

Hospital Costs for Left Ventricular Assist Devices for Destination Therapy: Lower Costs for Implantation in the Post-REMATCH Era

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Background: The use of left ventricular assist devices (LVADs) as an alternative to transplant, or destination therapy (end of life support), is an increasingly important option for patients with end-stage heart failure. Prior studies have examined hospital costs for LVAD implants performed during investigational studies (e.g., REMATCH), but none has been published since that trial was completed.

Methods: We performed a retrospective analysis of 23 consecutive patients who had a HeartMate XVE pump implanted as destination therapy at 2 high-volume ventricular assist device implant centers after US Food and Drug Administration approval in October 2003. We evaluated survival to discharge during the implantation hospitalization, hospital length of stay, and hospital costs, and compared them with outcomes reported from the REMATCH (RM) trial.

Results: All patients in this cohort implanted post-REMATCH (PRM) had class IV heart failure and were similar in age, gender, and nearly all other pre-implantation clinical measures to the RM subjects. Mean hospital costs for PRM patients were 40% lower than for RM patients when measured from implantation to discharge (\$128,084 vs \$210,187, $p < 0.01$). PRM patients who survived implantation hospitalization had 48% lower costs than those who did not survive (\$114,979 vs \$215,456, $p < 0.01$), a finding similar to the RM experience. PRM patients in this cohort were more likely to survive to discharge compared with RM patients (87.0% vs 67.3%, $p = 0.09$). Mean hospital length of stay was 25% lower in the PRM group (44 vs 33 days) but did not reach statistical significance ($p = 0.50$).

Conclusions: Outcomes with use of LVADs as destination therapy have improved in the post-REMATCH era, including significantly lower hospital costs as well as strong trends toward better survival to hospital discharge and shorter average length of stay. *J Heart Lung Transplant* 2006;25:778–84. Copyright © 2006 by the International Society for Heart and Lung Transplantation.

In 2002, the United States (US) Food and Drug Administration (FDA) approved the HeartMate (Thoratec Corporation, Pleasanton, CA) left ventricular assist device (LVAD) as long-term, destination therapy for patients with end-stage heart failure not eligible for heart transplantation. The Centers for Medicare and Medicaid Services (CMS) followed suit and approved reimbursement for the use of these devices as destination therapy starting in October 2003.¹

These landmark decisions by regulators and payers were based predominantly on the results of the Randomized Evaluation of Mechanical Assistance for the Treatment of Congestive Heart Failure (REMATCH) study (hereafter abbreviated RM), which was conducted from 1998 through 2001 at 21 major heart transplant centers in the United States.² This pivotal trial enrolled 129 patients with end-stage heart failure not eligible for a heart transplant and randomized them to receive either an LVAD ($n = 68$) or optimal medical management (OMM) ($n = 61$). At 2 years of follow-up, the study demonstrated that when LVADs were used as destination therapy, they were significantly superior to OMM in both patient survival ($p < 0.01$) and quality of life ($p = 0.007$, Minnesota Living with Heart Failure; $p = 0.0017$, New York Heart Association [NYHA] class).³

Longer-term follow-up of the RM cohort since the initial publication in 2001 has demonstrated that patient outcomes improved in the second half of enrollment in the trial, but only in the LVAD-treated patients, not the OMM patients.³ Importantly, these superior results found in those enrolled later (2000–2002) in the study have now been duplicated across multiple centers

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outside of the investigational setting.⁴⁻⁶ Although these reports pointed to improved patient survival and quality of life, no reports have provided updated estimates of LVAD destination therapy hospital costs.

The financial impact of destination therapy is another important outcome to consider for the medical community, hospital providers, third-party payers, and society alike. An analysis of hospital costs of 52 of 68 unselected patients for whom cost data could be obtained in the RM study found that the mean cost for the initial implant-related hospitalization was $\$210,187 \pm \$193,295$.⁷ However, hospital costs for patients who survived the index hospitalization were about half the costs compared with non-survivors ($\$159,271 \pm \$106,423$ vs $\$315,015 \pm \$278,713$).

