statement

The Impact of Age, Sex, Therapeutic Intent, Race, and Severity of Advanced Heart Failure On Outcomes in the MOMENTUM 3 Pivotal Trial

Dr. Daniel Goldstein– Presenting Author

This study discusses results associated with the HeartMate 3, which is an investigative device in the United States

The following relevant financial relationships exist related to this presentation:

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J.Cleveland, Consultant, Abbott

Introduction – MOMENTUM 3

- The first randomized controlled clinical trial of LVAS to enroll *all eligible* candidates irrespective of therapeutic intent (bridge to transplant [BTT] or destination therapy [DT])[1]
- Demonstrated improved 6-month outcomes with the HeartMate 3 (HM3) compared to the HeartMate II (HMII) LVAS[1]
- In this analysis, we provide outcomes by pre-specified subgroup analyses of age, sex, therapeutic intent, race, and severity of illness

[1]Mehra MR, Naka Y, Uriel N, Goldstein DJ, et al. N Engl J Med. 2017 Feb 2;376(5):440-450

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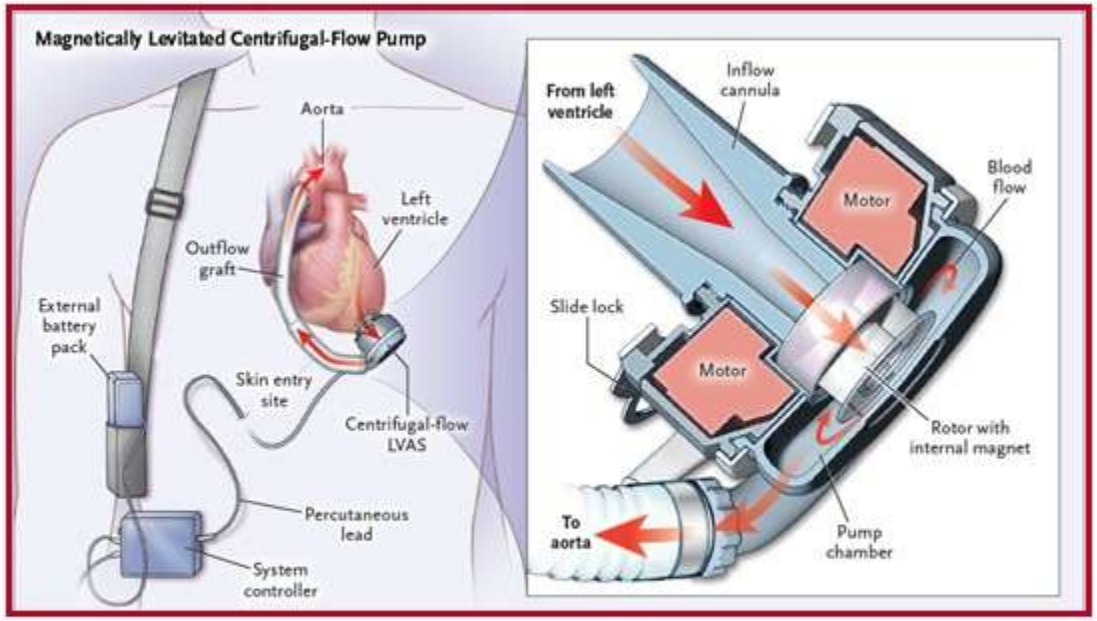
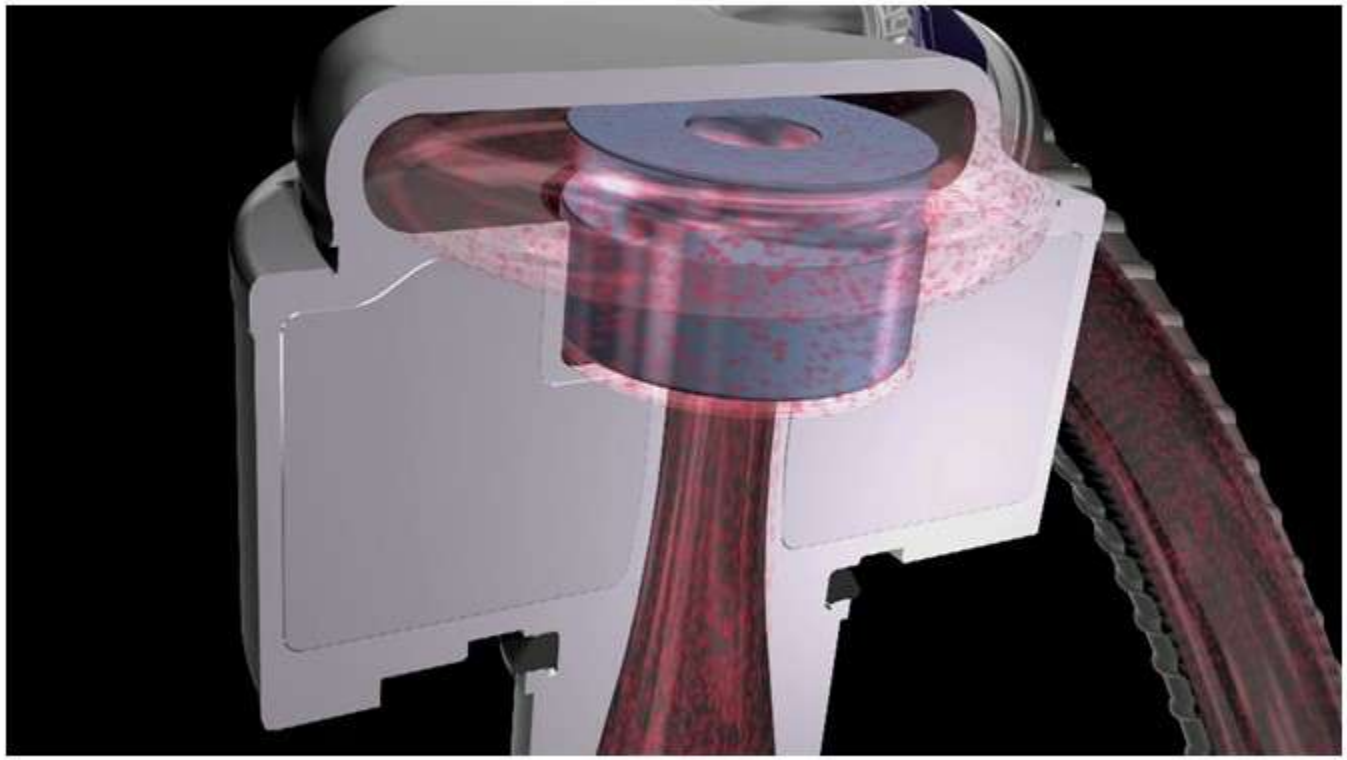
HeartMate 3 LVAS



The HeartMate 3 LVAS (St. Jude Medical, Inc.) is a centrifugal-flow, fully magnetically levitated blood pump engineered to minimize destruction of red blood cells and thrombosis

Investigational Device – Not Available for Commercial Use
ClinicalTrials.gov Identifier: NCT02224755

HeartMate 3: Engineering



Investigational Device – Not Available for Commercial Use
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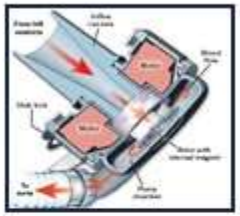
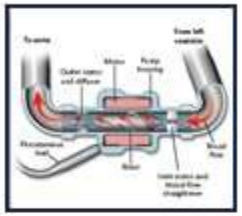
Study Design[1]



HeartMate 3

Patient meets MOMENTUM 3 eligibility criteria?

