

Temporal Changes in Hospital Costs for Left Ventricular Assist Device Implantation

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ABSTRACT *Background:* A recent prospective, randomized controlled trial demonstrated that a continuous-flow (CF) left ventricular assist device (LVAD) resulted in improved survival at 12 and 24 months compared to a pulsatile-flow (PF) device. The current study examines the hospitalization costs associated with treatment of New York Heart Failure Class IV patients when implanted with a CF LVAD and compares them to previously reported costs of a PF LVAD in the same population.

Methods: Hospital billing data were analyzed for CF LVAD patients in the HeartMate II Destination Therapy trial to determine costs associated with the implantation admission. Hospital charges were converted to costs using hospital specific cost-to-charge ratios. Hospital costs were evaluated based on patient outcomes and compared to previously reported results from patients who received a pulsatile flow LVAD in Randomized Evaluation of Mechanical Assistance for the Treatment of Congestive Heart Failure. Multivariate models were created to determine the primary determinates of cost.

Results: Hospital bills were available for 83 CF and 52 PF LVAD patients. Hospital length of stay and in-hospital mortality were lower in the CF cohort. Inflation-adjusted hospital costs were significantly lower for CF patients compared to PF patients (mean: \$193,812 vs. \$384,260, $p < 0.001$). Clinical factors that strongly influenced hospitalization costs included bleeding, respiratory failure, and infection.

Conclusions: There has been a 50% reduction in the hospitalization cost associated with LVAD implantation since 2001. Improvements in operative technique and postoperative management appear to play critical roles in the observed cost reduction. doi: 10.1111/j.1540-8191.2011.01292.x (*J Card Surg* 2011;*:1-7)

BACKGROUND

It is estimated at least 10% of the population over 65 years of age will develop heart failure, and this age group alone is projected to double to over 70 million in the United States alone by the year 2020. Thus the number of patients with advanced systolic heart failure will increase significantly in the next several decades.^{1,2,3} While progress has been made with current pharmacologic therapy for heart failure, an increasing number of patients become refractory to all current medical therapy and develop advanced, symptomatic heart failure.⁴ There have been significant gains in

the treatment of Class IV heart failure with mechanical blood pumps. Recent innovations have led to the development of devices that provide blood flow in a continuous mode allowing improved outcomes and a smaller design with greater durability as compared to earlier iterations of PF devices.⁵

Despite the improvements in clinical outcomes in left ventricular assist device (LVAD)-treated patients and the limited therapeutic options for Class IV heart failure, adoption of these pumps as a therapeutic mainstay has been slow and typically limited to specialized centers that offer other surgical treatments for advanced heart failure including transplantation. One potential limitation to a broader use of LVAD therapy is cost. Although there is limited data regarding the cost of managing advanced heart failure with alternative contemporary medical and electrical therapies, there is a perception that the cost of LVAD therapy is relatively high. Physician and hospital stakeholders have an appropriate obligation to understand the costs associated with providing this type of medical care.

Conflict of interest: Dr. Slaughter received grant support from Thoratec Inc. Robin Bostic is a Thoratec Inc. employee. Kuo Tong and Dr. Rogers are consultants for Thoratec Inc. Dr. Russo has no relevant disclosures.

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Given trends in improvement in clinical outcomes associated with CF LVADs, the objectives of the current study were to evaluate hospital costs associated with implantation of a CF LVAD, and compare hospital costs to previously reported results. In addition, we wanted to evaluate independent predictors of hospital costs for CF LVAD implantation, and develop a multivariate model to determine the impact of clinical and outcome variables on hospital costs.

MATERIALS AND METHODS

Patient populations and data collection

Cost data for this analysis were derived from two sources: (1) the primary cohort of the HeartMate II Destination Therapy (DT) Trial⁵ who received a CF LVAD ($n = 134$) between 2005 and 2007, and (2) patients from the LVAD arm of the Randomized Evaluation of Mechanical Assistance for the Treatment of Congestive Heart Failure (REMATCH) trial⁶ ($n = 68$) who received a PF LVAD from 1998 to 2001.

Standard billing forms (CMS-1450, Uniform Bill UB-04) that captured hospital charges during the implant hospitalization were received for 83 (62%) patients randomized to the CF LVAD in the HeartMate II Destination Therapy trial. Clinical and cost data were available for 77% of the PF LVAD patients in the REMATCH trial.⁷

Baseline and preoperative characteristics from patients for whom cost data were available were compared to characteristics of the entire study cohort from each trial to examine potential ascertainment bias.

