

Cost-Effectiveness of Thoracotomy Approach for the Implantation of a Centrifugal Left Ventricular Assist Device

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This study reports the first analysis regarding cost-effectiveness of left ventricular assist device (LVAD) implantation *via* thoracotomy. Cost-effectiveness of LVADs implanted *via* the traditional surgical approach of sternotomy has been improved through the years because of technological advances, along with understanding the importance of patient selection and postimplant management have on positively affecting outcomes. Given the positive clinical outcomes of the thoracotomy approach, we seek to study the cost-effectiveness of a centrifugal LVAD *via* this less invasive approach. We developed a Markov model. Survival and quality of life inputs (QALY) for

the LVAD arm were based on data from the LATERAL clinical trial. For the Medical Management arm, survival was derived from the Seattle Heart Failure Model. The heart transplant probability was derived from INTERMACS. Survival after heart transplantation used International Society for Heart and Lung Transplantation data. Cost inputs were calculated based on Medicare data and past literature. The incremental cost-effectiveness ratio was found to be \$64,632 per quality adjusted life year and \$57,891 per life year in the bridge to transplant indication. These results demonstrate further improvement in the overall cost-effectiveness of LVAD therapy and confirm implantation of LVADs *via* a less invasive approach as being cost-effective. *ASAIO Journal* 2020; 66:855–861.

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Worldwide prevalence of heart failure (HF) has been increasing over the last several decades.¹ Globally, more than 37.7 million people are living with HF.¹ In the United States, there are currently more than 6.5 million people diagnosed with HF,² with projections showing more than 8 million people will have HF by 2030.^{2,3} This is mainly because of the growing elderly population and the declining mortality because of improved management of cardiovascular disease.^{4,5} The increasing number of end-stage HF patients together with the limited availability of suitable organs, and the technological advances in mechanical circulatory support (MCS) devices has increased the number of ventricular assist device (VAD) implantations.⁶ The number of patients who will need to be supported on VADs for longer periods of time continues to increase.⁷

Superiority of VADs over optimal medical management (MM) in patients with advanced HF was demonstrated in 2001 in the REMATCH trial.⁸ Clinical outcomes have vastly improved over time. The traditional surgical approach for LVAD implantation is through a median sternotomy. However, less invasive nonsternotomy approaches have been increasingly utilized with very positive outcomes.^{9–12} In HVAD LATERAL, the first trial to evaluate LVAD implantation *via* a thoracotomy approach, freedom from disabling stroke was 98% at 1 year and survival was 87% at 2 years.¹² Length of stay was also reduced by 30% for enrolled patients implanted *via* thoracotomy compared with enrolled patients implanted through sternotomy in the previous HVAD bridge to transplant (BTT) Continued Access Protocol (CAP) trial.¹²

Economic analysis of less invasive LVAD surgical procedures is limited. To our knowledge, there has been no data reporting cost-effectiveness of LVAD implantation *via* thoracotomy approach. LVAD cost-effectiveness outcomes have

been improving through the years as technology advances. In 2004, they were reported at \$804,000/QALY,¹³ then decreased to approximately \$200,000/QALY.¹⁴⁻¹⁶ Given the positive clinical outcomes of the thoracotomy implantation approach, we aim to assess the cost-effectiveness of LVADs implanted *via* thoracotomy compared with optimal MM and heart transplantation in the BTT population.

Materials and Methods

Model Structure

A Markov model was developed to estimate the cost-effectiveness of the thoracotomy approach for implantation of a centrifugal flow LVAD in BTT patients. The model compared LVAD patients implanted *via* thoracotomy to optimal MM patients; heart transplantation was available for both arms. There were two basic health states, “Alive” and “Dead” (Figure 1). Additionally, there were several poststroke health states reflecting the different modified Rankin Scale (mRS) score strokes. Cycle period was 1 month. Every month, patients alive were exposed to therapy-related adverse events (AEs) and death. The model applied variable mortality rates every cycle up to 10 years post-implantation. A lifetime horizon and payer perspective were employed. The model was built in Microsoft Office Excel 365 ProPlus (version 1902). Finally, costs and benefits were discounted at 3% per annum.

