Health Care Resource Use and Cost Implications in the MOMENTUM 3 Long-term Outcome Study:

A Randomized Controlled Trial of a Magnetically Levitated Cardiac Pump in Advanced Heart Failure

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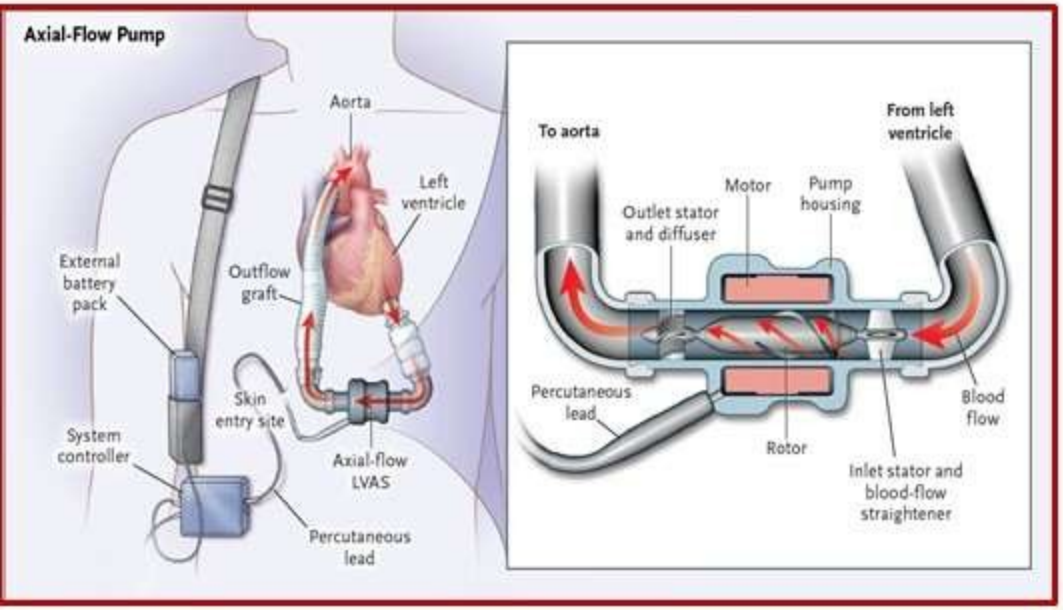
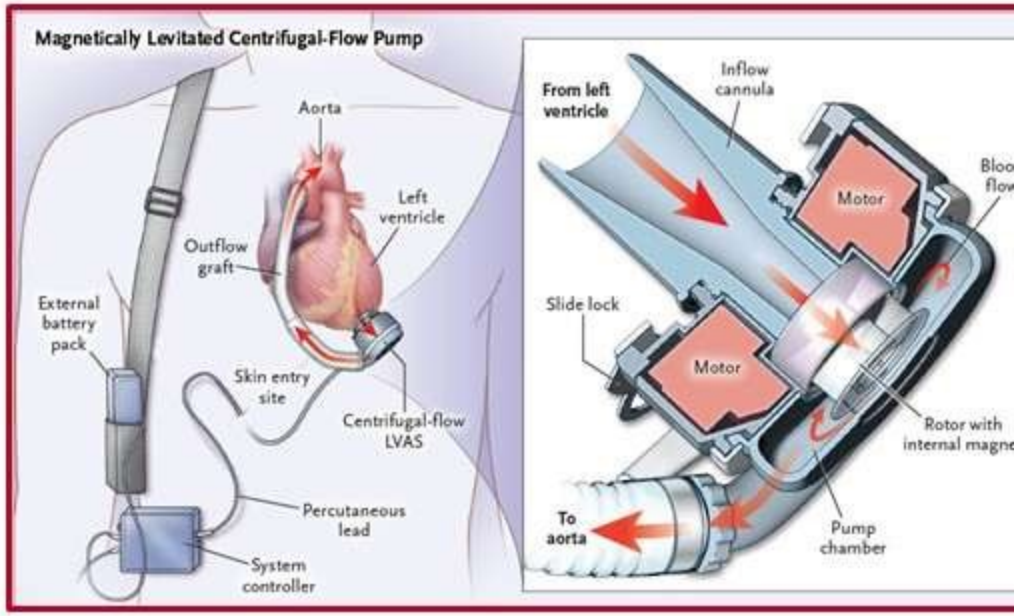
Background