Costing methodology

Consistent with previous cost analyses, only implant hospital bills were evaluated. Physician services, outpatient follow-up services, and re-hospitalization services were excluded in the current study.

From bills collected for CF LVAD patients, the hospital admission date, discharge date or death date, total billed charges, and billed charges from the date of LVAD implantation to discharge or death (the time period reported in previous studies) were determined. Hospital days and associated costs accrued prior to CF LVAD implantation were excluded from analysis. Survival status was verified with clinical data adjudicated on September 30, 2009, at which time all patients examined in this study were no longer hospitalized following device implantation. All hospital bills included charges for the LVAD implantation procedure and device charges.

Hospital charges were converted to hospital costs using an established methodology that has been applied to cost studies of LVADs and other technologies.^{7,8} Specifically, billed charges were multiplied by each hospital's most recently available ratio of cost-to-charges (as reported by the Centers for Medicare and Medicaid Services) to determine the cost per hospitalization.⁹ All hospital costs for CF LVAD and PF LVAD patients were adjusted to 2009 \$US using the Consumer Price Index for hospital services.¹⁰

Statistical analyses

Continuous variables are reported with mean and standard deviation and compared with 2-tailed t-tests. Categorical variables are presented as percentages and compared with two-sample Z-tests for proportions or chi-square testing. Hospital length of stay (LOS) and costs from LVAD implant to discharge or death are described with medians and range. Comparisons for LOS and costs were performed between PF patients and CF patients and between survivors and nonsurvivors of the initial implant hospitalization. Cost data were compared using a Mann-Whitney U test.

Cost predictors

Multivariate modeling was used to determine the primary factors that determined hospital costs for patients receiving a CF LVAD. Cost data were log-transformed in the multivariate regression models. Age, gender, bypass minutes, and operative and postoperative events were included as independent variables in multivariate regression models. The events evaluated included perioperative bleeding (within 24 hours of the implant), late bleeding (after 24 hours), cardiac arrhythmias, sepsis, pump housing infection, nonpump related infection, myocardial infarction, neurologic dysfunction, peripheral thromboembolism, renal dysfunction, respiratory failure, right heart failure, stroke, and device malfunction. The definition of each of these adverse events has been previously published.⁵ Unlike the PF LVAD patients in REMATCH, survival was not associated with decreased costs for CF LVAD patients in the HeartMate II trial, so cost prediction models did not include stratification by survival status.

To reach a final model with independent predictors, a full model that included all the potential factors was used at the outset followed by a backward elimination approach. Variables were sequentially removed if the associated significance level was less than a pre-specified threshold of 0.1. This threshold was chosen due to the relatively small number of observations in the model ($N = 83$). The unlogged estimate of the coefficient was provided for each independent predictor in the final model. All analyses and statistical tests were performed using SAS version 9.1.3 (SAS Institute, Cary, NC, USA).

RESULTS

Inclusion and exclusion criteria for REMATCH and the HeartMate II Destination Therapy trial have been published.^{5,6} In short, patients were required to have advanced heart failure symptoms, a left ventricular ejection fraction of $<25\%$, and evidence of an impaired functional capacity or the need for continuous infusion inotropic support.

The baseline characteristics of patients enrolled in each trial for whom there are cost data are shown in Table 1. PF LVAD patients were older than the CF LVAD patients (mean age 67.6 vs. 62.5, $p = 0.009$). Nearly 80% of both cohorts were male. PF LVAD patients were more likely to have an ischemic etiology

TABLE 1
Comparison of Patient Demographics and Baseline Clinical Characteristics: CF Patients with Cost Data versus PF Patients with Cost Data