A number of improvements have been introduced since the RM study that might further influence the cost-effectiveness of this therapy, including device modifications^{8,9} and publication of guidelines for patient selection and management.¹⁰⁻¹² The purpose of this study was to evaluate the destination therapy hospitalization outcomes and cost data gathered at 2 sites since the RM trial and compare them with similar published data from the RM trial. This post-RM (PRM) study examines direct index hospital costs only. Like the report of costs for LVAD therapy in RM,⁷ we did not evaluate costs for physician services, outpatient care and subsequent rehospitalizations, or long-term patient survival.

METHODS

Patient Populations

The PRM patient population was derived from a retrospective analysis at the 2 highest enrolling US centers performing destination therapy procedures after FDA approval (Advocate Christ Medical Center, Oak Lawn, IL; LDS Hospital, Salt Lake City, UT). Both facilities were listed on the destination therapy accreditation list and approved by CMS, which established a baseline level of expertise in conducting LVAD implantation procedures.¹³ One center was a participating site in RM, and one was not. This second center also does not perform heart transplantations.

We identified all consecutive patients who received the newer model HeartMate XVE LVAD for destination therapy between February 2003 and November 2004 ($n = 23$). To be reimbursed for the procedure, all patients had to meet payer medical policy guidelines of NYHA class IV heart failure, with selection criteria similar to the RM patients. The RM patient population used for comparison has been previously characterized and reported.^{2,3} The 52 RM patients represented an unbiased subset of the 68 patients in the RM trial who received an LVAD. This subset included all those for whom complete information relevant to a cost-analysis

was available and was to be representative of the entire RM LVAD group.⁷

Determination of Total Hospital Length of Stay and Costs

The analyses for both RM and PRM patients were identical. Survival of the initial hospitalization was determined for each patient based on discharge disposition on standard billing forms (CMS-1450, UB-92). For each patient in this study, we reviewed UB-92 forms to abstract hospital admission date, discharge date, and total billed charges for the hospital episode. From the bill, we determined hospital length of stay (LOS). Total hospital charges were converted to hospital costs by using a well-established methodology that has been applied to cost studies of LVADs and other technologies.^{7,14} Specifically, billed patient charges were multiplied by each hospital's most recently available ratio of cost to charges to derive the cost per patient hospitalization.

Hospital charges for each patient included charges for the LVAD device and were included in the cost analysis. We also gathered detailed billing data for the entire LOS and confirmed the date of each LVAD implant. This information allowed us to evaluate LOS and hospital costs from implantation date to hospital discharge, which parallels the analysis from the RM cost study, as well as total hospitalization costs.

Comparisons of Hospital Survival, Length of Stay, and Hospital Costs

Previous reports from the RM study were limited to costs and LOS from date of randomization to discharge or death, not hospital admission to discharge. We performed a similar analysis, but we also analyzed total hospital LOS and costs utilizing data similarly, using the time from admission to hospital discharge. Finally, we performed subgroup analyses on PRM patients, including comparisons of hospital LOS and costs based on year of hospital discharge and survivors vs non-survivors. We also identified the average pre-implantation hospital costs, which were not reported in the analysis of the RM patients. Because we did not have access to the month or year of hospital discharge and hospital costs for every RM cost patient, we took a conservative approach and did not adjust hospital costs for inflation, which would have increased RM hospital costs relative to PRM costs.

Statistical Methods

The LOS and cost for LVAD therapy are not normally distributed, so the data are expressed as both means \pm standard deviation (range) and medians with ranges. Analyses were performed using BASE 11.0 (SPSS, Chicago, IL). Statistical tests of LOS and costs were per-

Table 1. Post-REMATCH and REMATCH Comparison Between Patient Demographics

	PRM	RM	<i>p</i>
N	23	52	
Mean age at implant (years)	65 ± 9	67 ± 9	0.19
Gender (% Male)	87.0%	78.8%	0.53
Serum creatinine (μmol/L)	1.6 ± 0.6	1.8 ± 0.6	0.28
Systolic blood pressure (mm Hg)	104 ± 16	106 ± 16	0.51
Diastolic blood pressure (mm Hg)	62 ± 9	62 ± 11	0.89
Pulmonary capillary wedge pressure (mm Hg)	20 ± 7.4	25 ± 9.7	0.03
Cardiac index (l/min/m ²)	2 ± 0.5	2 ± 0.6	0.57
Left ventricular ejection fraction (%)	20 ± 5.4	17 ± 5.4	0.06

PRM, post-REMATCH; RM, REMATCH.

formed using *t*-tests and the Mann-Whitney *U* test. Chi-square and Fischer's exact tests were used for categorical variables. A 2-tailed *p* < 0.05 was considered to be statistically significant.