- **Continuous-flow Left Ventricular Assist Systems (LVAS) improve survival and quality of life in patients with advanced heart failure refractory to medical therapy[1,2]**



The HeartMate II LVAS is a mechanical bearing axial continuous-flow blood pump approved for *both* Bridge-To-Transplant (BTT) and Destination Therapy (DT) patients



The HeartMate 3 LVAS is a centrifugal-flow, fully magnetically levitated blood pump engineered to minimize destruction of red blood cells and thrombosis

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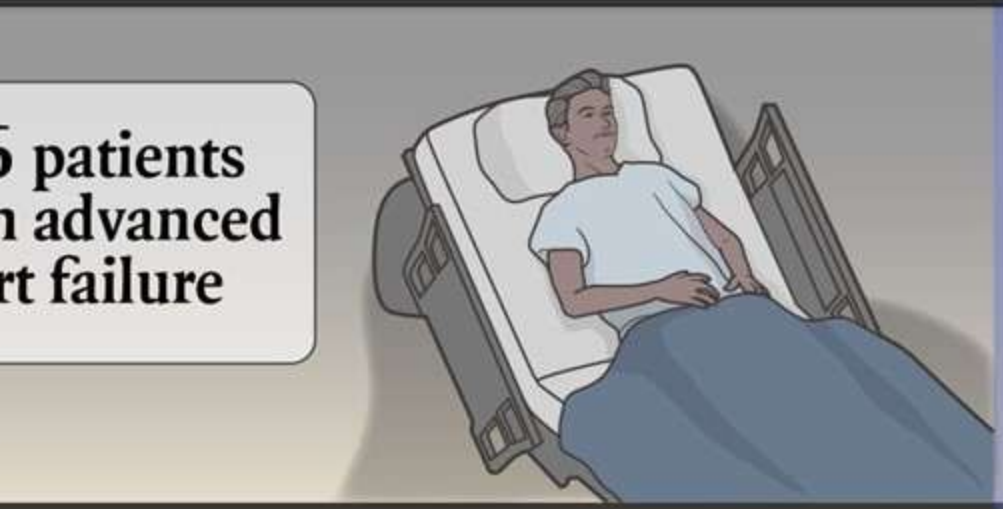
vanced Heart Failure Treated with Continuous-Flow Left Ventricular Assist Device. *N Engl J Med.* 2009;361(23):2241-2251.
wo-Year Outcomes with a Magnetically Levitated Cardiac Pump in Heart Failure. N Engl J Med. 2018;378(15):1386-1395.

omes with a Magnetically Levitated Cardiac Pump in Heart Fa

MULTICENTER, UNBLINDED, RANDOMIZED TRIAL



5 patients
n advanced
rt failure

	Centrifugal flow		Axial flo
	N=190		N=176
vival free of disabling ke or reoperation for pump function at 2 yr	79.5%	P<0.001	60.2%
stroke	10.1%	P=0.02	19.2%
peration for pump malfunction	1.6%	P<0.001	17.0%

Objectives

- Compare and contrast re-hospitalizations for "device attributable events" and "device-unrelated events" (post index hospitalization)
- Assess costs based on payer reimbursements, either public or private funded
- Determine relative cost differences between the HeartMate 3 and HeartMate II LVAS groups, irrespective of intended goal of therapy (BTT or DT)

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ethods

illing data collected for in-patient hospitalizations (other than Index implant hospitalization)

verage payer cost (2017 US$) based on billing data retrieved from CMS Medicare

atabase[1] and Marketscan™ commercial database[2-3]

issing billing data imputed based on regression modeling (Gaussian, Gamma and LASSO

