Cost-Effectiveness of a Small Intrapericardial Centrifugal Left Ventricular Assist Device

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There is limited data on the cost-effectiveness of continuous-flow left ventricular assist devices (LVAD) in the United States particularly for the bridge-to-transplant indication. Our objective is to study the cost-effectiveness of a small intrapericardial centrifugal LVAD compared with medical management (MM) and subsequent heart transplantation using the respective clinical trial data. We developed a Markov economic framework. Clinical inputs for the LVAD arm were based on prospective trials employing the HeartWare centrifugal-flow ventricular assist device system. To better assess survival in the MM arm, and in the absence of contemporary trials randomizing patients to LVAD and MM, estimates from the Seattle Heart Failure Model were used. Costs inputs were calculated based on Medicare claim analyses and when appropriate prior published literature. Time horizon was lifetime. Costs and benefits were appropriately discounted at 3% per year. The deterministic cost-effectiveness analyses resulted in $69,768 per Quality Adjusted Life Year and $56,538 per Life Year for the bridge-to-transplant indication and $102,587 per Quality Adjusted Life Year and $87,327 per Life Year for destination therapy. These outcomes signify a substantial improvement compared with prior studies and re-open the discussion around the cost-effectiveness of LVADs. *ASAIO Journal* 2020; 66:862–870.

Key Words: mechanical circulatory support, left ventricular assist device, cost-effectiveness, bridge-to-transplant, destination therapy

Heart Failure (HF) causes significant mortality and morbidity in the United States (U.S.) and worldwide.[1,2] In the U.S., 6.5 million people over 20-years old have HF.[3] Despite medical advances, there is greater than 50% mortality at 5 years post-diagnosis.[3] Medical costs of HF accounted for $29 billion in 2015 and are projected to be $64 billion by 2035.[1] Most HF-related hospitalizations and deaths are observed in patients with advanced disease.[4] Cardiac transplantation is effective, but donor availability is limited.[5]

Left ventricular assist devices (LVADs) have become important tools for the management of advanced HF as bridge-to-transplantation (BTT) or destination therapy (DT). The increasing number of end-stage HF patients together with organ shortages and technological advances in mechanical circulatory support (MCS) has increased the MCS devices used in these patients.[5] Overall, between 2009 and 2016, 43% of recipients were bridged with some type of MCS, LVAD, right ventricular assist device (RVAD), total artificial heart (TAH), and extracorporeal membrane oxygenation (ECMO).[6] In the United States, between 2007 and 2017, 50% of adult heart transplant recipients were ventricular assist device (VAD) supported.[7]

With growing waitlists, LVAD utilization is increasing. Due to improvement in their long-term outcomes, United Network for Organ Sharing (UNOS) lowered the status of stable LVAD patients on the allocation system with the 2018 revision. These changes are expected to result in longer wait times for LVAD patients compared with the previous system.[8] These trends underscore the importance of cost-effectiveness evaluations of LVAD therapy in an era when health care cost is a major focus.

Economic evaluations have previously demonstrated relatively high incremental cost-to-benefit ratios of LVADs using multistate Markov-cohort and state-transition models, typically above acceptable thresholds.[9,10] In 2004, a $807,700 per Quality-Adjusted Life Years (QALY) value was estimated for DT.[11] For the same indication, Rogers *et al.*[10] used the Blue Cross/Blue Shield Technology Evaluation Center assessment to assign optimal medical management (MM) or LVAD and found an incremental cost-effectiveness ratio (ICER) of $198,184/QALY. Long *et al.*[9] used a state-transition model to simulate treatments including LVAD as BTT and calculated $226,300/

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QALY (BTT) and $201,600/QALY (DT). Lastly, Baras Shreibati *et al.*[12] arrived at an estimate of $209,400/QALY for ambulatory DT. All these cost-effective analyses, however, were based on previous LVAD generations and likely overestimate costs while underestimating benefits.

The HeartWare HVAD (Medtronic, Minneapolis, MN) is a commercially available full-support centrifugal VAD designed to be implanted completely within the pericardial space and approved for use in patients with advanced heart failure for BTT and DT. The MM arm that was used as the comparator reflects care provided under modern Guideline-Directed Medical Therapy.[13,14] Given progressive improvement in LVAD outcomes, this analysis seeks to reestimate the U.S. cost-effectiveness of the HVAD pump, in the contemporary era. It was hypothesized that improved outcomes and decreased costs would result to favorable cost-to-benefit ratios.