Mortality and Transition Probabilities

The LATERAL trial was used to populate the survival and AE rates of the LVAD arm.¹² In the LATERAL trial, the lateral thoracotomy implant approach was evaluated; mean age was 54.2 (± 11.5) years, 77.1% were male, and 62.5% Caucasian¹² (see Table S1, Supplementary Digital Content 1, <http://links.lww.com/ASAIO/A510>). The Lateral cohort consisted of typical BTT patients similar to historical baseline BTT characteristics. Considering that greater than 80% were in INTERMACS Profile 1-3,

Table 1. Monthly Transition Probabilities—LVAD

Event	Rate	References
Stroke		28
Ischemic	0.005	
Hemorrhagic	0.003	
Pump exchange		28
VAD thrombus	0.002	
VAD failure	0.001	
Driveline infection	0.010	28
GI bleed	0.020	28
Severe right heart failure (requiring RVAD)	0.0004	28
Other adverse events	0.005	28
Heart transplant rate	2.83%	18

The values presented at the table are transformed monthly event rates as used in the model.

LVAD, left ventricular assist device; VAD, ventricular assist device; GI, gastrointestinal; RVAD, right ventricular assist device.

along with the inclusion of patients in cardiogenic shock, this is reflective of contemporary candidates for cardiac transplantation.¹² Despite the limited access of thoracotomy for concomitant procedures, 6% of the patients underwent a concurrent procedure.¹² Individual patient data from the LATERAL¹² trial were used to plot time-to-death for the LVAD cohort. The International Society for Heart and Lung Transplantation¹⁷ data for continuous flow BTT VAD recipients (years: January 2005–June 2016) were employed for posttransplant survival for both cohorts. Weibull statistical models were fitted and ultimately informed predicted survival. The maximum available follow-up in the trial was used. MM survival was modeled utilizing the Seattle Heart Failure Model (SHFM) by applying the hazard ratio (HR) derived from its MM cohort, 0.23. LVAD AE rates were derived from the LATERAL¹² trial and MM AE rates were derived from the literature¹⁶ and shown in Tables 1 and 2. LVAD AEs included pump exchange because of pump thrombosis or VAD failure, ischemic and hemorrhagic stroke (mRS ≥ 4 patients became transplant ineligible), driveline infection, gastrointestinal (GI) bleeding, severe right HF (requiring right

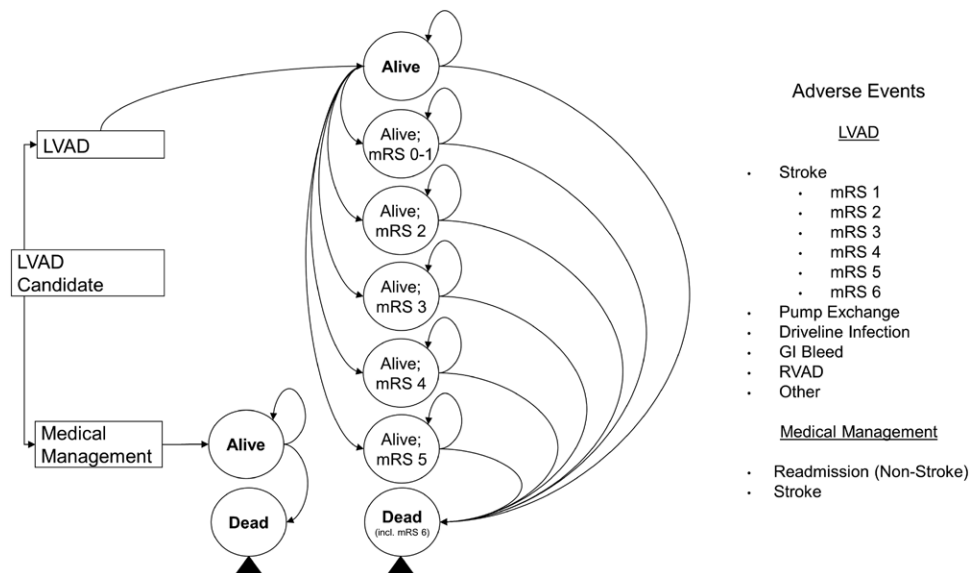


Figure 1. Model schematic. LVAD, left ventricular assist device; mRS, modified Rankin Scale; GI, gastrointestinal; RVAD, right ventricular assist device.