Randomization 1:1



HeartMate II

Short Term (ST) Cohort
N=294
6-month follow-up

Long Term (LT) Cohort
N=366
24-month follow-up

Full Study Cohort
N=1028
24-month follow-up for powered secondary endpoint

Intent-to-Treat (ITT) Population
N=294

HeartMate 3 N=152

HeartMate II N=142

Treatment failures
(not treated with study device)
N=1

Death: 1

Treatment failures
(not treated with study device)
N=4

No LVAD implant: 1
Withdrawal of consent: 1
Transplant: 1
Implanted with non-study LVAD: 1

As Treated Population
N=289

Implanted with HeartMate 3 N=151

Implanted with HeartMate II N=138

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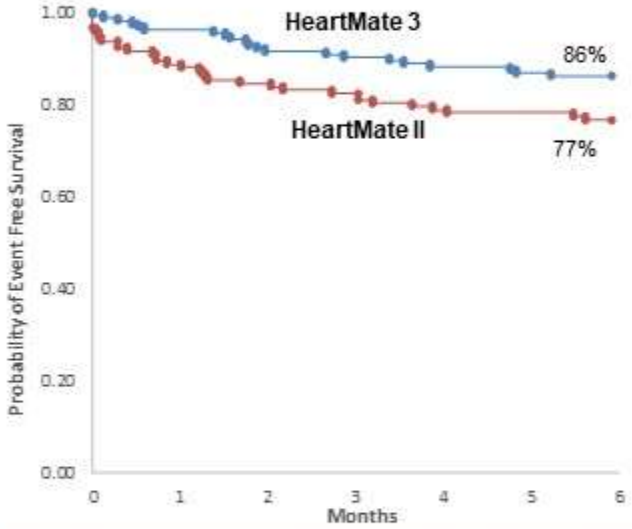
[1]**Mehra MR, Naka Y, Uriel N, Goldstein DJ, et al.** *N Engl J Med. 2017 Feb 2;376(5):440-450*

MOMENTUM 3 – Primary Endpoint Analysis Outcome[1]

Survival at 6 months free of disabling stroke or reoperation to replace or remove the pump (ITT)



Non-inferiority Analysis
Absolute difference +9.4% (95% LCB -2.1%), P<0.0001

Superiority Analysis
HR 0.55, (95% CI 0.32-0.95), P=0.037

	HM3 (n=152) n (%)	HMII (n=142) n (%)	HR (95% CI)
Success	***131 (86.2%)***	***109 (76.8%)***	***0.55 (0.32 - 0.95)***
Reasons for Failure – 180 days			
Did not receive assigned pump	1(1%)	4 (3%)	0.23 (0.03 – 2.09)
Disabling stroke	6 (4%)	4 (3%)	1.31 (0.37 - 4.64)
Reoperation to repair or replace pump*	***1 (1%)***	***11 (8%)***	***0.08 (0.01 - 0.60)***
Death	13 (9%)	14 (10%)	0.82 (0.38 - 1.73)

LCB, lower confidence boundary, HR, hazard ratio, and CI, confidence interval

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[1]*MehraMR, Naka Y, Uriel N, Goldstein DJ, et al.* N Engl J Med. 2017 Feb 2;376(5):440-450

Study Population and Data Analysis

Study Population

- HM3 and HMII patients enrolled into the MOMENTUM 3 trial in the "***as treated***" cohort for the primary endpoint (N=289)

Data Analysis

- Cox Proportional Hazards Modeling utilized to:
  - ***Analysis 1:*** Determine if any of the pre-specified subgroups influenced the outcome differences between HM3 compared to the HMII LVAS
  - ***Analysis 2:*** Perform multivariate analyses to Identify the subgroups with the highest impact on primary endpoint success in the **combined (HM3+HMII)** as treated cohort

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Baseline Characteristics (As-Treated)

Characteristic	HeartMate 3 (n=151)	HeartMate II (n=138)
Age (years) – Median (Range)	64 (19 - 81)	61 (24 - 78)
Male sex [N (%)]	120 (79)	111 (80)
Race [N (%)]		
White	103 (68)	105 (76)
Black or African American	37 (25)	23 (17)
Other*	11 (7)	10 (7)
Body surface area (m^2)	2.1 ± 0.3	2.1 ± 0.3
Ischemic cause of heart failure [N (%)]	68 (45)	68 (49)
History of stroke [N (%)]	12 (8)	14 (10)
Concomitant medication or intervention [N (%)]		
Intravenous inotropic agents	131 (87)	118 (86)
Diuretics	***133 (88)***	***133 (96)***
ACE inhibitor	37 (25)	37 (27)
Angiotensin II -receptor antagonist	10 (7)	18 (13)
Beta blocker	91 (60)	77 (56)
CRT/CRT-D	59 (39)	50 (36)
ICD/CRT-D	100 (66)	97 (70)
IABP	18 (12)	18 (13)

*Other: includes Asian, Native Hawaiian or Pacific Islanders
**Diuretic use was statistically significant (P=0.01)

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Baseline Characteristics (As Treated)

Characteristic	HeartMate 3 (n=151)	HeartMate II (n=138)
LVEF (%)	17.1 ± 5.0	17.4 ± 4.9
Arterial blood pressure (mmHg)		
*Systolic**	***110 ± 16***	***106 ± 12***
Diastolic	67 ± 10	66 ± 10
Mean arterial pressure	81 ± 11	79 ± 10
PCWP (mmHg)	23 ± 9	22 ± 9
CI (liters/min/m^2)	1.9 ± 0.5	2.0 ± 0.7
PVR (Wood Units)	3.2 ± 1.7	3.1 ± 1.6
RAP(mmHg)	10 ± 6	11 ± 7
Serum sodium (mmol/liter)	135.6 ± 3.9	135.0 ± 4.2
Serum creatinine (mg/ml)	1.4 ± 0.4	1.4 ± 0.4
INTERMACS Profile [N (%)]		
1	1 (1)	2 (1)
2	50 (33)	43 (31)
3	76 (50)	69 (50)
4	22 (15)	22 (16)
5-7†	2 (1)	2 (1)
Intended Use of device at implant – [N (%)]		
Bridge to Transplant (BTT)	40 (26)	36 (26)
Bridge to Candidacy	27 (18)	24 (17)
Destination Therapy (DT)	84 (56)	78 (57)