Materials and Methods

Model Structure

Markov modelling, adhering to contemporary recommendations,[15,16] was employed. The model was built in Microsoft Excel. The structure employed two basic health states: "Alive" and "Dead" (see Figure S1, Supplemental Digital Content 1, http://links.lww.com/ASAIO/A511). Cohorts enter the model alive and at every 1-month cycle are exposed to risks of therapy-relevant adverse events (AEs) and death. The model applied variable mortality rates every cycle up to 10 years postimplantation. Strokes were modelled with additional health states defined for when they occur—stroke-related states equate to different severities. BTT patients may additionally have transplants become available. Mortality occurrence was evaluated before AEs and, in turn, AEs before transplant. Discounting of costs–benefits was applied at 3% (**Figure 1**).

Model Inputs: Mortality

Mortality was sourced from prospective trials employing the Medtronic HeartWare HVAD system. Individual patient-level data were used to plot time-to-death or transplantation. In the BTT model, mean age was 53.2 (± 11.72) years, 28.8% were female and 68.1% Caucasian (Table S1, Supplemental Digital Content 2, http://links.lww.com/ASAIO/A511).[17,18] In the DT model, mean age was 63.3 (± 11.4) years, 18.2% were female and 71.8 white (Table S2, Supplemental Digital Content 3, http://links.lww.com/ASAIO/A511).[19] The maximum available follow-up in every trial was used. The survival of BTT patients used patient-level data combining ADVANCE BTT and associated Continued Access Protocol (CAP).[17,18] DT survival used ENDURANCE Supplemental trial.[19] ADVANCE BTT could not be used posttransplantation because of censoring. Thus, posttransplant survival was derived from published UNOS data of VAD-bridged recipients.[20] Weibull statistical models were fitted and ultimately informed predicted survival. MM mortality used the SHFM by applying hazard ratios (HRs) derived from its MM cohort (**Figure 2**).

Model Inputs: Adverse Events

AE rates were derived from study data. Two-year data AE rates were employed to account for variation over time of the main LVAD AEs. AEs studied included pump thrombosis (accounting for pump exchanges when they occur), VAD failure–related pump exchanges, driveline infections, Right HF, ischemic/hemorrhagic strokes, gastrointestinal bleedings, and AEs that could require hospitalization. Stroke functional outcomes used the modified Rankin Scale (mRS) score[21] 24-weeks, (or latest available) postevent. mRS ≥ 4 patients became transplant ineligible. MM stroke rates were literature based.[12] Major event monthly probabilities are summarized in **Table 1** and detailed in Tables S3–S4 (Supplemental Digital Content 4 and 5, http://links.lww.com/ASAIO/A511).