	CF Patients (N = 83)	PF Patients (N = 52)	P-Value
Mean age at implant (years)	62.5 ± 12.9	67.6 ± 9.3	0.009
Male (%)	78.3	78.9	0.942
Ischemic cause of heart failure (%)	59.0	80.8	0.0087
Left ventricular ejection fraction (%)	19.3 ± 8.3	17.7 ± 5.4	0.195
Systolic blood pressure (mm Hg)	107.5 ± 16.8	101.3 ± 16.1	0.037
Diastolic blood pressure (mm Hg)	62.2 ± 12.0	61.2 ± 10.4	0.621
PCWP (mm Hg)	23.3 ± 6.9	25.4 ± 9.7	0.196
Cardiac index (l/min/m ²)	2.1 ± 0.6	2.0 ± 0.6	0.207
Heart rate (beats/min)	82.2 ± 13.9	87.1 ± 16.6	0.0658
PVR (woods units)	2.8 ± 1.6	3.3 ± 1.8	0.1079
Serum sodium (mmol/L)	135.9 ± 4.3	134.7 ± 5.5	0.1876
Serum creatinine (mg/dL)	1.6 ± 0.6	1.8 ± 0.6	0.0246
Digoxin (%)	39.8	84.6	<0.0001
Loop diuretics (%)	80.7	94.2	0.0281
ACE inhibitors (%)	30.1	57.7	0.0015
Angiotensin II receptor blocker (%)	7.2	11.5	0.3919
Beta blockers (%)	56.6	23.1	0.0001
Intravenous inotropes (%)	54.2	67.3	0.1320
NYHA classification(%)*			
III	45.1	3.8	<0.0001
IV	54.9	96.2	

*NYHA Class was available for only 71 of CF LVAD patients. ACE = angiotensin converting enzyme; NYHA = New York Heart Association; PCWP = pulmonary capillary wedge pressure; PVR = pulmonary vascular resistance. Continuous variables represented as mean ± standard deviation.

of heart failure, a lower systolic blood pressure, and higher serum creatinine than CF LVAD patients. PF LVAD patients also had a higher rate of use of several medications including digoxin, loop diuretics, and

ACE inhibitors, but a lower rate of use of beta blockers. Nearly all PF LVAD patients were NYHA Class IV, but only approximately half of CF LVAD patients were classified as Class IV.

TABLE 2
Comparison of Patient Demographics and Baseline Clinical Characteristics: CF Patients with Cost Data and Overall CF Patients

	CF Patients with Cost Data (N = 83)	Overall CF Patients (N = 134) (Slaughter ⁵)	P-Value
Mean age at implant (years)	62.5 ± 12.9	62 ± 12	0.772
Male (%)	78.3	81	0.730
Ischemic cause of heart failure (%)	59.0	66	0.371
Left ventricular ejection fraction (%)	19.3 ± 8.3	17.0 ± 5.5	0.015
Systolic blood pressure (mm Hg)	107.5 ± 16.8	104 ± 14	0.100
Diastolic blood pressure (mm Hg)	62.2 ± 12.0	61 ± 13	0.497
PCWP (mm Hg)	23.3 ± 6.9	24 ± 8	0.510
Cardiac index (l/min/m ²)	2.1 ± 0.6	2.0 ± 0.6	0.234
Heart rate (beats/min)	82.2 ± 13.9	84 ± 15	0.378
PVR (woods units)	2.8 ± 1.6	3.3 ± 1.6	0.026
Serum sodium (mmol/L)	135.9 ± 4.3	134.7 ± 4.3	0.047
Serum creatinine (mg/dL)	1.6 ± 0.6	1.6 ± 0.6	>0.999
Digoxin (%)	39.8	50	0.195
Loop diuretics (%)	80.7	92	0.003
ACE inhibitors (%)	30.1	32	0.874
Angiotensin II receptor blocker (%)	7.2	9	0.831
Beta blockers (%)	56.6	53	0.664
Intravenous inotropes (%)	54.2	77	0.001
NYHA classification(%)*			
III	45.1%	24.6%	0.004
IV	54.9%	75.4%	

*NYHA Class was available for only 71 patients with cost data and only 126 patients of the overall cohort. ACE = angiotensin converting enzyme; NYHA = New York Heart Association; PCWP = pulmonary capillary wedge pressure; PVR = pulmonary vascular resistance. Continuous variables represented as mean ± standard deviation.

TABLE 3
Comparison of Length of Stay and Hospital Cost

	CF Patients (N = 83)	PF Patients (N = 52)	P-Value
In-hospital death N (%)	7 (8)	16 (31)	0.001
LOS from implant to discharge or death (days)			
Mean \pm SD	27.2 \pm 17.2	44.7 \pm 47.6	0.014
Median	22	28	
Min–Max	1–105	0–269	
Hospital cost (\$)			
Mean \pm SD	193,812 \pm 71,027	384,260 \pm 340,456	<0.001
Median	186,156	245,445	
Min–Max	78, 261–411, 424	113, 730–1,837,573	

Min = minimal; Max = maximum; SD = standard deviation.