* Systolic blood pressure (P= 0.01) was statistically significant;
† There were no subjects with INTERMACS 6 and 7 in either groups; PCWP denotes pulmonary capillary wedge pressure and PVR pulmonary vascular resistance

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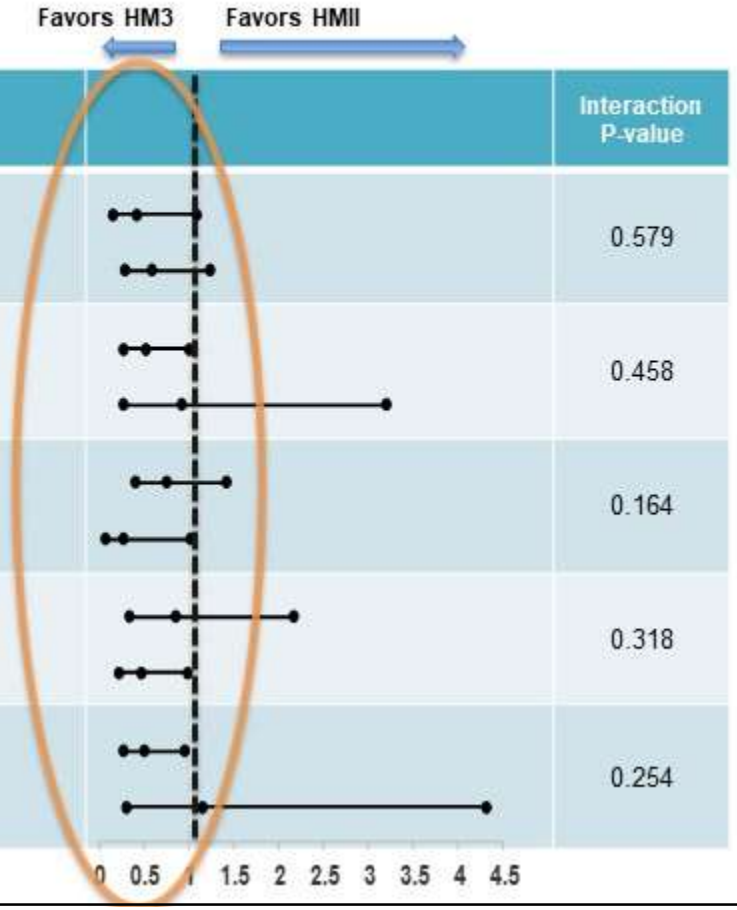
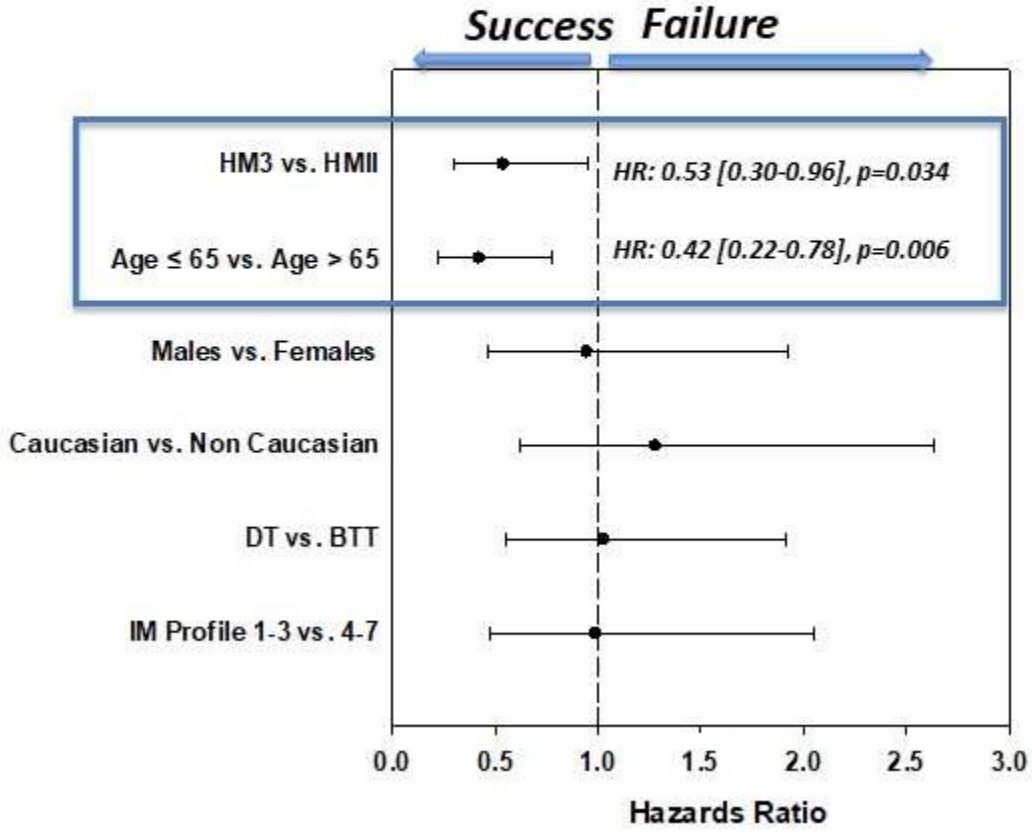
Relative Interaction of the HM3 vs HMII LVAS Within Pre-Specified Subgroups

Variable	Subgroups	HR [95% CI]	Interaction P-value
Age (years)	≤65 (n = 178)	0.42 [0.17-1.09]	0.579
	>65 (n = 111)	0.59 [0.28-1.25]	
Sex	Male (n = 231)	0.53 [0.28-1.01]	0.458
	Female (n = 58)	0.93 [0.27-3.21]	
Race	Caucasian (n = 208)	0.76 [0.40-1.43]	0.164
	Non-Caucasian (n = 81)	0.27 [0.07-1.03]	
Intended Use	BTT/BTC (n = 127)	0.86 [0.34-2.17]	0.318
	DT (n = 162)	0.47 [0.23-0.99]	
INTERMACS Profile	INTERMACS 1-3 (n = 241)	0.51 [0.27-0.96]	0.254
	INTERMACS 4-5 (n = 48)	1.16 [0.31-4.33]	