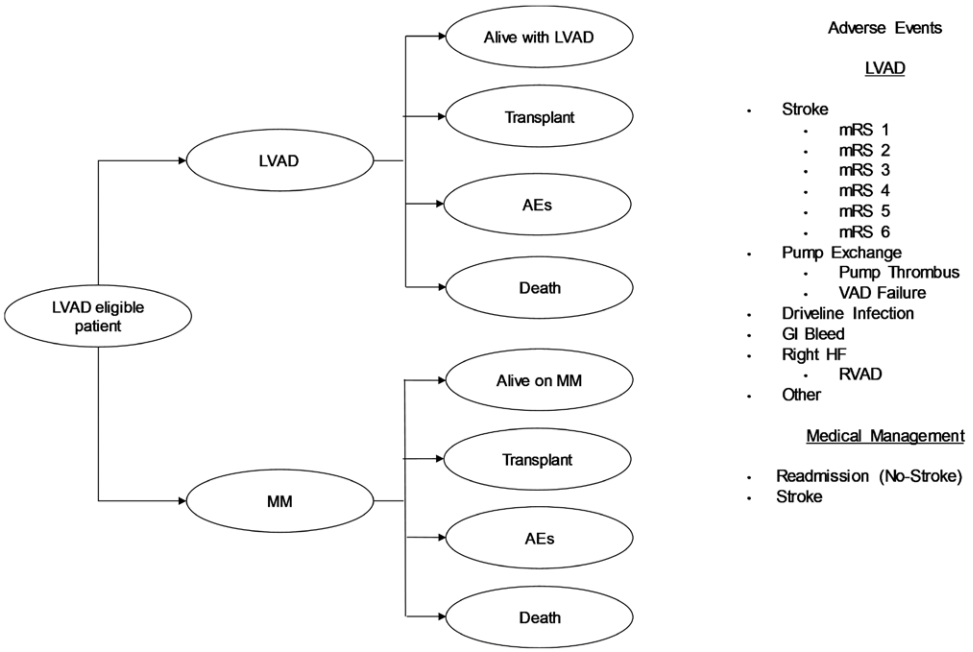

Figure 1. "Simplified" model representation. LVAD, left ventricular assist device; MM, medical management; AE, adverse event; mRS, modified Rankin Scale; GI, gastrointestinal; HF, heart failure.

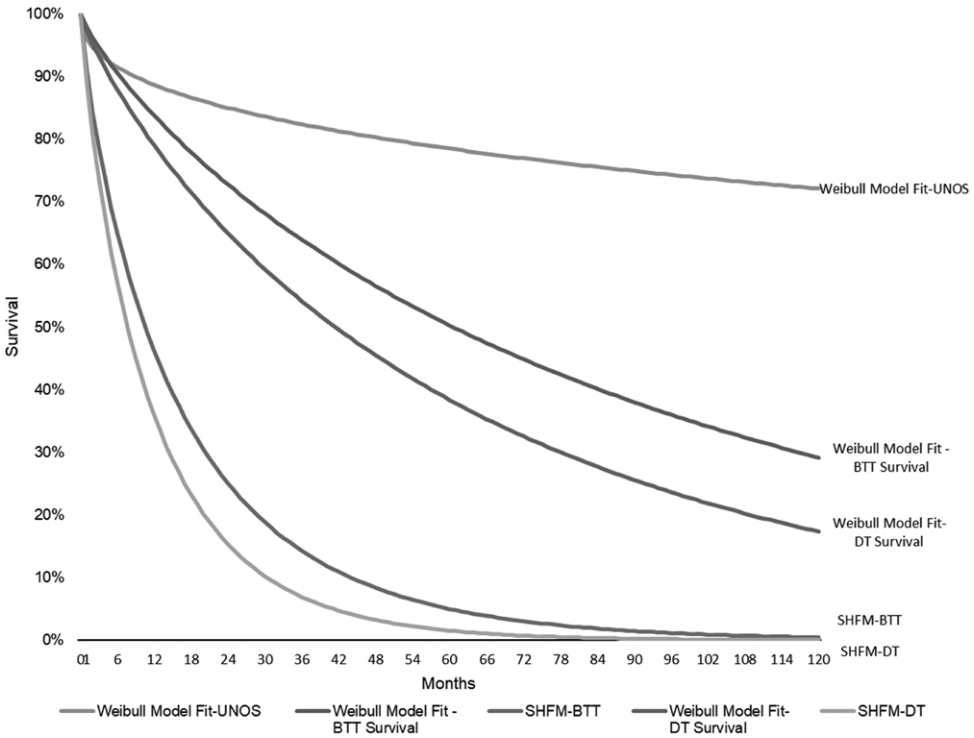

Figure 2. Survival curves—BTT and DT. UNOS, United Network for Organ Sharing; BTT, bridge to transplant; DT, destination therapy; SHFM, Seattle Heart Failure Model. full color online

Model Inputs: Probability of Transplant (BTT)

BTT patients have uniform monthly transplant probabilities informed by the latest reported data from the Interagency Registry for Mechanically Assisted Circulatory Support (INTERMACS) (34% at 12 months).[22]

Model Inputs: Costs

We conducted claims analyses since literature searches revealed data paucity. Sample selection and variable creation was performed using the Instant Health Data (IHD) platform (BHE, Boston, MA) and 100% Medicare sample data from CY2015–2016. For all costs, hospitalizations involving bi-ventricular assist devices (BiVADs) 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. Only in the case of gastrointestinal bleeding remainder AE codes were included. Strokes were identified using Medicare Severity Diagnosis Related Groups. Stroke costs included the hospitalization, the period to 90-days postevent and longer-term costs. Costs up to 90-day postevent were based on claims and after 90 days, on the literature.[23] Claims were also used to assess other AE costs; for these costs associated with each of the explicitly modelled AEs were subtracted from the total inpatient and outpatient cost more than 12 months postdischarge. Outliers were adjusted for by excluding subjects whose costs exceed 1.96 times the standard deviation of the mean. All costs were adjusted to reflect 2017 prices (see **Table 2**).