The baseline characteristics of CF LVAD patients with cost data were also compared to the entire CF LVAD trial cohort (Table 2). Most characteristics were similar, but patients with cost data had a higher left ventricular ejection fraction, lower pulmonary vascular resistance, higher serum sodium, were less likely to be treated with loop diuretics and intravenous inotropes, and had a lower likelihood of NYHA Class IV symptoms than the overall CF LVAD cohort. The PF LVAD group with cost data have previously been compared to the group with no cost data and no significant differences were found.⁷

Length of stay, in-hospital survival, and hospitalization costs are shown in Table 3. The mean and median LOS from implantation to discharge in the CF LVAD patients were 27 and 22 days, respectively, and the in-hospital mortality rate was 8%. PF LVAD patients had a significantly longer LOS (mean: 45 days; median: 28 days) and a higher in-hospital mortality rate (31%). Hospital costs from implantation to discharge were reduced by 50% for CF patients relative to PF patients (mean: \$193,812 vs. \$384,260, $p < 0.001$). Relative to the mean, the standard deviation of hospital costs was considerably lower for CF patients compared to PF patients (Table 3).

There was a trend towards a shorter mean LOS from device implantation to discharge in CF LVAD survivors compared to PF LVAD survivors (27 days vs. 34 days, $p = 0.07$). While in-hospital mortality was strongly associated with LOS for PF LVAD patients (34 days for survivors vs. 68 days for nonsurvivors, $p = 0.09$), LOS was similar for both survivor and nonsurvivor CF LVAD patients (27 days vs. 26 days, respectively, $p = 0.79$). For the CF LVAD the relationship between LOS, cost and survival for both trials is shown in Figure 1. Cohort costs were not highly dependent on survival status (\$193,068 vs. \$201,893 for survivors and nonsurvivors, respectively, $p = 0.92$). However, in the PF cohort, costs for nonsurvivors were nearly double those for survivors (\$578,241 vs. \$298,046, respectively, $p = 0.16$). When only the survivors were considered, costs were reduced by 35% for the CF LVAD patients (\$193,068 vs. \$298,046, $p = 0.007$) (Fig. 1B).

Total hospital costs broken down into resource categories were compared between CF and PF LVAD

patients (Fig. 2). Costs for the LVAD pump make up the largest share of the hospitalization cost for both CF and PF LVAD patients. Although the cost of the pump was similar over time (about \$65,000 for both cohorts), it makes up a larger share of the total cost for CF LVAD patients because total hospitalization costs were lower than for PF LVAD patients. The most noticeable difference between groups in resource category costs was the significantly lower percent of costs spent on ICU and regular floor days for CF LVAD patients. This is likely due to the reductions in shorter LOS for CF LVAD patients.

Predictors of implantation costs

Multivariate regression models performed explained approximately 35% of the variability observed in CF LVAD implantation costs. Table 4 presents the independent cost predictors in the final model. Adverse events were significant drivers of LVAD implantation cost. Perioperative and late bleeding, respiratory failure, and infectious complications were the major determinants of implantation cost.

In the absence of these events, the predicted costs for implant hospitalization would be \$147,722. Presence of late bleeding and respiratory failure was associated with an incremental cost of \$52,537 and \$38,076, respectively. Similarly, perioperative bleeding and infections increased the cost by \$21,502 and \$37,721, respectively. Compared to PF devices, perioperative bleeding and late bleeding remain drivers of implantation costs for CF devices. However, sepsis and pump housing infection were no longer significant predictors.

DISCUSSION

The current analysis is the first study to report hospital costs associated with CF LVAD implantation. Following adjustment for inflation, implant hospitalization costs were reduced by 50% for CF LVAD patients compared to PF LVAD patients. Shorter LOS and fewer adverse events with newer generation LVAD technology appear to be the primary drivers of reduced cost suggesting that experience with mechanical circulatory support coupled with improved patient selection and