Table 2. Monthly Transition Probabilities—Medical Management

Event	Rate	References
Stroke		
Ischemic	0.002	29
Hemorrhagic	0.001	29
Readmission (apart from stroke)	0.300	16
Heart transplant rate	2.83%	18

The values presented at the table are transformed monthly event rates as used in the model.

ventricular assist device), and other AEs that could require hospitalization. Heart transplant rate was sourced by the Interagency Registry for Mechanically Assisted Circulatory Support (INTERMACS)¹⁸ (34% at 12 months). Survival curves used in the model are shown in **Figure 2**. Actual and modeled LVAD survival curves are shown in Figure S1 (Supplementary Digital Content 2, <http://links.lww.com/ASAIO/A510>).

Costs

Administrative claims analyses were conducted to inform the majority of cost inputs in the model. The 100% Medicare limited data set from CY2015 to 16 were used. The Medicare cohort was extracted using the Instant Health Data (IHD) platform (BHE, Boston, MA). Sample selection and creation of analytic variables were performed using the IHD platform (BHE, Boston, MA). Statistical analyses were undertaken with R, version 3.2.1 (R Foundation for Statistical Computing, Vienna Austria) and Microsoft Office Excel 365 Plus. For all costs, hospitalizations involving biventricular assist devices were excluded.

Our general costing approach was to identify hospitalizations in LVAD implanted patients and for which the primary diagnostic code matched the AE in question and other studied AE codes were absent. Sole exception was gastrointestinal bleeding for which remainder AE codes were not excluded. Strokes were identified using Medicare Severity Diagnosis Related Groups (MS-DRGs). Stroke costing included the hospitalization, the period to 90 days postevent and longer-term costs. Costs up to 90 days postevent were based on claims and after 90 days, on the literature.¹⁹ Claims were also used to assess other AE costs; for these we subtracted the cost associated with each of the explicitly modeled AEs from the total inpatient and outpatient cost over 12 months postdischarge. Outliers were managed by excluding subjects whose costs exceeded 1.96 times the standard deviation of the mean. All costs were adjusted to reflect 2018 prices either on the IHD platform or using the medical care specific CPI from the Bureau of Labor Statistics.²⁰ The CMS 2019 DRGs were used for the LVAD/right ventricular assist device implantation and heart transplantation. Costs used in the model are presented in **Table 3**.

Utilities

Individual patient data from contemporary HeartWare HVAD trials were used to calculate VAD-specific and thoracotomy-specific utilities.^{12,21–24} LATERAL,¹² ADVANCE BTT+CAP,^{21,24} and ENDURANCE²² used EQ-5D-3L and ENDURANCE Supplemental²³ used EQ-5D-5L as instruments to measure quality-of-life improvements in the trials. “Living with LVAD” utility was calculated as the average across all available timepoints in nonmajor AE patients from the LATERAL¹² trial. “Living on MM” utility was based on the preimplant measurement from the