Table 1. Probabilities of Major Events per Monthly Cycle—BTT and DT

Event	BTT	DT	Reference
Stroke			
Ischemic	0.007	0.014	†‡
Hemorrhagic	0.007	0.005	†‡
Pump exchange			
VAD thrombus	0.003	0.005	†‡
VAD failure	0.002	0.001	†‡
Driveline Infection	0.021	0.020	†‡
GI bleed	0.023	0.048	†‡
RHF	0.031	0.023	†‡
RVAD	11%	7%	†‡
Other AEs	0.043	0.380	†‡
MM stroke	0.002	0.002	[12]
MM readmission (apart from stroke)	0.300	0.300	[12]
Heart transplant rate	2.83%	—	[22]

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

*Based on ENDURANCE Supplemental[19] Data. Medtronic Internal Data on File.

†Based on ADVANCE BTT + CAP[17,18,40] Data. Medtronic Internal Data on File.

BTT, bridge-to-transplant; DT, destination therapy; VAD, ventricular assist device; GI, Gastrointestinal; RHF, right heart failure; RVAD, right ventricular assist device; AE, adverse event; MM, medical management

Model Inputs: Healthcare Utilities

ADVANCE BTT + CAP and ENDURANCE included EQ-5D-3L and ENDURANCE Supplemental EQ-5D-5L. MM utilities, "Living on MM" were based on the preimplant measurement from the respective clinical trial. "Living with LVAD" utilities equated the average across all available timepoints in nonmajor AE patients. AE decrements used the average before–after score difference by patient. See **Table 3**.

Scenario and Other Sensitivity Analyses

Scenario analyses were run to test result uncertainty. Literature-derived utilities substituted individual patient data.

Table 2. Main Inputs—Costs

Parameter	Cost ($)	Source
LVAD implantation	148,181	*
LVAD monthly outpatient	3,050	[12]
MM monthly outpatient	3,465	[12]
Living with LVAD >10 years—annual	19,887	†
Living on MM > 10 years—annual	9,744	†
Heart transplantation	148,181	*
Living after HT—annual	15,586	‡
Stroke		
First 90 days	27,364	‡
mRS 0—monthly	936	[23]
mRS 1—monthly	964	[23]
mRS 2—monthly	1,115	[23]
mRS 3—monthly	1,915	[23]
mRS 4—monthly	3,876	[23]
mRS 5—monthly	5,698	[23]
Pump exchange	148,181	*
Driveline infection	13,416	‡
GI bleed	9,796	‡
RHF		
RVAD	148,181	*
no RVAD	5,374	‡
Other AEs	9,041	‡
MM readmission (apart from stroke)	12,748	[12]

All costs were adjusted to reflect 2017 prices either on the IHD platform or using the medical care–specific CPI from the bureau of labor statistics.[38]

*CMS 2018 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.[39]

‡Medicare claims analysis.

LVAD, Left ventricular assist device; HT, heart transplantation; mRS, Modified Rankin Scale; GI, gastrointestinal; RHF, right heart failure; RVAD, right ventricular assist device; AE, adverse event; MM, medical management.

The cost of LVAD implantation and heart transplantation was increased to account for variation in the payment between CMS and commercial payers. HR sourced from the SHFM was tested. For BTT, monthly transplant rates were varied. Finally, deterministic and probabilistic sensitivity analyses were run. One-way sensitivity included rates of stroke, driveline infection, and pump exchange. Minimum was zero; maximum was quadruple the base–case values. In the probabilistic sensitivity analysis (PSA), the key parameters of the model are represented as distributions instead of being point estimates as in the base-case models. These key parameters are randomly sampled, and the model is run many times to generate ICER values.[24]

Results

Cost-Effectiveness Results

Deterministic analyses resulted in $69,768/QALY for BTT and $102,587/QALY for DT. BTT patients had total costs of $514,568 with LVAD and $222,196 without. For DT, total LVAD costs were $404,691 and $93,754 with MM. On a LY basis, ICERs were $56,538/LY for BTT and $87,327/LY for DT. Results are detailed in **Tables 4** and **5**.