RESULTS

Patient Demographics

We identified 23 consecutive patients from the 2 centers who underwent LVAD destination therapy implantation between February 2003 and November 2004 and for whom cost data were available. Demographics were similar between PRM and RM patients (Table 1) and did not differ by year of implant. Ischemic heart disease remained the most common etiology of their heart

failure in both cohorts. Of the 23 patients, 11 were implanted in 2003, and 12 in 2004. The date of transplant age, LOS, and outcomes for each patient are listed in Table 2.

Hospital Survival and Length of Stay

The survival to hospital discharge in this PRM cohort was superior to the RM study by 1.29-fold, (87.0% vs 67.3% *p* = 0.09) (Figure 1). The mean hospital LOS from device implantation to discharge was lower for the PRM patients at 33 ± 21 days vs 44 ± 71 days (*p* = 0.50). The mean total hospital LOS, including time from admission to implantation, was 41 ± 27 days for this PRM group (*p* = 0.89), reflecting an average time from

Table 2. Post-REMATCH Patient and Hospitalization Details

Patient	Gender	Implant date	Age at implant	Total hospital LOS	Discharge disposition	LOS implant to discharge
1	M	1/29/2003	51	17	Alive	9
2	M	4/18/2003	57	69	Alive	60
3	F	5/6/2003	70	93	Dead	77
4	M	5/19/2003	79	99	Alive	43
5	M	7/29/2003	60	46	Alive	31
6	M	8/8/2003	74	25	Alive	17
7	F	10/29/2003	72	127	Alive	90
8	M	10/9/2003	66	25	Alive	23
9	M	11/20/2003	67	18	Alive	15
10	M	11/28/2003	71	34	Dead	25
11	M	12/2/2003	72	23	Alive	22
12	M	1/16/2004	66	36	Alive	29
13	M	2/4/2004	66	63	Dead	47
14	F	2/11/2004	43	17	Alive	16
15	M	2/19/2004	64	38	Alive	35
16	M	3/11/2004	51	22	Alive	18
17	M	3/30/2004	77	44	Alive	43
18	M	4/7/2004	60	33	Alive	22
19	M	5/6/2004	75	43	Alive	32
20	M	6/24/2004	52	63	Alive	54
21	M	9/27/2004	61	36	Alive	19
22	M	10/6/2004	65	27	Alive	15
23	M	11/1/2004	68	27	Alive	21

LOS, Length of Stay.

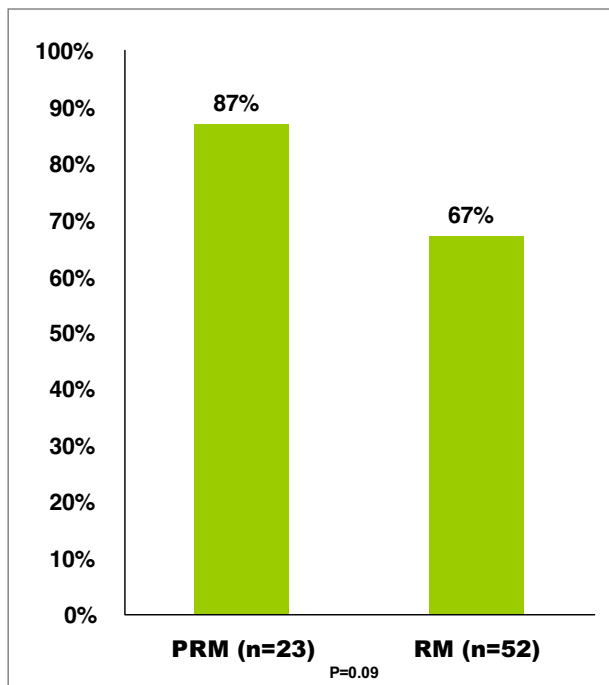


Figure 1. Post-REMATCH (PRM) and REMATCH (RM) comparison between survivors of hospitalization.

hospital admission to actual device implantation of 8 ± 24 days. The difference in LOS between PRM survivors (35 ± 21 days) and RM survivors (31 ± 19 days) was not significantly different.