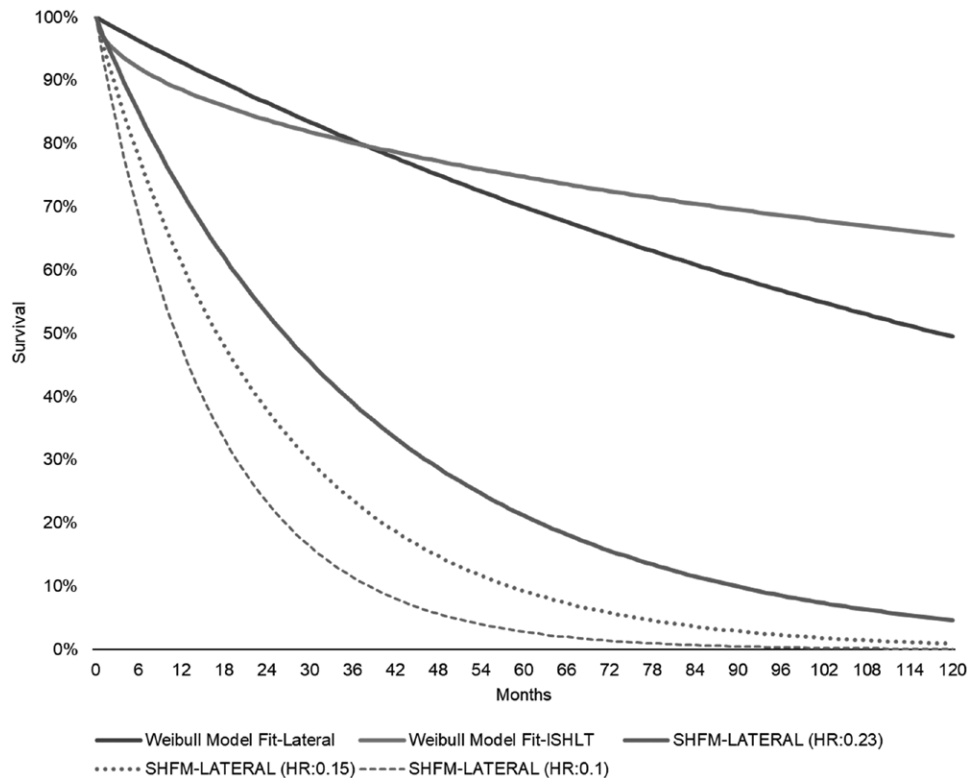


Figure 2. Survival curves in the model. SHFM, Seattle Heart Failure Model; ISHLT, International Society for Heart and Lung Transplantation. full color
online

Table 3. Costs

Event	Cost (\$)	References
LVAD implantation	154,565*	
LVAD monthly outpatient	3,187	16
MM monthly outpatient	3,515	16
Living with LVAD > 10 years—annual	18,377†	
Living on MM > 10 years—annual	9,005†	
Heart transplantation	154,565*	
Living after HT—annual	16,807‡	
Stroke		
First 90 days	27,904‡	
Follow-up		19
mRS 0—monthly	956	
mRS 1—monthly	984	
mRS 2—monthly	1,138	
mRS 3—monthly	1,955	
mRS 4—monthly	3,956	
mRS 5—monthly	5,816*	
Pump exchange	154,565*	
Driveline infection	13,681‡	
GI bleed	9,990‡	
RVAD	78,676§	
Other adverse events	9,220‡	
MM readmission (apart from stroke)	12,934	16

All costs were adjusted to reflect 2018 prices either on the IHD platform or using the medical care-specific CPI from the Bureau of Labor Statistics.²⁰

*CMS 2019 DRGs (i.e., 91.5% DRG 001 and 8.5% DRG 002).

†DRG 291 for cost estimation; event rate post 18-month resource use in Smedira.³⁰

‡Medicare claims analysis.

§CMS 2019 DRG 215.

LVAD, left ventricular assist device; MM, medical management; HT, heart transplantation; mRS, modified Rankin Scale; GI, gastrointestinal; RVAD, right ventricular assist device.

ADVANCE BTT+CAP^{21,24} trial. AE decrements used the average before–after score difference by patient utilizing the ADVANCE BTT+CAP,^{21,24} ENDURANCE,²² and ENDURANCE Supplemental²³ questionnaires. Utilities are presented in **Table 4**.

Sensitivity and Scenario Analyses

Besides the base–case analysis, we ran several sensitivity and scenario analyses to test uncertainty in results. One-way sensitivity analysis was performed for the major LVAD AEs including pump exchange, stroke, driveline infection, and GI bleed (minimum was 0, maximum was +100% increase from the base case values). Additionally, a probabilistic sensitivity analysis (PSA) was run where key inputs of the model were varied $\pm 25\%$ and 1,000 simulations were performed. For the scenario analyses, first the MM survival was lowered by using lower HRs. Second, the heart transplant rate was lowered in the model because of the recent changes on the United Network for Organ Sharing (UNOS) donor allocation criteria. Stable LVAD patients have a lower status under the new allocation system. And third, the AE rates of the LATERAL¹² thoracotomy trial was substituted with the ADVANCE BTT + CAP^{7,21} sternotomy trial.