Scenario Analyses

Several scenario analyses investigated the impact of alternative inputs. Specifically, for the values of the "Living with LVAD" and "Medical Management" states, literature values[25] were used and coupled with a scenario under which transplanted patients have higher utility after transplant.[26] Grady *et al.*[25] used INTERMACS patients while Sharples *et al.*[26] used data from U.K. VAD patients (both analyses based their values on EQ-5D data[25,26]). Solely using Grady *et al.*[25] resulted to a DT ICER of $119,391 and a BTT ICER of $68,556/QALY while, after Sharples *et al.*[26] was applied, it became $69,187/QALY (Table S5, Supplemental Digital Content 6, http://links.lww.com/ASAIO/A511).

Table 3. Main Inputs—Utilities

Event	BTT	DT
Living with LVAD	0.77	0.80
Living on MM	0.59	0.64
Living after HT	0.77	N/A
Stroke		
mRS 0	0.77	0.80
mRS 1	0.77	0.80
mRS 2	0.67	0.70
mRS 3	0.67	0.70
mRS 4	0.55	0.58
mRS 5	0.55	0.58
Pump exchange		
VAD Thrombus	0.73	0.76
VAD Failure	0.53	0.57
Driveline infection	0.77	0.80
GI bleed	0.73	0.76
RHF	0.76	0.79
Other AEs	0.77	0.80
MM readmission (apart from stroke)	0.59	0.64

Individual patient data from ADVANCE BTT+CAP,[17,40] ENDURANCE,[28] and ENDURANCE Supplemental.[19]

BTT, bridge to transplant; DT, destination therapy; LVAD, left ventricular assist device; IPD, individual patient data; HT, heart transplantation; mRS, modified Rankin Scale; GI, gastrointestinal; RHF, right heart failure; RVAD, right ventricular assist device; AE, adverse event; MM, medical management.

Table 4. Results—Bridge to Transplant

	QALYs		LYs	
	LVAD	MM	LVAD	MM
QALYs/LYs	8.89	4.70	11.58	6.41
Medical Costs ($)	514,568	222,196	517,964	222,196
ICER ($/QALY/LY)	69,768		56,538	

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

Table 5. Results—Destination Therapy

	QALYs		LYs	
	LVAD	MM	LVAD	MM
QALYs/LYs	3.83	0.80	4.81	1.25
Medical Costs ($)	404,691	93,754	404,691	93,754
ICER ($/QALY/LY)	102,587		87,327	

LVAD, left ventricular assist device; MM, medical management; ICER, incremental cost-effectiveness ratio; QALYs, quality-adjusted life years; LY: life years.

To account for variations between CMS and commercial payers both BTT and DT model were also run with a 20% and 25% increase in the cost of LVAD implantation and heart transplantation. The results showed an increase in the ICER, as expected. For BTT the ICER under the 20% increase was $79,997/QALY and under 25%, $82,554/QALY. For DT, these were $114,752/QALY (20% increase) and $117,793/QALY (25% increase). (See Table S6, Supplemental Digital Content 7, http://links.lww.com/ASAIO/A511.

The HR for mortality of the LVAD patients against MM was much more impactful. In one-way sensitivity, it included a low HR of 0.105[10,27] and a high of 0.52[27] (basecase 0.23). The ICER for BTT ranged from $62,123 to $104,366/QALY for BTT. DT ICERs remained robust for both values with minimal impact of the HR to the indication's cost-effectiveness ($104,534 to $104,922/QALY). In a threshold analysis, the HR against MM needed to take values above 0.55 to make the ICER increase higher than 10% of the basecase (≥$110,000/QALY). See Table S7, Supplemental Digital Content 8, http://links.lww.com/ASAIO/A511

Finally, specifically for the BTT indication, the model was also run with lower transplant rates of 25% and 15%