Subgroups Impacting Primary Endpoint Success in Combined (HMII+HM3) Cohort (N=289)



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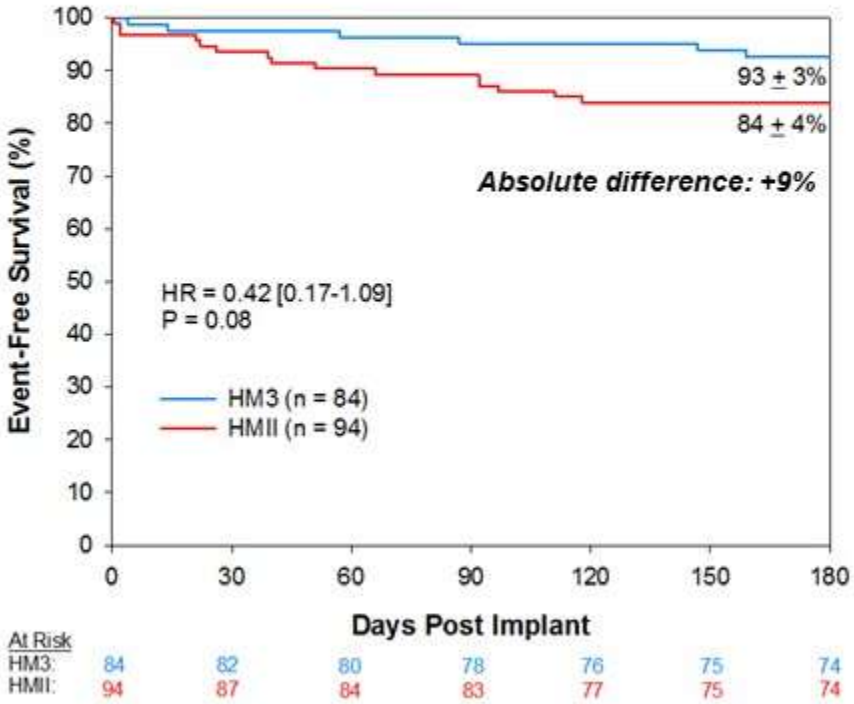
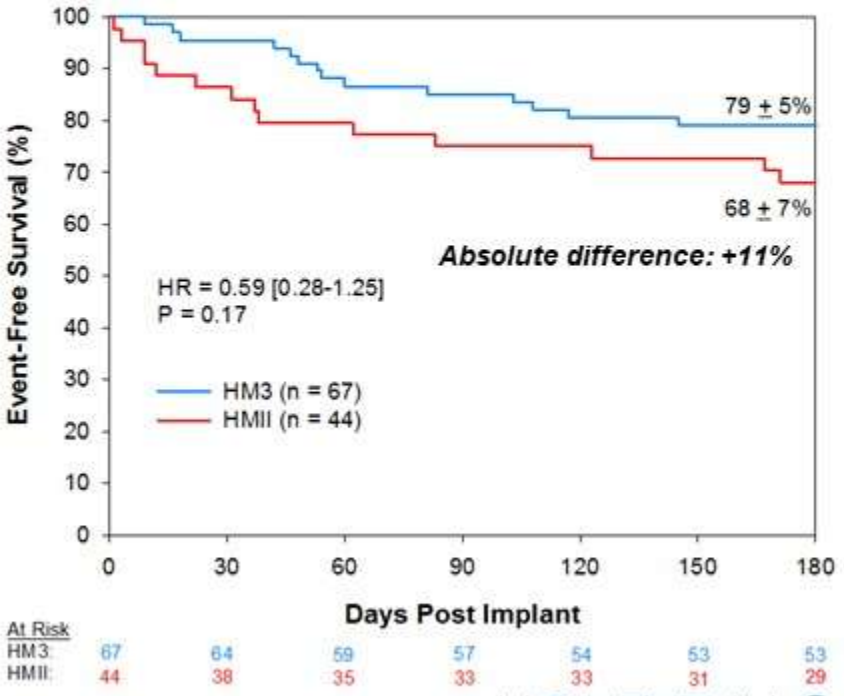
Results: Impact of Age on Primary Endpoint Outcomes

Age ≤ 65 (N=178)



At Risk							
HM3:	84	82	80	78	76	75	74
HMII:	94	87	84	83	77	75	74

Age > 65 (N=111)



At Risk							
HM3:	67	64	59	57	54	53	53
HMII:	44	38	35	33	33	31	29

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Results: Primary Endpoint Components:

HM3 vs. HMII by Age Group

Age ≤ 65 years (N=178)

Variable	HM3 (n = 84)	HMII (n = 94)	P
Primary endpoint Success	78 (92.9%)	79 (84.0%)	0.10
Primary Endpoint Failure (First Event)	6 (7.1%)	15 (16%)	
- Disabling stroke	1 (1.2%)	2 (2.1%)	1.00
- Reoperation	1 (1.2%)	7 (7.5%)	0.07
- Death*	4 (4.8%)	6 (6.4%)	0.75

*HM3: Right Heart Failure (n=3), hemorrhagic stroke (n = 1)
HMII: Abdominal bleeding (n=1), right heart failure (n=4), ventricular fibrillation (n = 1)

Age>65 years (N=111)

Variable	HM3 (n = 67)	HMII (n = 44)	P
Primary endpoint Success	53 (79.1%)	30 (68.2%)	0.26
Primary Endpoint Failure (First Event)	14 (21.9%)	14 (31.8%)	
- Disabling stroke	5 (7.5%)	2 (4.6%)	0.70
- Reoperation	0 (0.0%)	4 (9.1%)	***0.02***
- Death*	9 (13.4%)	8 (18.2%)	0.59

*HM3: anoxic brain injury (n = 1), driveline disconnect (n=1), GI bleed (n = 1), cancer (n=1), respiratory failure (n=1), right heart failure (n=1), sepsis (n=2), subdural hematoma (n=1)
HMII: Aortic dissection (n=1), hepatic failure (n=1), pneumonia (n = 1), right heart failure (n=5)