- Length of hospitalization
- Adverse events associated with hospitalization
- Patient characteristics

ne HM 3 was compared to the HM II -using Bootstrap methods (x1500) for accuracy

- Admissions per patient-year
- Hospital days per patient-year
- Average cumulative cost per patient-year

ms.gov/Research-Statistics-Data-and-Systems/Files-for-Order/LimitedDataSets/ (accessed online April 29th 2018)
health.com/markets/life-sciences/products/data-tools/marketscan-databases (accessed online April 29th 2018)
ls.gov/opub/mlr/2018/home.htm (accessed online April 29th 2018)

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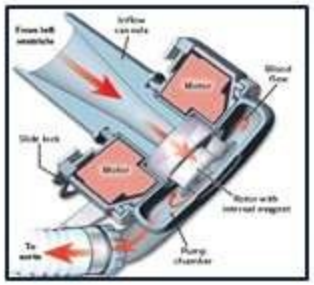
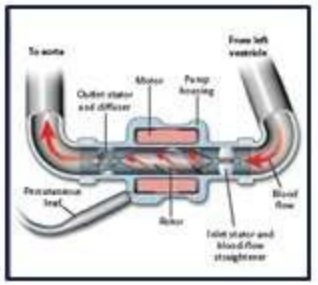
CONSORT Diagram





Patient meets MOMENTUM 3 eligibility criteria?

Randomization 1:1

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

Intent-to-Treat Population N=366

HeartMate 3 N=190

HeartMate II N=176

Withdrawn before implant N = 1 *Death: 1*

Withdrawn before implant N = 4 *No LVAD implant: 1* *Withdrawal of consent: 1* *Transplant: 1* *Implanted with non-study LVAD: 1*

As-Treated Population N=361

Implanted with HeartMate 3 N=189

Implanted with HeartMate II N=172

Outcome before discharge N = 12 *Death: 12*

Outcome before discharge N = 12 *Death: 9* *Transplant: 1* *Exchange to non-study LVAD: 2*

Analysis Population N=337

Discharged on HeartMate 3 support N=177

Discharged on HeartMate II support N=160

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Baseline Characteristics

Characteristic	HeartMate 3 (n=177)	HeartMate II (n=160)
Median age – years (range)	64 (19-81)	61 (24-84)
Male sex – no. (%)	140 (79)	128 (80)
Race or ethnic group – no. (%)		
White	115 (65)	119 (74)
Black	51 (29)	29 (18)
Other	11 (6)	12 (8)
Ischemic cause of heart failure – no. (%)	75 (42)	76 (48)
Intended goal of pump support – no. (%)		
Bridge to transplantation	45 (25)	38 (24)
Bridge to candidacy for transplantation	30 (17)	24 (15)
Destination therapy	102 (58)	98 (61)
Medications at discharge – no. (%)		
Diuretic	142 (80)	118 (74)
ACE inhibitor	58 (33)	47 (29)
Angiotensin II Antagonist	12 (7)	9 (6)
Beta blocker	85 (48)	82 (51)
Anticoagulant/antiplatelet	176 (99)	159 (99)
Inotropes	5 (3)	2 (1)
NYHA class I or II at discharge – no. (%)	81 (48)	76 (51)
LVEF at discharge - %	18 ± 8	19 ± 9
MAP at discharge – mm Hg	81 ± 9	81 ± 10
Serum sodium at discharge – mmol/liter	135 ± 3	135 ± 4
Serum creatinine at discharge – mg/dl	1.1 ± 0.4	1.1 ± 0.4

There were no significant differences between groups. ACE = angiotensin-converting enzyme, NYHA = New York Heart Association, LVEF = left ventricular ejection fraction, MAP = mean arterial pressure.