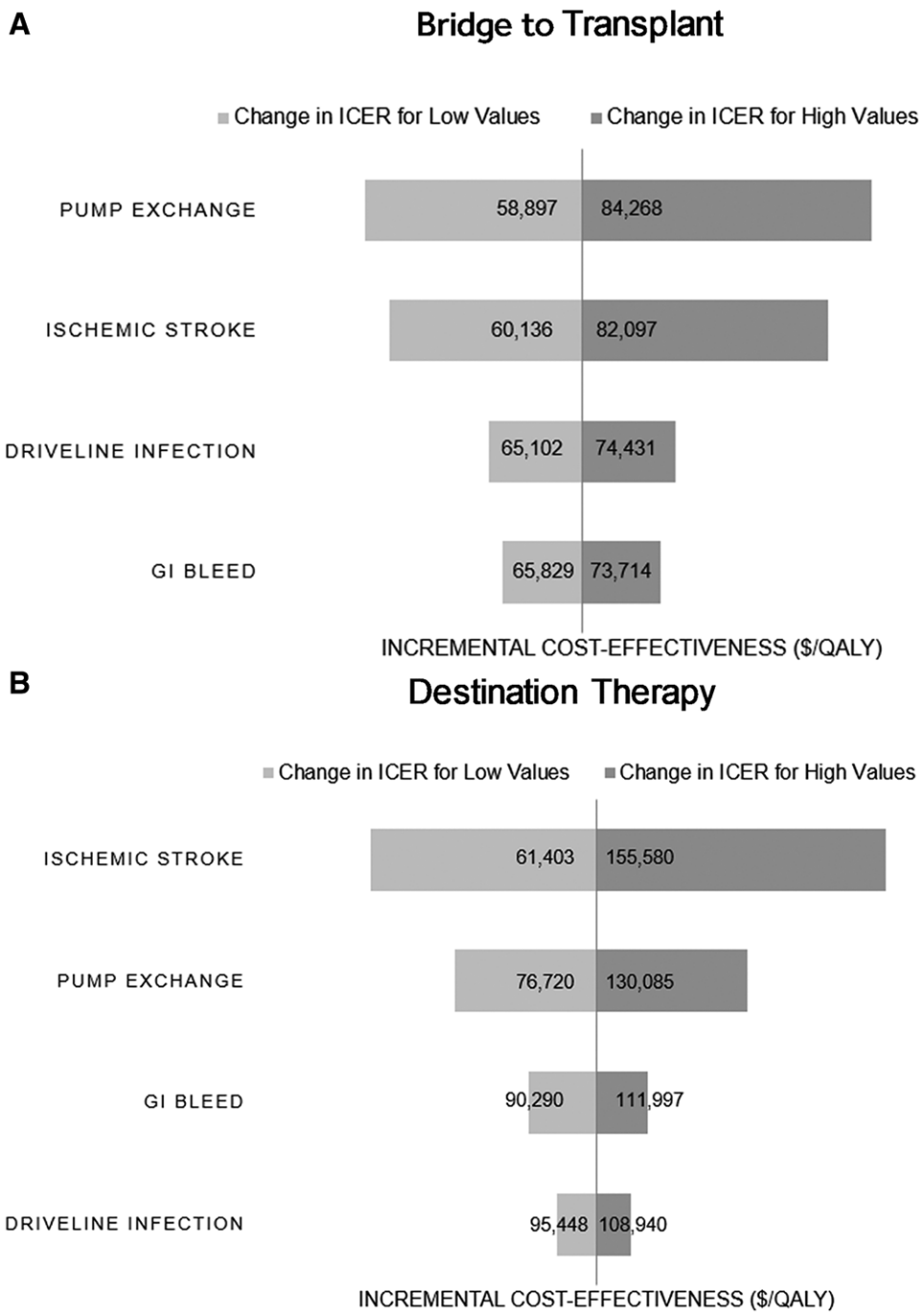

Figure 3. Tornado diagram—One-way sensitivity analyses on major adverse events. ICER, Incremental Cost-Effectiveness Ratio; GI, gastrointestinal; QALY, Quality-Adjusted Life Years.