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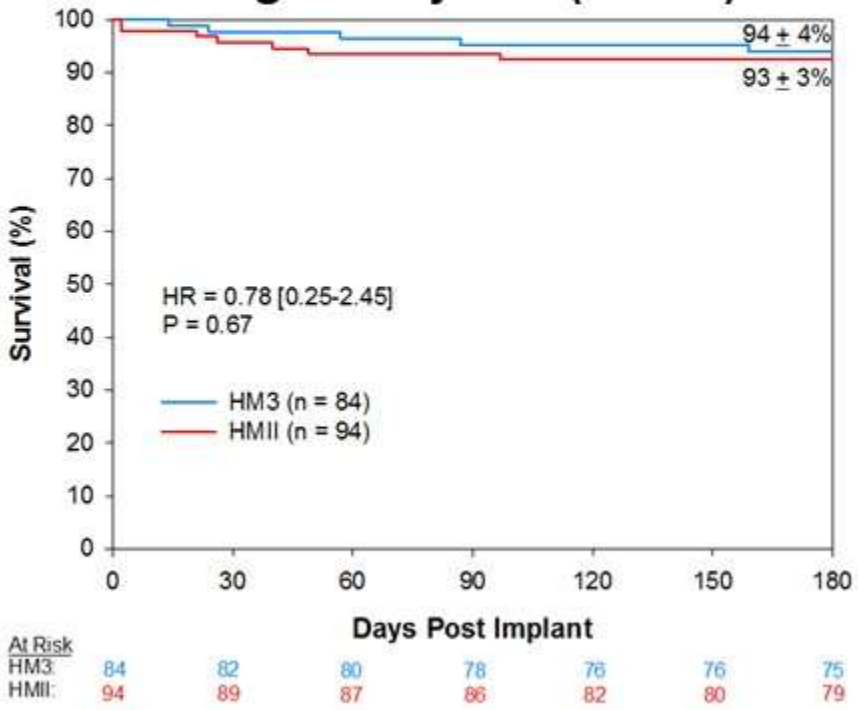
Overall Survival

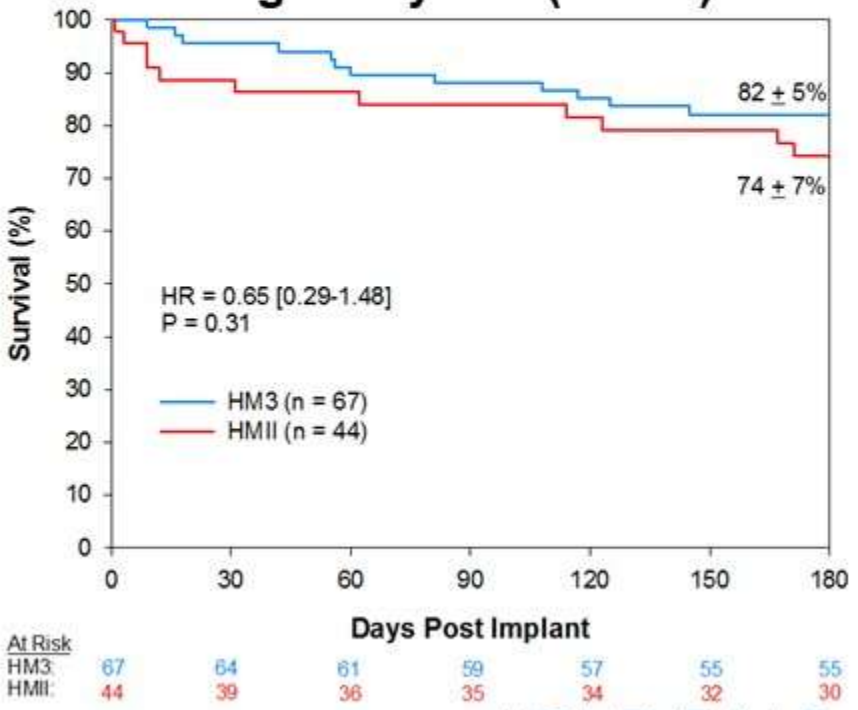
HM3 vs. HMII Stratified by Age

Age ≤ 65 years (N=178)



At Risk							
HM3:	84	82	80	78	76	76	75
HMII:	94	89	87	86	82	80	79

Age>65 years (N=111)



At Risk							
HM3:	67	64	61	59	57	55	55
HMII:	44	39	36	35	34	32	30

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Key Differences in Characteristics: Age ≤ 65 and > 65 years in the Combined (HM3+HMII) Cohorts

Characteristic	Age≤65 (n=178)	Age>65 (n=111)
Male sex [N(%)]	147 (83)	84 (76)
Caucasian Race [N(%)]*	***118 (66)***	***90 (81)***
Ischemic cause of heart failure – [N(%)]*	***75 (42)***	***61 (55)***
LVEF [N(%)]	17.0 ± 5.2	17.6 ± 4.5
PCWP (mmHg)	23 ± 9	22 ± 9
CI (liters/min/m²)	1.9 ± 0.6	2.0 ± 0.6
RAP (mmHg)	11 ± 7	10 ± 5
Serum creatinine (mg/ml)*	***1.3 ±0.4***	***1.5 ±0.4***
INTERMACS Profile [N(%)]		
1	3 (2)	0 (0)
2	56 (31)	37 (33)
3	92 (52)	53 (48)
4	25 (14)	19 (17)
5-7†	2 (1)	2 (2)
Therapeutic Intent [N(%)]		
Bridge to Transplant (BTT)	***63 (35)***	***13 (12)***
Bridge to Candidacy (BTC)	***39 (22)***	***12 (11)***
Destination Therapy (DT)	***76 (43)***	***86 (77)***

Race (p = 0.02), ischemic etiology (p = 0.04), therapeutic intent (p<0.01) and serum creatinine were significantly different

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Differences in Key Adverse events: Age ≤ 65 and > 65

Adverse Event	Age ≤ 65 (N=178)		Age > 65 (N=111)		P
	Patients (%)	Events	Patients (%)	Events	
Any Bleeding	***53 (30%)***	***90***	***51 (46%)***	***105***	***0.006***
GI Bleeding	22 (12%)	39	23 (21%)	44	0.07
Any Stroke	14 (8%)	16	13 (12%)	13	0.30
Hemorrhagic Stroke	6 (3%)	6	6 (5%)	6	0.55
Ischemic Stroke	10 (6%)	10	7 (6%)	7	0.80
Disabling Stroke	***5 (3%)***	***5***	***9 (8%)***	***9***	***0.05***
Other Neurological event	10 (6%)	10	7 (6%)	7	0.80
Suspected Thrombosis	10 (6%)	12	4 (4%)	6	0.58
Right Heart Failure	43 (24%)	46	36 (32%)	39	0.14
Renal Failure	***9 (5%)***	***10***	***20 (18%)***	***20***	***<0.001***
Major Infection	63 (35%)	90	48 (43%)	86	0.21
Driveline Infection	21 (12%)	23	6 (5%)	9	0.10