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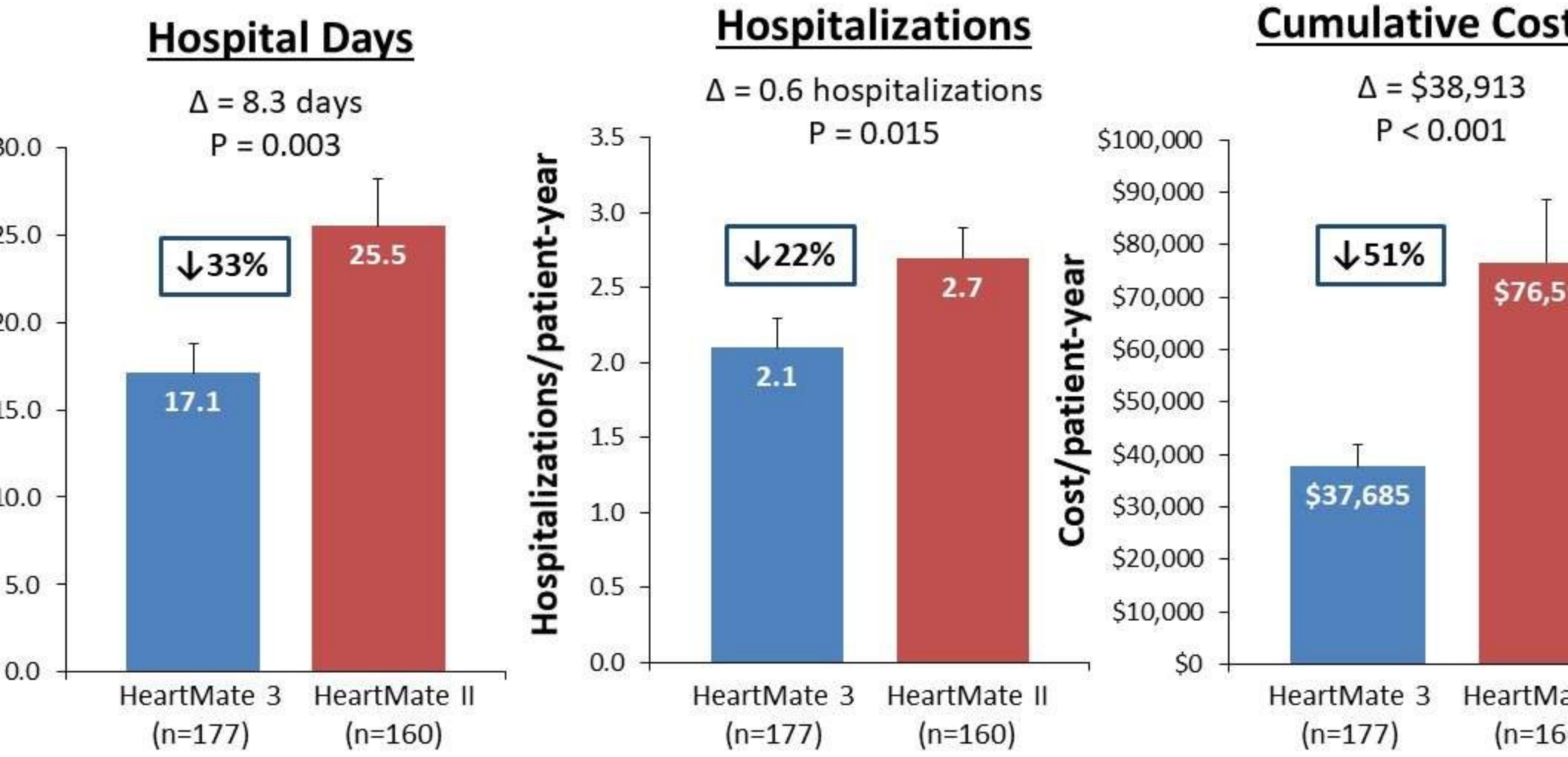
Hospital Days, Hospitalizations and Cumulative Costs