RESULTS

Base Case

The base case results were \$ 64,632/QALY and \$ 57,891 per life-year (LY). LVAD patients had higher lifetime costs and higher lifetime benefits. Total cost for the LVAD arm was

Table 4. Utilities

Event	Utility
Living with LVAD	0.795
Living on medical management	0.591
Living after heart transplantation	0.795
Stroke	
mRS 0—monthly	0.795
mRS 1—monthly	0.795
mRS 2—monthly	0.697
mRS 3—monthly	0.691
mRS 4—monthly	0.573
mRS 5—monthly	0.573
Pump exchange	
VAD thrombus	0.755
VAD failure	0.559
Driveline infection	0.795
GI bleed	0.752
RVAD	0.786
Other adverse events	0.795
MM readmission (apart from stroke)	0.591

Individual patient data from LATERAL¹², ADVANCE BTT+CAP,^{21,24} ENDURANCE,²² and ENDURANCE Supplemental.²³

LVAD, left ventricular assist device; mRS, modified Rankin Scale; GI, gastrointestinal; VAD, ventricular assist device; RVAD, right ventricular assist device; MM, medical management.

Table 5. Base–Case Results

	Costs	Life Years	QALYs
LVAD	551,934	12.31	9.77
Medical management	334,117	8.55	6.40
Difference	217,817	3.76	3.37
ICER (\$/LY)		57,891	
ICER (\$/QALY)			64,632

LVAD, left ventricular assist device; ICER, incremental cost-effectiveness ratio; LY, life years; QALY, quality adjusted life years.

\$551,934 and for MM \$334,117. Total LYs were 12.31 vs. 8.55 for LVAD bridged to a transplant and MM cohorts who proceeded to transplant without a LVAD, respectively. The QALYs accrued by the LVAD patients bridged to transplant were 9.77 vs. 6.40 by the MM patients who proceeded to transplant without a LVAD. Results are presented in **Table 5**.

Sensitivity and Scenario Analyses

One-way sensitivity analysis. One-way sensitivity analysis was run on the main LVAD AEs. The ICER was most sensitive to pump exchange and stroke rates however less sensitive to GI bleed and driveline infections. Overall the changes in the ICER were rather low with the values varying from 6% to 9%. Results are presented in **Figure 3**.

Probabilistic sensitivity analysis. The PSA found a probabilistic ICER of \$64,915/QALY (95% CI, \$35,609–\$94,221/QALY). ICERs were less than \$50,000/QALY in 15.5% of simulations and in 98.4% less than \$100,000/QALY (**Figure 4**).

Scenario analyses. Three different scenario analyses were run. The first scenario was to run the model with lower LVAD HRs (0.15 and 0.1) than the base–case (0.23) for the MM survival. The HR of 0.15 resulted in an ICER of \$61,336/QALY and the HR of 0.1 resulted in an ICER of \$59,527/QALY (see Table S2–S3, Supplementary Digital Content <http://links.lww.com/ASAIO/A510>).

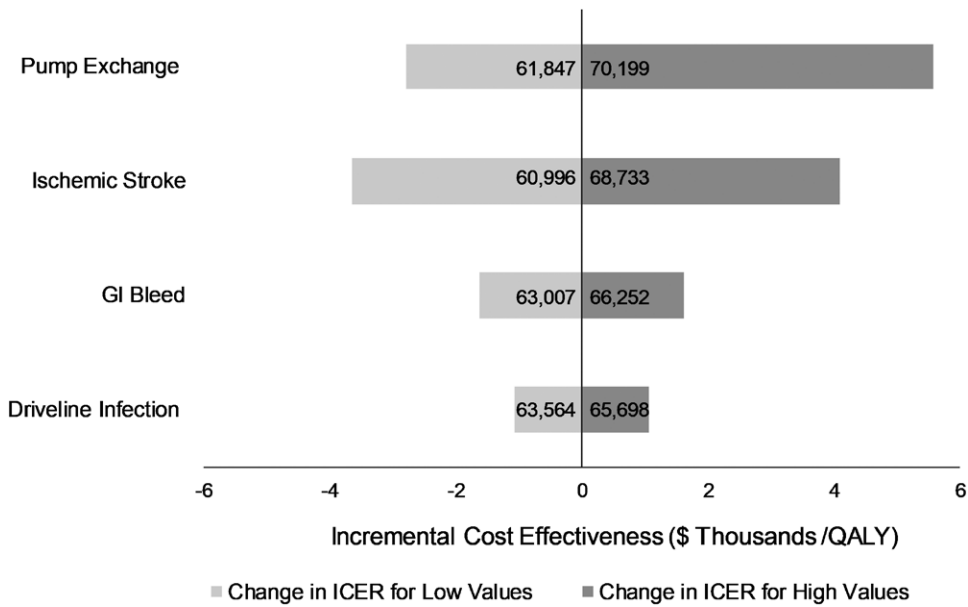


Figure 3. Tornado diagram—one-way sensitivity analysis. GI, gastrointestinal; QALY, quality adjusted life years; ICER, incremental cost-effectiveness ratio. [full color online](#)