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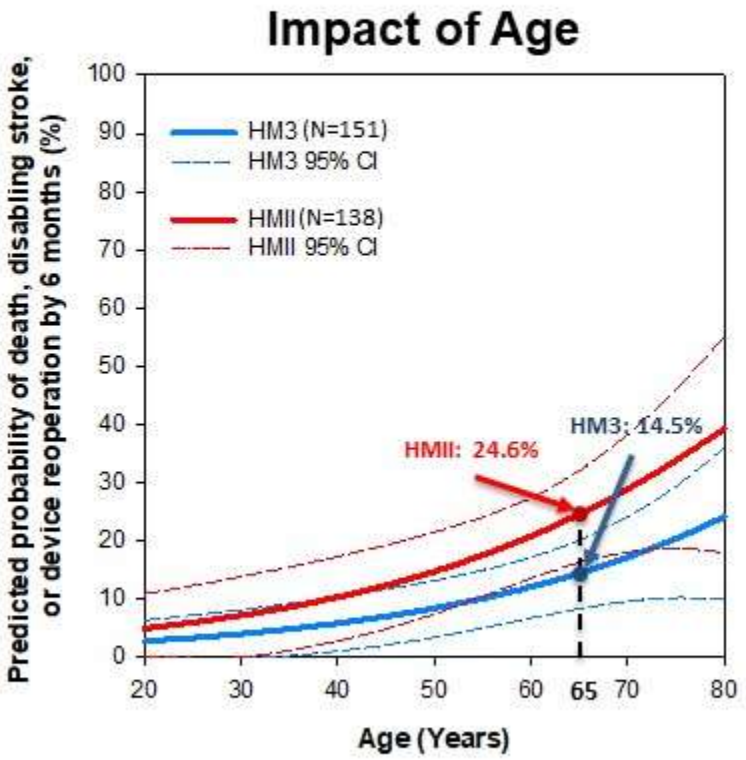
Impact of Age as a Continuous Variable



P (HM3 vs. HMII) = 0.04; P (Age) = 0.01

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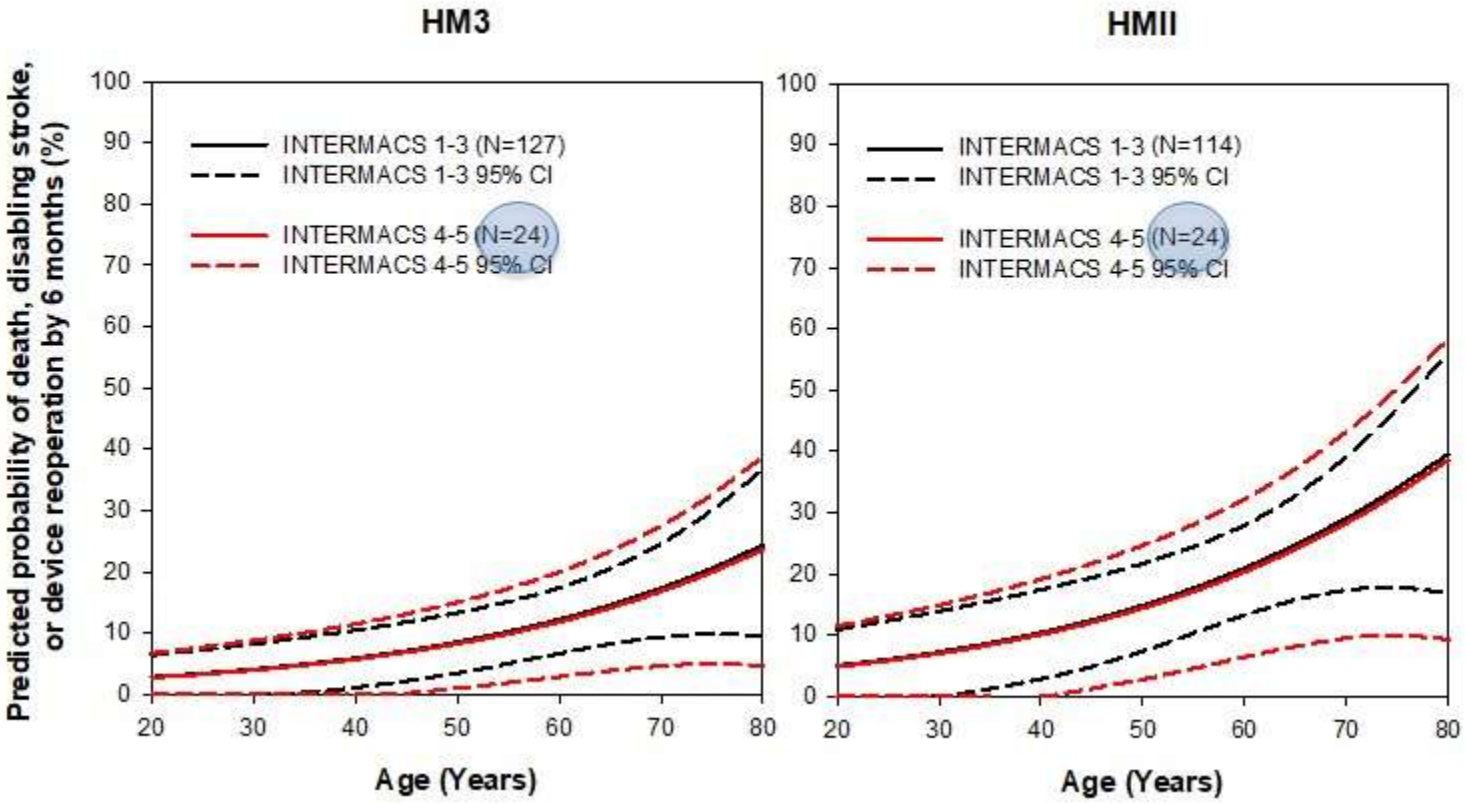
Primary Endpoint Failure at 6 Months:

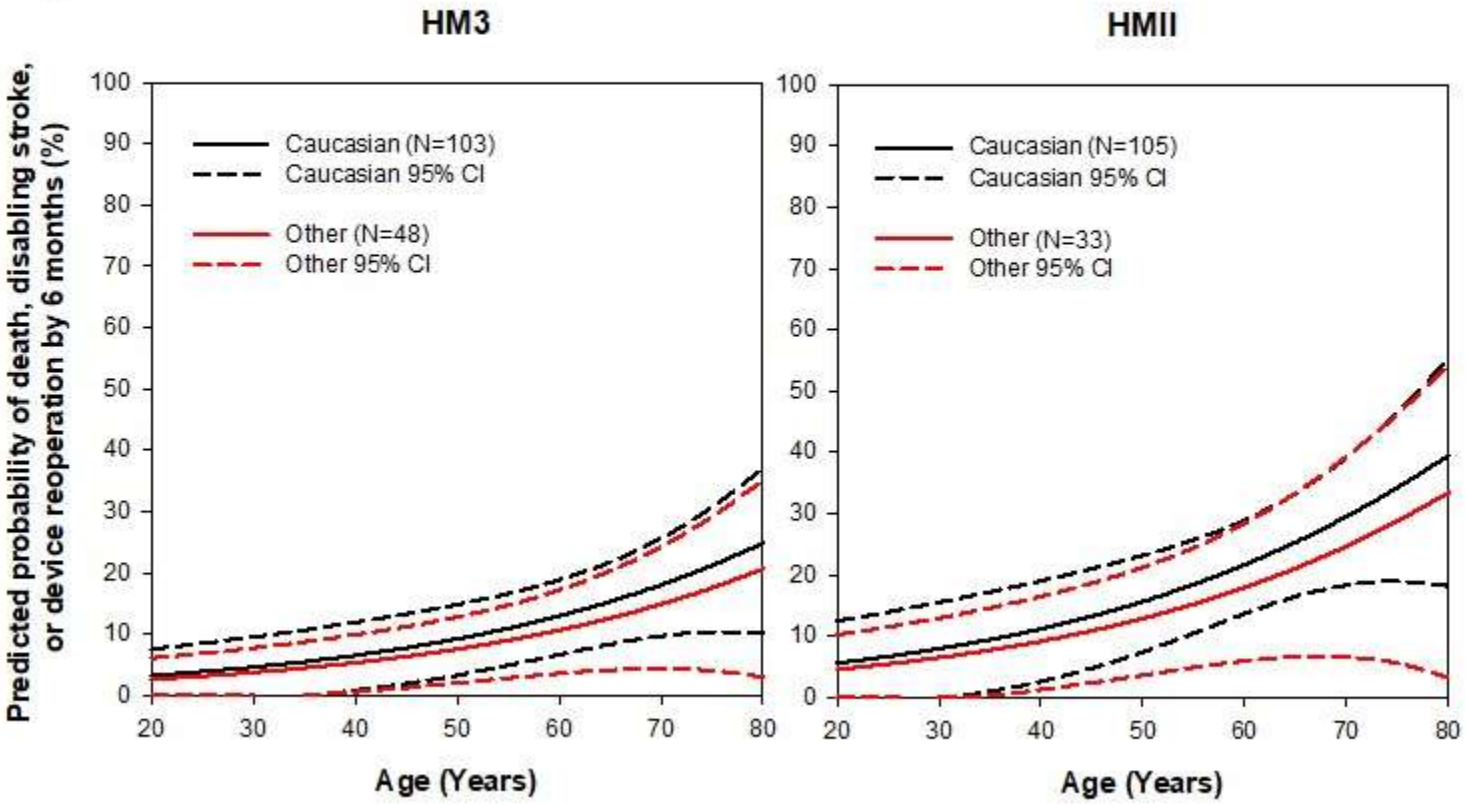
Impact of Age and Severity of Illness



P (HM3 vs. HMII) = 0.04; P (Age) = 0.02; P (INTERMACS Profile) = 0.93

Primary Endpoint Failure at 6 Months:

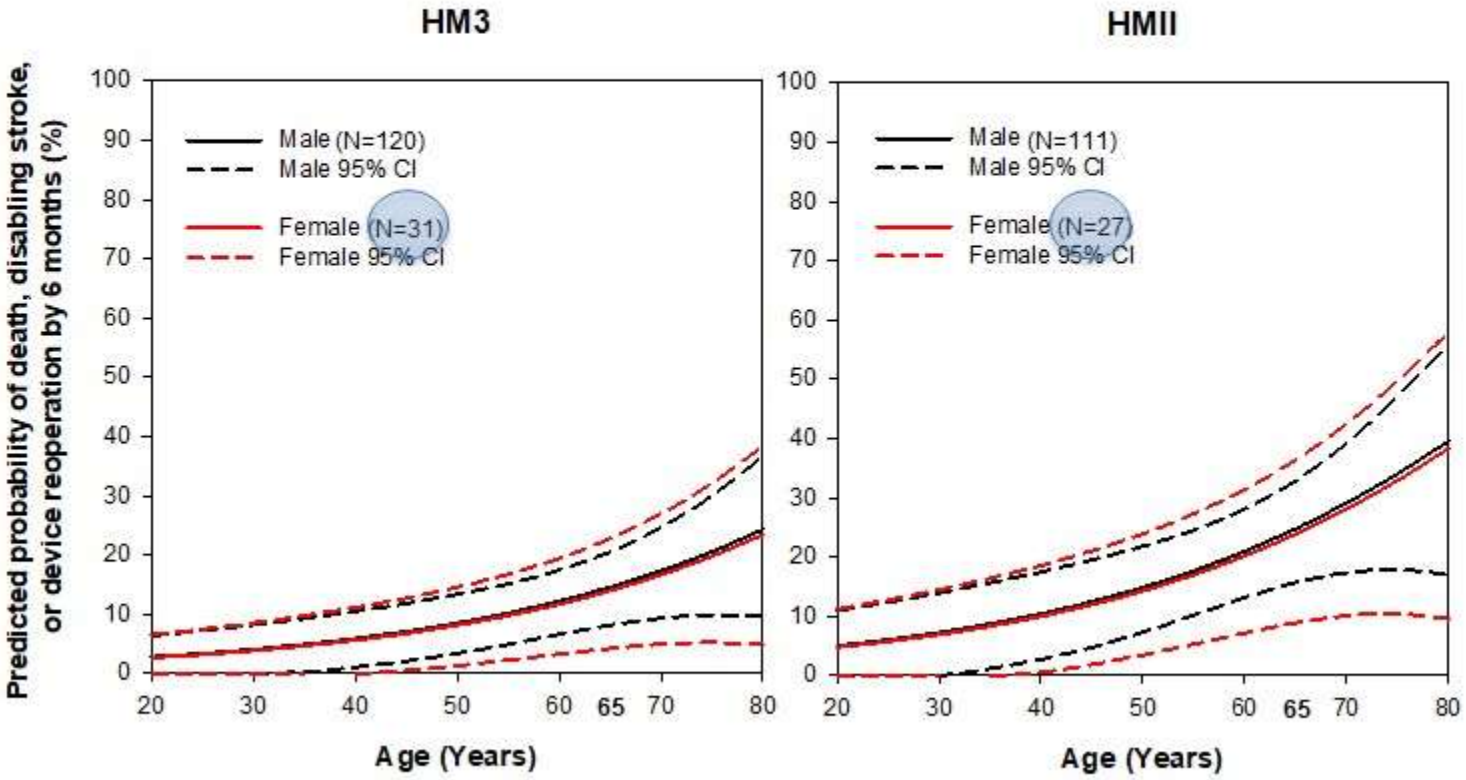
Impact of Age and Race



P (HM3 vs. HMII) = 0.05; P (Age) = 0.01; P(Race) = 0.56

Primary Endpoint Failure at 6 Months:

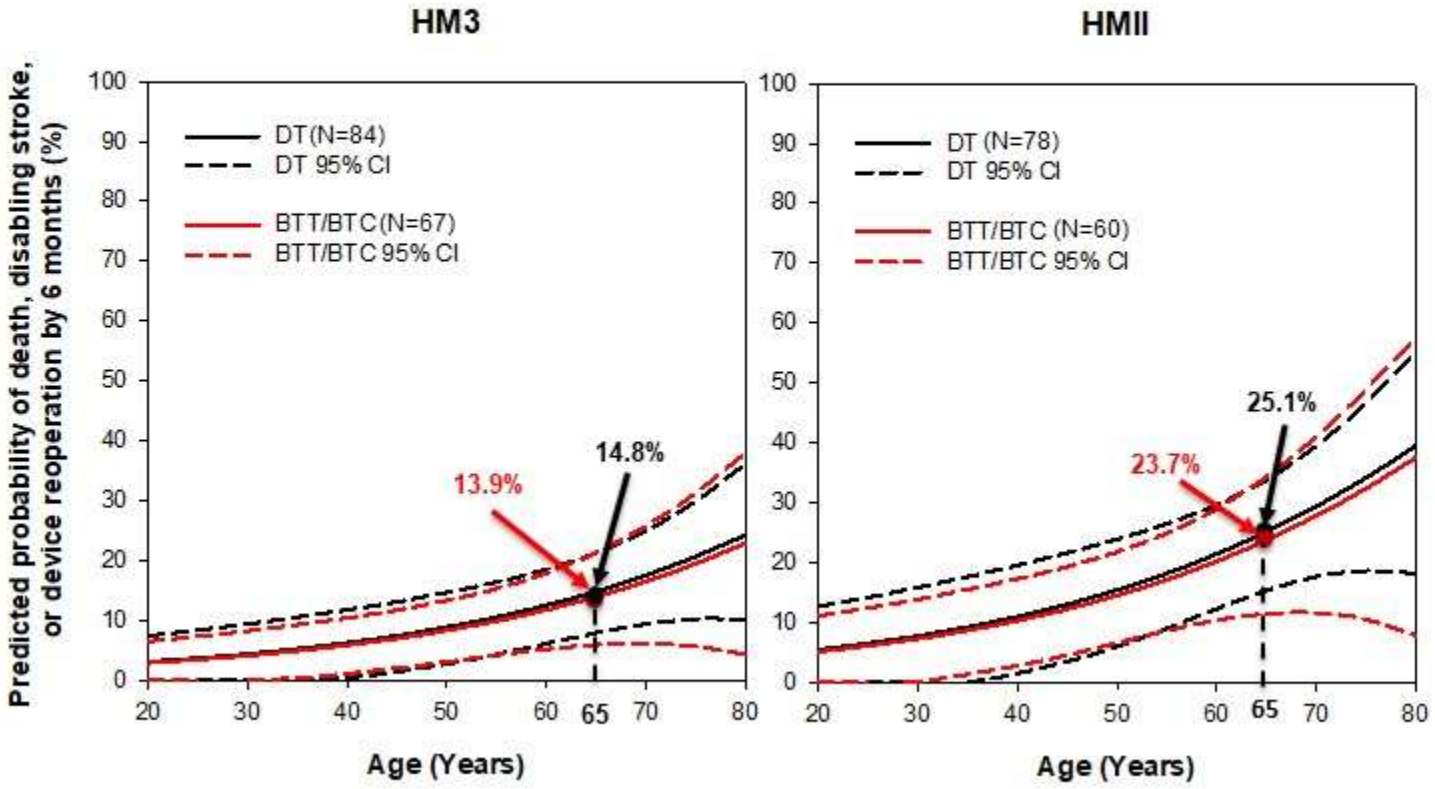
Impact of Age and Sex



P (HM3 vs. HMII) = 0.04; P (Age) = 0.01; P(Gender) = 0.90

Primary Endpoint Failure at 6 Months:

Impact of Age and Therapeutic Intent



P (HM3 vs. HMII) = 0.04; P (Age) = 0.02; P(Therapeutic Intent) = 0.83

Limitations

- Study findings represent a secondary analysis and should be viewed as *exploratory* since:
  - This 6-months short term cohort represents the first US experience and is only a limited proportion (294/1028, 28.5%) of the total MOMENTUM 3 IDE trial
  - Follow-up was limited to 6 months of post implant (6/24, 25% of planned)

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Conclusions

- Improvement in clinical outcomes with the HM3 compared to HMII, are independent of the singular influence of any specific pre-specified subgroup
- Younger age and the utilization of HM3 vs HMII LVAS were independently associated with a greater likelihood of primary endpoint success
- Sex, therapeutic intent (BTT or DT), severity of illness, and race, when adjusted for age, do not influence primary endpoint success

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Study Status and Future Directions……

- The MOMENTUM 3 trial (N=1028) is now fully enrolled, and is in follow-up phase
- The two year follow-up in the long term cohort (N=366) will be available next year
- Further analysis of the sub-groups will be performed in the full cohort of patients

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THANK YOU !

On behalf of the MOMENTUM 3 Trial Team

dgoldste@montefiore.org

MOMENTUM 3

Abbott
6101 Stoneridge Dr., Pleasanton, CA 94588 USA, Tel: 1 925 847 8600
Cardiovascular.Abbott/HeartMate3

Rx Only
Brief Summary: Prior to using these devices, please review the Instructions for Use for a complete listing of indications, contraindications, warnings, precautions, potential adverse events and directions for use.

HeartMate 3™ LVAS Indications: The HeartMate 3™ Left Ventricular Assist System is indicated for providing short- and long-term mechanical circulatory support (e.g., as bridge to transplant or myocardial recovery, or destination therapy) in adult and pediatric patients with advanced refractory left ventricular heart failure and with an appropriate body surface area.

HeartMate 3™ LVAS Contraindications: The HeartMate 3 Left Ventricular Assist System is contraindicated for patients who cannot tolerate, or who are allergic to, anticoagulation therapy.

HeartMate 3™ LVAS Adverse Events: Adverse events that may be associated with the use of the HeartMate 3 Left Ventricular Assist System are: death, bleeding, cardiac arrhythmia, localized infection, right heart failure, respiratory failure, device malfunctions, driveline infection, renal dysfunction, sepsis, stroke, other neurological event (not stroke-related), hepatic dysfunction, psychiatric episode, venous thromboembolism, hypertension, arterial non-central nervous system (CNS) thromboembolism, pericardial fluid collection, pump pocket or pseudo pocket infection, myocardial infarction, wound dehiscence, hemolysis (not associated with suspected device thrombosis) or pump thrombosis.

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