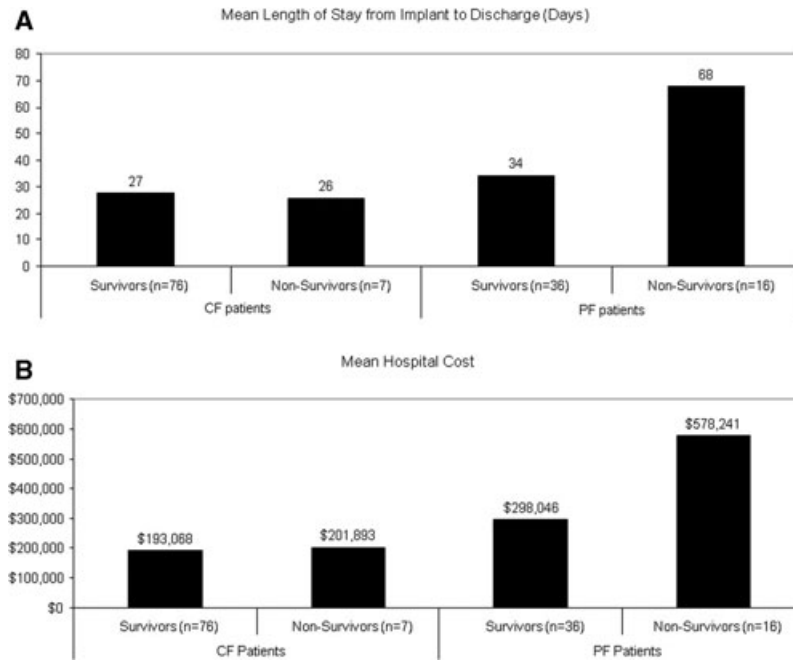


Figure 1. Comparison of LOS and hospitalization cost by in-hospital survival status. Data from the REMATCH (PF, pulsatile flow) and HeartMate II Destination Therapy (DT) trials (CF, continuous flow) are shown. (A) Mean LOS stratified by survival status during the implantation hospitalization. Nonsurvivors in REMATCH had a LOS that was twofold higher than survivors (34 vs. 68 days, $p = 0.09$). Survival did not influence LOS in the HeartMate II DT trial. (B) Mean hospitalization cost for each trial stratified by survival status. Nonsurvivors in REMATCH had an incremental cost of \$280,245 compared with \$8825 in the HeartMate II DT trial.

postimplant management strategies are critical components of the observed cost reduction. These data are consistent with previous studies that demonstrated a time-dependent reduction in hospital costs associated with PF LVAD therapy. Specifically, hospital costs from the time of implantation to hospital discharge decreased from \$210,000 (2001 \$US) in REMATCH⁷ to \$128,000 in a nonclinical trial population (2003 and 2004 \$US).⁸

Nearly all aspects of the LVAD evaluation and implantation process influence the overall cost of patient management. Enrollment criteria for REMATCH and HeartMate II Destination Therapy trials were designed to

select critically ill patient cohorts. These subjects had severe ventricular dysfunction, evidence of end-organ hypoperfusion, and a markedly abnormal hemodynamic profile despite the use of intravenous inotropic agents in 65% of patients in REMATCH and 77% of patients in the HeartMate II Destination Therapy study. Others have reported that these same preoperative characteristics, among others, resulted in longer LOS, higher hospitalization costs, and higher rates of morbidity and mortality in patients undergoing cardiac surgery.^{11,12} Since much of the postimplant morbidity associated with LVAD implantation is linked to pre-operative characteristics including hepatic

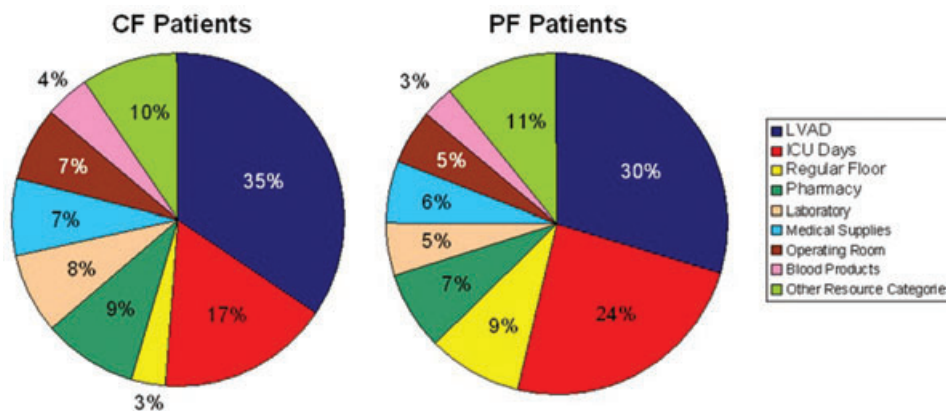


Figure 2. Breakdown of costs by resource category for CF and PF patients. The total mean hospital costs of several resource categories are shown. The total mean cost for patients includes costs from implant to discharge or death. Other resource categories include therapy, other diagnostics, imaging, renal, and other services. CF = continuous flow; PF = pulsatile flow.