Hospital Costs

Total hospital costs from implantation to discharge decreased by 40% and were significantly lower for this group of PRM patients compared with those reported from the RM study ($\$128,048 \pm \$52,936$ vs $\$210,187 \pm \$193,295$, $p < 0.01$). The mean cost for the entire hospitalization was $\$148,350 \pm \$67,512$ for these PRM patients ($p = 0.053$), including the cost of pre-implantation care, which averaged $\$22,302$ (Table 3). Hospital costs from implantation to discharge for survivors of the hospitalization were 28% lower for PRM compared with RM survivors ($\$114,979 \pm \$34,962$ vs $\$159,271 \pm \$106,423$, $p = 0.03$) (Table 3).

Subset Analyses by Time Period of Early vs Late PRM Patients

Significant improvement inpatient survival was noted when early (1998–2000) vs late (2000–2002) enrollment in the RM study was compared.³ We therefore analyzed PRM patients in this study based on the time of LVAD implantation (2003 vs 2004). A reduction was noted in both total LOS and time from implantation to hospital discharge between those who received implants in 2004 vs 2003. The 11 patients who received implants in 2003 had a mean total LOS of 37 ± 27 days vs 29 ± 13 days for the 2004 cohort ($p = 0.38$) (Table 3). Total hospital costs also decreased slightly from $\$133,944$ in 2003 to $\$122,714$ in 2004 ($p = 0.63$).

Table 3. Summary of Analyses

	N	LOS					Costs				
		Mean	SD	Median	Min	Max	Mean	SD	Median	Min	Max
<i>Post-REMATCH vs REMATCH—entire hospitalization</i>											
PRM	23	41	27	34	17	127	\$148,350	\$67,512	\$124,349	\$84,816	\$314,213
RM	52	44	71	29	N/A	N/A	\$210,187	\$193,295	\$137,717	\$72,583	\$1,123,565
		$p = 0.89$					$p = 0.053$				
<i>Post-REMATCH vs REMATCH—implant to discharge</i>											
PRM	23	33	21	25	9	90	\$128,084	\$52,936	\$112,315	\$73,125	\$295,052
RM	52	44	71	29	N/A	N/A	\$210,187	\$193,295	\$137,717	\$72,583	\$1,123,565
		$p = 0.50$					$p < 0.01$				
<i>Post-REMATCH early (2003) vs Post-REMATCH late (2004)—implant to discharge</i>											
PRM early (2003)	11	37	27	25	9	90	\$133,944	\$66,097	\$107,277	\$73,125	\$295,052
PRM late (2004)	12	29	13	26	15	54	\$122,714	\$39,584	\$121,492	\$77,839	\$211,601
		$p = 0.38$					$p = 0.63$				
<i>Post-REMATCH vs REMATCH survivors—implant to discharge</i>											
PRM survivors	19	31	19	23	9	90	\$114,979	\$34,962	\$103,548	\$73,125	\$200,208
RM survivors	35	35	21	N/A	N/A	N/A	\$159,271	\$106,423	\$136,700	N/A	N/A
		$p = 0.46$					$p = 0.03$				
<i>Post-REMATCH survivors vs non-survivors—implant to discharge or death</i>											
PRM survivors	19	31	19	23	9	90	\$114,979	\$34,962	\$103,548	\$73,125	\$200,208
PRM non-survivors	3	50	26	47	25	77	\$215,456	\$77,739	\$211,601	\$139,716	\$295,052
		$p = 0.35$					$p < 0.01$				

LOS, length of stay; SD, Standard deviation; Min, minimum; Max, maximum.