The second scenario was to lower the heart transplant rate to better capture the current situation under the revised UNOS allocation system. As the transplant rate was decreasing, the ICER was decreasing, approaching the \$50,000/QALY threshold. At a transplant rate of 20% (decreased from 34% of the base-case), the ICER dropped to \$58,545/QALY and at 10%, to \$54,856 (see Table S4–S5, Supplementary Digital Content <http://links.lww.com/ASAIO/A510>).

Finally, the third scenario was to substitute the AE rates of the thoracotomy trial (LATERAL)¹² with AE rates from a sternotomy trial (ADVANCE BTT + CAP)^{7,21} and compare the two cohorts (thoracotomy vs. sternotomy AE profile). Results showed thoracotomy was dominant over sternotomy. Patients with the thoracotomy AE rates gained more QALYs (9.77 vs. 9.42) and accrued lower costs (\$551,934 vs. \$572,871) than patients with the sternotomy AE rates (see Table S6, Supplementary Digital Content, <http://links.lww.com/ASAIO/A510>).

Discussion

This report is the first cost-effectiveness analysis of the thoracotomy approach to LVAD implantation. Previous studies have evaluated the traditional implantation surgical approach of sternotomy, with outcomes showing a positive trend in cost-effectiveness. ICERs started from \$802,700/QALY in 2004¹³ using data from the REMATCH trial⁸ [1998–2001, destination therapy (DT) indication] and then decreased to \$198,184/QALY in 2012¹⁴ using HeartMate II trial data²⁶ (2005–2007, DT indication). In 2014, values remained similar with \$201,600/QALY for the DT indication and \$226,300/QALY for the BTT indication using INTERMACS data from the period 2006 to 2012.¹⁵ In 2017, there was an assessment for ambulatory patients (INTERMACS 4–7) with DT indication resulting in an ICER of \$209,400/QALY (INTERMACS data 2009 to 2014).¹⁶ The current study reconfirms the positive trend and demonstrated an even lower ICER of \$64,632/QALY for the

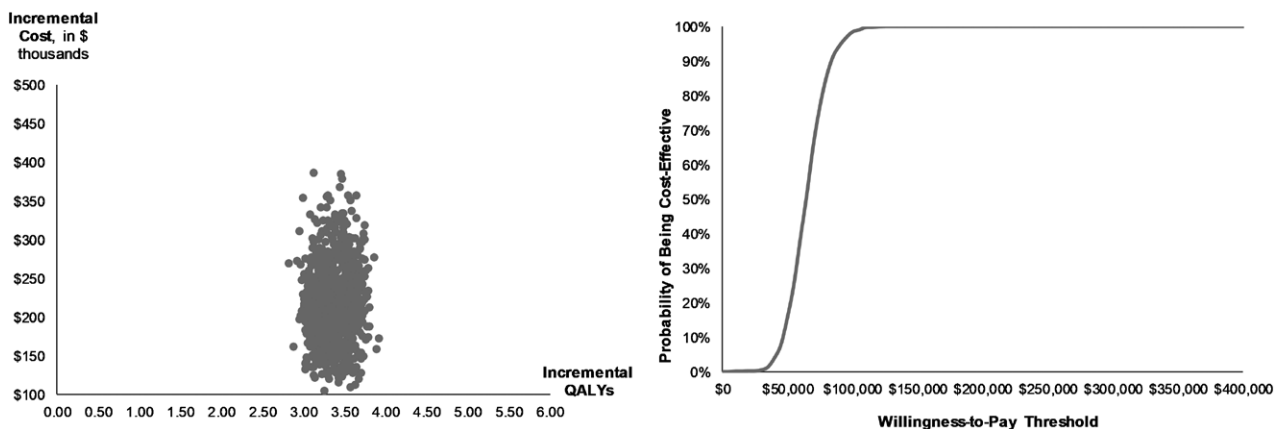


Figure 4. Incremental cost-effectiveness ratio scatter plot and cost-effectiveness acceptability curve (CEAC). QALY, quality adjusted life years. [full color online](#)

thoracotomy approach in the BTT indication using HVAD LATERAL trial data (2015–2016, BTT thoracotomy).¹²