TABLE 4
Impact of Adverse Event on Cost

Adverse Event	Incremental Costs
No complications	\$147,722
Late bleeding (after 24 hours)	\$52,537
Respiratory failure	\$38,076
Perioperative bleeding	\$21,502
Infection (other than sepsis and pump housing infection)	\$37,721

The presence of postoperative bleeding, respiratory failure, and infection represents incremental hospitalization cost.

dysfunction and malnutrition, it is reasonable to assume that moving this therapy into a population with less advanced heart failure may favorably impact LOS and cost further.

Operative technique and postoperative management also play critical roles in cost determination. Patients with peri- and postoperative bleeding, respiratory failure, or a postimplant infection had incremental hospitalization costs of \$22,000 to \$53,000. These figures highlight the need for meticulous perioperative management and the development and dissemination of best practices.¹³ As mechanical circulatory support becomes a standard therapy for advanced heart failure, it is likely that LVAD programs will begin undertaking process improvement initiatives focused on reducing LOS and adverse events. Data reported from the Interagency Registry for Mechanically Assisted Circulatory Support (INTERMACS) will further assist in identifying factors that impact outcomes, adverse events, and costs.¹⁴ The Joint Commission for Hospital Accreditation destination therapy certification process will also continue to refine efforts to reduce adverse events and improve processes of care surrounding this patient population.

The in-hospital mortality reduction has greatly reduced the unpredictability of patient outcomes and associated financial risk to the hospital (mean costs of \$193,812 and a standard deviation of \$71,027). A relatively small standard deviation can help hospital administrators better anticipate and predict hospital costs associated with this therapy.

Early postimplant death was a critical determinant of cost in the REMATCH trial. Mechanically supported patients who did not survive the implant hospitalization had a twofold increase in LOS (34 vs. 68 days) with a mean cost increase of \$280,195. The same phenomenon was not observed in HeartMate II

Destination Therapy trial. The mean difference in LOS between the survivors and nonsurvivors was 1 day, and the mean cost difference was only \$8,825.

Physicians and hospital administrators are keenly interested in how patient risk factors may impact the incremental costs of VAD implantation. Perioperative and late bleeding, respiratory failure, and infectious complications (nonsepsis, nonpump housing infection) were the major determinants of implantation cost. Other patient demographic variables such as age were not significant as determined by descriptive (Table 5) and multivariate analyses. Additional work on how incoming clinical risk factors and patient selection impact costs is warranted.

There are several limitations to our study. Complete hospital billing and cost data were available for only 83 of the 134 CF LVAD patients from the HeartMate II Destination Therapy trial. The clinical characteristics of the 83 patients were representative of the overall cohort for most characteristics, but differed in important areas including left ventricular ejection fraction, the use of loop diuretics and intravenous inotropes, and NYHA classification, so we cannot be certain that the costing subset is truly reflective of all hospital cost profiles. Additionally, patients in this cost analysis were enrolled in a clinical trial and may have incurred costs included in hospital bills due to clinical protocol requirements. Hospital bills were not audited to eliminate these artifacts. Therefore, it is possible that the hospital costs in this study may not be reflective of "real world" patients implanted with CF LVADs outside of the clinical trial setting.

The hospital costs for CF LVAD patients in the HeartMate II Destination Therapy trial are similar to hospital cost data reported by Miller et al. following adjustment for inflation (\$128,084, 2003/2004 \$US).⁸ It should be noted, however, that Miller reported results from 2 high volume centers with considerable experience in managing LVAD patients and excluded patients enrolled in clinical trials. Additional post-trial cost data should be collected to determine if similar reductions in cost are experienced following the HeartMate II Destination Therapy trial. These data would help inform ongoing analyses of the economics and cost effectiveness of LVAD programs.^{15,16}

In conclusion, the current study demonstrates that CF LVAD patients experience superior clinical outcomes compared to PF LVAD patients as well as reduced hospital implantation costs and cost variability. These improvements should assist patients, physicians, hospitals, and payers make informed decisions regarding access to this important therapy for advanced stage heart failure patients.

TABLE 5
Comparison of Hospital Cost by Age for the CF Cohort

	<65 years	≥65 years	P-value
N	39	44	
Mean ± SD	192,119 (83,309)	195,313 (59,010)	0.620
Median	196,149	184,791	

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