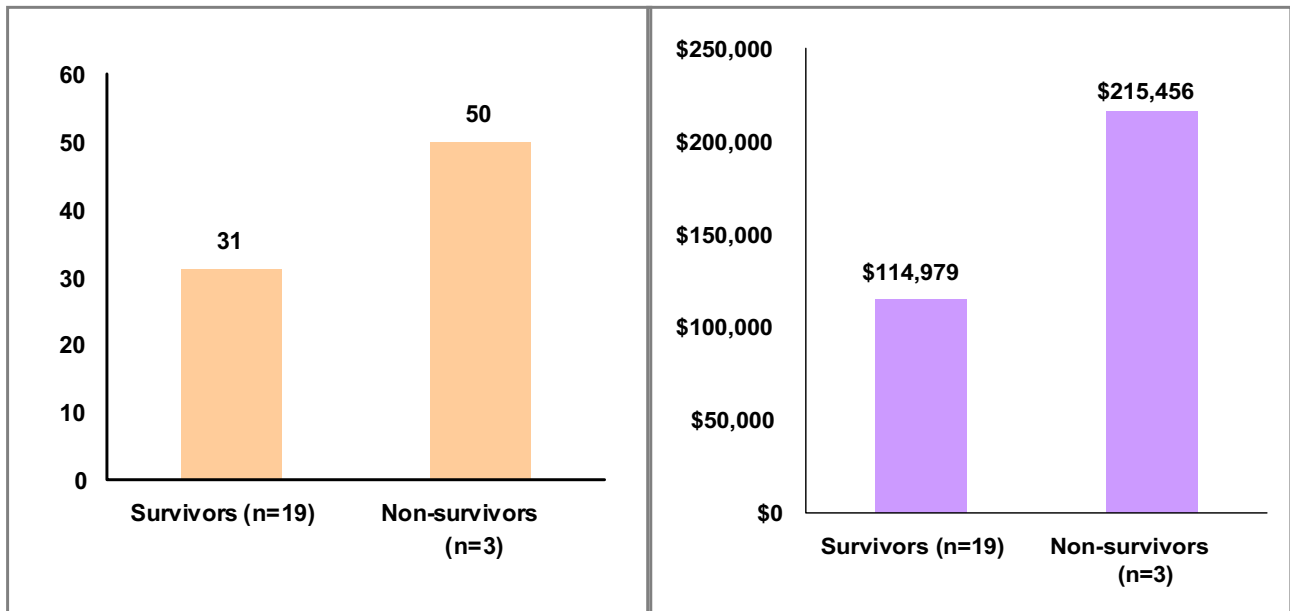


Figure 2. Post-REMATCH length of stay (left) and cost comparison of survivors vs non-survivors (right).

Subset Analysis of Survivors vs Non-Survivors

We also compared the implantation-to-discharge hospital LOS for 22 PRM survivors vs non-survivors (Table 3) and found that the LOS was longer, but not statistically significant, between the 2 groups (31 ± 19 days PRM vs 50 ± 26 days RM, $p = 0.35$). Like the RM study, however, we did observe nearly 50% lower costs for the PRM survivors of the hospitalization implantation-to-discharge LOS compared with non-survivors ($\$114,979 \pm \$34,942$ vs $\$215,456 \pm \$77,739$) ($p < 0.01$) (Figure 2).

DISCUSSION

This study provides additional evidence that LVAD destination therapy outcomes continue to improve in the PRM era.⁴⁻⁶ Hospitalization data from these 23 patients who received implants at the 2 highest volume centers also confirms significantly lower costs, even without an adjustment for inflation. The data also demonstrate improving trends in hospital survival and shorter LOS. Although the data for mean LOS from implantation to discharge were not significantly different in this small study, the 25% decrease in overall LOS is encouraging. Importantly, LOS significantly improved between the first and second year of the analysis, even at these experienced centers. The observation that the difference in LOS between RM and PRM survivors is smaller than the magnitude of difference with all patients indicates that the LOS for non-survivors is largely accountable for the trend toward a decreasing overall LOS.

Improved outcomes and lower costs since RM may be attributable to several factors, including improved patient selection,¹⁰⁻¹² improved adherence to pub-

lished guidelines on management, especially for infection prophylaxis,¹⁴⁻¹⁶ which was the leading cause of morbidity and mortality in the RM study,^{3,4} and continued improvements in device design and durability.^{8,9} The importances of patient selection on the costs of LVAD therapy are reflected by the differences in cost for survivors vs non-survivors in both the RM study and in this PRM group. Identification of risk factors associated with mortality before hospital discharge is an area in need of further improvement and current investigation.^{5,12} The experience in 250 patients who have undergone placement of the HM XVE device from November 2001 to December 2005 is being analyzed for development of a composite risk score to allow pre-operative risk stratification and identification of patients at high risk for poor outcomes.^{5,17}