Normalized over patient time in study



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ifference shown is for HeartMate II – HeartMate 3. P values derived from bootstrap simulation (x1500)

ospitalizations for Device Attributable Events (DAE)

l bleeding, driveline infection, stroke, pump thrombosis, RHF, and suspected device malfunc

HeartMate 3:

2.1 average hospitalizations/patient-year
537 hospitalizations

368 non-DAE
ospitalizations (69%)

169 DAE
hospitalizations (31%)

Average cost
$13,845

p=0.015

HeartMate II:

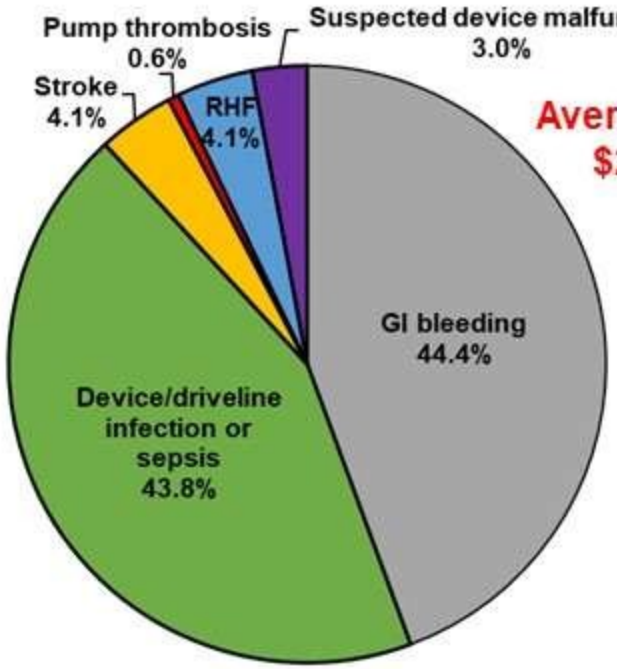
2.7 average hospitalizations/patient-year
501 hospitalizations

293 non-DAE
hospitalizations (58

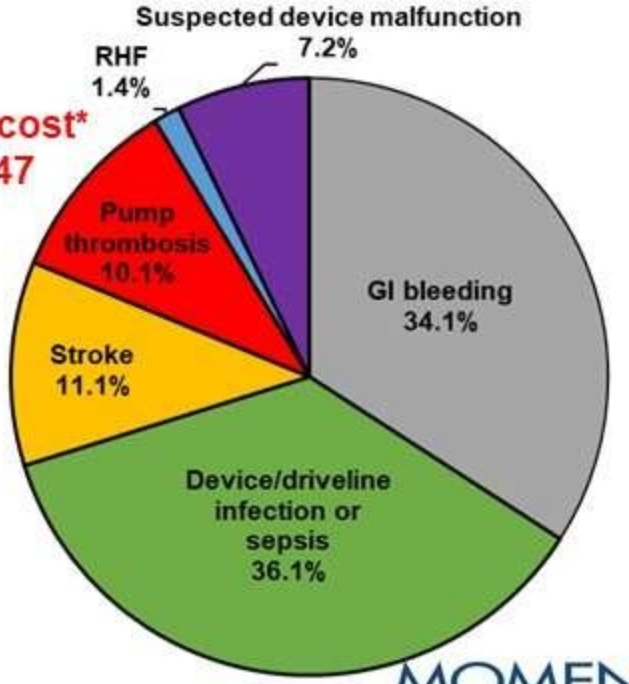
208 DAE
hospitalizations (42%)