Drivers of these results include the use of contemporary LVAD and MM data. In the modern era, LVAD survival has been improving. The LATERAL trial demonstrated very high survival (1-year 89%, 2-year 87%) and an improved clinical profile especially in bleeding and avoidance of severe right HF complications.¹² Patients were also discharged earlier from the ICU. A potential mechanism of protecting RV function is that the lateral approach reduces the distortion of cardiac geometry: The pericardium is only partially opened, and thereby position and geometry of the right ventricle (RV) are fully maintained. The potential benefit of preserving RV geometry and function leads to a limited ability to perform concomitant procedures. Aortic valve replacement can be performed *via* a thoracotomy approach. Mitral, tricuspid, or patent foramen ovale procedures can potentially be accomplished *via* an upper hemisternotomy or right thoracotomy but are more challenging. There were two aortic valve replacements, and one mitral valve repair performed in the LATERAL patient population, as well as an additional six other concomitant procedures. In addition, evolving patient management recommendations have an important role in the improved outcomes and decreased resource utilization. For example, improved blood pressure management is associated with a reduced stroke rate.²³ These improved clinical outcomes lead to better economic outcomes because of lower ICU and total length of stay and/or less readmissions. Lastly, utilizing inputs from the SHFM data for the MM survival arm allows a more accurate and contemporary assessment.

The HR from SHFM was used to model survival in the MM arm. Although the most appropriate input may have been a value from a randomized clinical trial, current data are unavailable as the last clinical trial in the U.S. comparing LVAD and MM patients was REMATCH which enrolled patients ineligible for heart transplantation from 1998 to 2001.⁸ In the modern era, there is no longer clinical equipoise to randomize advanced HF patients to medical therapy; hence, more contemporary MM data will not likely be available. Even though a number of studies use HR ratios from REMATCH for the MM cohort survival,^{14,15} we decided to use a more contemporaneous HR, this of SHFM because of improved LVAD survival with the newest generation devices.

Under the revised heart allocation system since 2018, LVAD patients are status 4 and are anticipated to stay longer on the waiting list as they are lower relative priority compared with the prior allocation system.²⁵ Newer, longitudinal data on the rate of heart transplantation under the current UNOS heart allocation system are not available yet. As such, the transplant rate used in the model is the UNOS heart allocation in place before the revision implemented in October 2018. For that reason, the sensitivity analyses included scenarios where the heart transplant rate was variably decreased. It was found that the more the transplant rate of LVAD patients decreased, the more cost-effective the LVAD implantation *via* thoracotomy became. This difference is amplified significantly by the superior survival demonstrated in the LATERAL trial.¹²

One last analysis compared two LVAD cohorts; the thoracotomy cohort and a second cohort, in which sternotomy AE rates were substituted for the thoracotomy AE rates and all other inputs were unchanged. Since less invasive implantation techniques have been associated with improved clinical outcomes,

this comparison was an opportunity to define the impact this difference could have on cost-effectiveness of thoracotomy compared with sternotomy. Results showed the thoracotomy cohort was far more cost-effective and dominant over the sternotomy AE profile cohort. The thoracotomy patients accrued higher benefits (QALYs) at a lower cost. However, it is noted that the ADVANCE BTT + CAP²¹ trial is a much earlier trial than LATERAL¹² and the model cannot account for the learning curve, technical improvements in the device or improved MM techniques.

Current changes in heart allocation were not included in the paper. It is speculated though that the new allocation system favors the use of short-term devices as BTT. Early analyses show an increase in temporary MCS device use and possible worse posttransplant clinical outcomes.^{25,27} Although temporary MCS is historically associated with permanent hospitalization, the costs per patient likely exceed by far the amount calculated here for LVAD therapy. More data under the new allocation rules are needed.

In this study, the cost-effectiveness of thoracotomy as an implantation strategy for a centrifugal LVAD was assessed for the first time. Progress in surgical technique as well as patient management led to greatly improved outcomes. The results show that thoracotomy BTTVAD is a cost-effective strategy. From the standpoint of survival, as well as an economic point of view, there is strong evidence to use durable LVADs as the default BTT strategy in properly selected advanced HF patients.

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