In addition to careful patient selection, many strategies may favorably impact the outcomes and associated costs with LVAD therapy. One that has been shown to favorably affect overall costs was recently reported by Murray et al.¹⁸ They compared the LOS and costs of LVAD therapy in a small cohort of patients before and after the introduction of a multidisciplinary team approach that not only selected appropriate candidates for the procedure and the timing of device implantation but also focused on specific individual patient needs post-implantation to shorten the time to hospital discharge. They showed that this approach did not shorten intensive care unit time, but they were able to demonstrate a significant reduction in the time patients spent on the step-down floor after transfer out of the intensive care unit post-LVAD implantation to hospital discharge. Their approach also reduced subsequent

readmissions compared with patients who received an implant before the team approach was implemented.

Patients who require LVAD therapy are often older and more physically debilitated at the time of LVAD implantation and often benefit from post-operative programs of intense physical therapy and rehabilitation. These data suggest that programs with the multidisciplinary team approach and rehabilitation facilities available will likely see lower costs associated with this therapy.

Medicare and private payer reimbursement levels for implantable heart assist systems have also increased steadily. Since the RM trial, third-party payers have begun to recognize the value and complexity of this procedure to the point where Medicare and other payers now reimburse the same amount for an implantable heart assist system as for heart transplantation.^{19,20}

Unfortunately, data are very limited on the cost of medical therapy for advanced heart failure patients,²¹⁻²⁴ especially patients who have true end-stage heart failure and may be candidates for LVAD therapy. This lack of data significantly limits any direct comparison of these 2 primary forms of therapy or estimate of cost-effectiveness. The cost estimates for the first year post-VAD implantation will always be higher compared with medical therapy, in part because of the shorter life expectancy resulting from the very high mortality with medical therapy.² The comparisons of cost or cost-effectiveness of medical therapy vs LVAD for destination therapy need to be analyzed, much like the comparison of dialysis vs kidney transplantation, where the total cost for the aggressive therapy, kidney transplantation, is not lower than medical dialysis therapy until 3 years post-transplantation. However, almost none of the patients with advanced stage D²⁵ heart failure who are managed with medical therapy alone will be alive after 3 years² to allow this type of comparison.

Our study has several limitations. The patient sample was limited to the 2 leading implant volume US centers and may not reflect the experience at other institutions. The outcomes and costs reported may therefore represent the "best case" for this therapy. To date, there are no data published to confirm improved outcomes in LVAD therapy with higher volume experience. The 2 centers are, however, diverse in terms of geographic location, population density, and previous experience. Only 1 of the 2 centers performs heart transplantation, and only 1 participated in RM. These centers may therefore reflect changes in the composition of hospitals that perform destination therapy today. Their experience however, shows the outcomes that are now possible with LVAD therapy.

Finally, our analysis is limited to the initial hospitalization. Additional long-term post-hospital discharge data on survival and costs, including rehospitalizations and equipment rental or purchase, would enhance our

understanding of the overall efficacy and costs of this therapy in the PRM era. Our group is in the process of gathering this data to provide a longer-term perspective.

CONCLUSIONS

Outcomes for destination therapy with LVADs for end-stage heart failure have improved in the post-REMATCH era and are associated with significantly lower costs and trends toward improving survival and shorter length of hospital stay. Such improvements are impressive given the increasing severity of illness in patients with end-stage heart failure. This technology offers the clinician an increasingly cost-effective treatment option that prolongs survival and also improves quality of life compared with medical management alone.³

Patient selection may be the most important determinant of outcome and cost. To assure the best outcomes, the use of VADs as destination therapy should largely be restricted to an elective procedure after careful preoperative risk analysis and medical optimization to reduce risk. Validation of a risk scoring system based on preoperative risk factors associated with adverse outcomes and enhanced center compliance with published guidelines on patient management are likely to lead to improved patient outcomes and lower costs with LVAD therapy. These important initiatives, coupled with device-related changes to enhance durability, may lead to outcomes that allow destination therapy to eventually rival the economic and clinical outcomes of heart transplantation in patients who are typically older and not candidates for heart transplantation.

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