Average cost
$14,651

P<0.001



Average cost*
$21,780



Average cost*
$46,547

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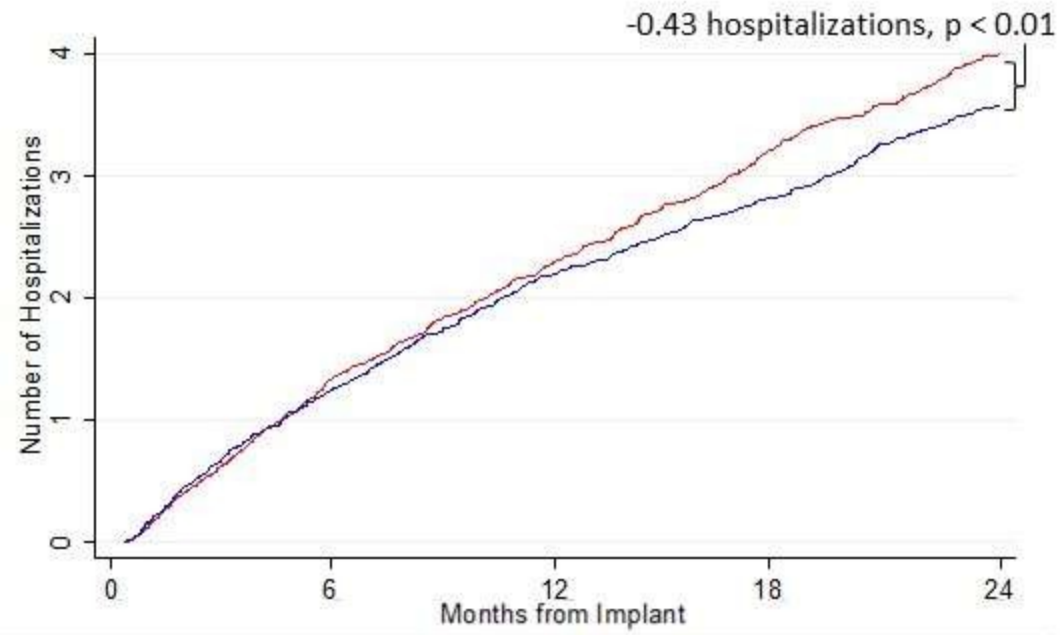
lospitalizations due to DAEs were more expensive for HMII (p<0.001)

ost Implant Hospitalizations and Costs Over Time

Conditional Hospitalizations

Expected number of hospitalizations conditional on subject remaining in the study

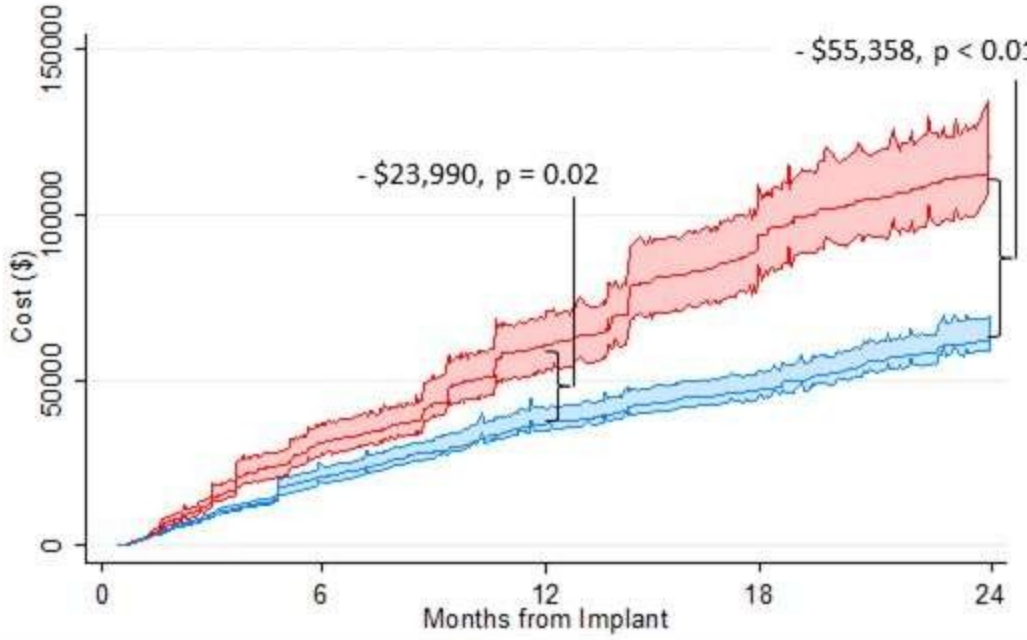


HM 3	177	165	146	127	117
HM II	160	141	121	99	86

HM II — HM 3

Conditional Cost

Expected cumulative cost conditional on subject remaining in the study at that time point



HM 3	177	165	146	127	117
HM II	160	141	121	99	86

HM II IQR — HM 3 IQR
HM II Conditional Cost — HM 3 Conditional Cost

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ter-Quartile Range

Cumulative Costs by Intended Goal of Therapy

Normalized over patient time in study

	HeartMate 3	HeartMate II	Difference*	P V
tients	n=102	n=98		
ge cumulative cost per patient-year	$31,183 ± 5,024	$70,956 ± 12,258	$39,773	<0
ge days in hospital per patient-year	17.5 ± 2.2	27.3 ± 3.3	9.7	0.
ge hospitalizations per patient-year	2.0 ± 0.2	3.0 ± 0.3	1.0	0.
atients	n=75	n=62		
ge cumulative cost per patient-year	$46,529 ± 7,474	$85,518 ± 20,538	$38,989	0.
ge days in hospital per patient-year	16.6 ± 2.7	22.6 ± 4.3	6.0	0
ge hospitalizations per patient-year	2.3 ± 0.3	2.3 ± 0.3	0	0

ce shown is for HeartMate II – HeartMate 3. †P values derived from bootstrap simulation (x1500)

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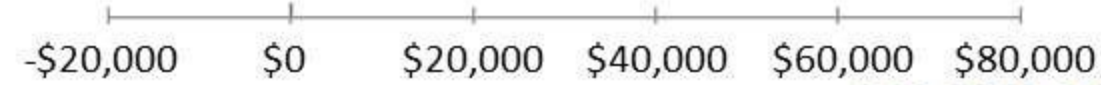
umulative Cost Difference

ub-Group Analysis

Variable	Group	Cost Difference per Patient-Year*	Interacti P Value
Gender	Male (n=268)		0.73
	Female (n=69)		
Intended Use	Destination Therapy (n=200)		0.98
	Bridge to Transplant (n=137)		
Insurance Type	Medicare Insurance (n=239)		0.67
	Commercial Insurance (n=98)		
Study Outcome	Expired (n=45)		0.95
	Transplanted (n=81)		
	Ongoing (n=203)		



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dian values are shown for HeartMate II – HeartMate 3 with interquartile range

Sensitivity Analysis of "Global Cost"

(Health care utilization including costs for index hospitalizations and estimates for heart transplant and death)

	HeartMate 3 (N=189)	HeartMate II (N=172)	Difference	P Value†
Costs Accumulated over 2-years				
Average cumulative cost over study period	$473,774±17,504	$539,376±23,347	$65,602	0.009

*Difference shown is for HeartMate II – HeartMate 3. †P values derived from bootstrap simulation (x3000)

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Conclusions

- Long term (2-year) clinical superiority demonstrated by the HeartMate 3 is also associated with lower medical resource use (re-hospitalizations) **and** reduced costs when compared to the HeartMate II axial-flow pump
  - 8.3 fewer hospital days per patient-year
  - 50% reduction in average cost per patient-year
- These savings were driven by more expensive hospitalizations for *device attributable events* in the HeartMate II arm
- Cost savings were similar in both BTT and DT patients

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Simultaneously Published online at http://circ.ahajournal

THANK YOU to MOMENTUM 3 INVESTIGATORS, LVAD COORDINATORS and The HEART TEAM

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cular.Abbott/HeartMate3

mary: Prior to using these devices, please review the Instructions for Use for a complete listing of indications, contraindications, warnings, s, potential adverse events and directions for use.

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

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

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

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