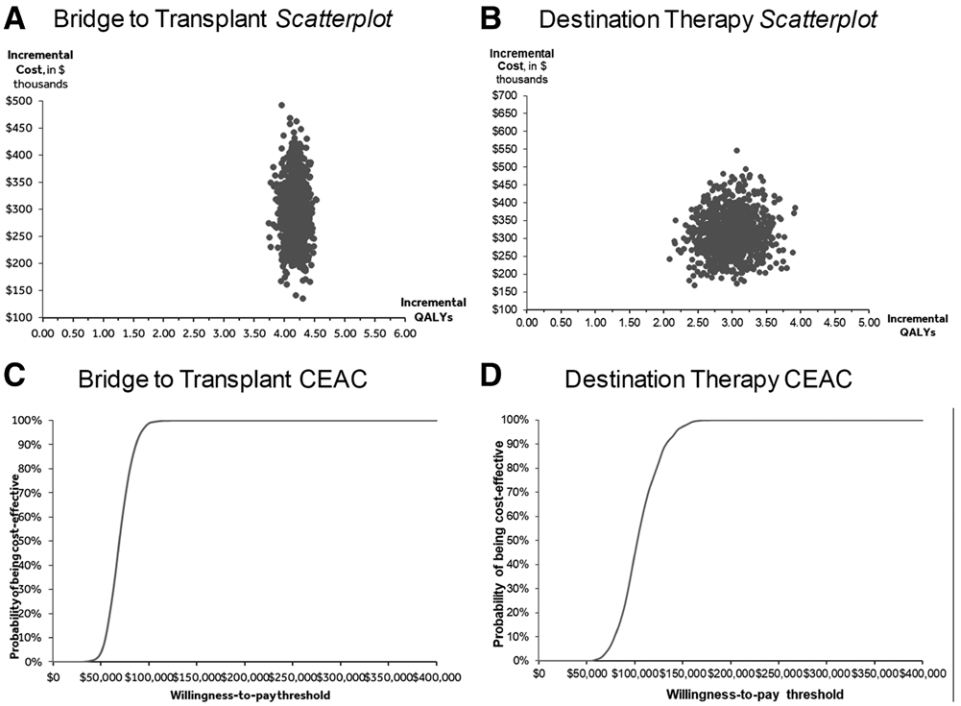

Figure 4. Incremental cost-effectiveness ratio scatterplot and cost-effectiveness acceptability curve (CEAC): (**A**) bridge-to-transplant scatterplot, (**B**) destination–therapy scatterplot, (**C**) bridge-to-transplant CEAC, and (**D**) destination-therapy CEAC. QALY< Quality-Adjusted Life Years.

(basecase 34% per year).[22] The ICER increased as the transplant rate decreased but remained below $76,000/QALY. More specifically, at a transplant rate of 25% the BTT ICER was found to be $71,165/QALY and at 15%, was found to be $75,694/QALY (basecase $69,768/QALY). See Table S8, Supplemental Digital Content 9, http://links.lww.com/ASAIO/A511.

One-Way Sensitivity Analyses

One-way sensitivity analyses on AEs showed estimates sensitive to stroke and pump exchange rates. Gastrointestinal bleeding and driveline infections played smaller roles. For BTT, strokes varied ICERs $60,136 to $82,097/QALY while pump exchanges caused variances from $58,897 to $84,268/QALY. For DT, ICERs ranged from $61,403 to $155,580/QALY due to stroke rates and from $76,720 to $130,085/QALY due to pump exchanges (**Figure 3**).

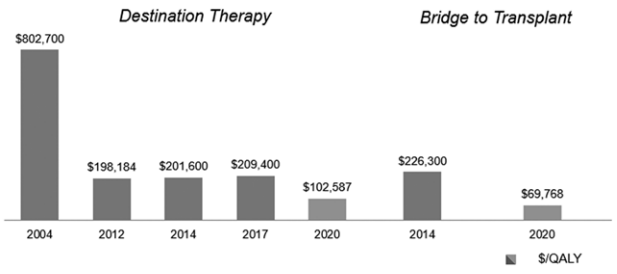

Figure 5. LVAD cost-effectiveness studies—U.S. Special Report 2004.[11] Rogers *et al.* (2012)[10]; Long *et al*. (2014)[9]; Baras Shreibati *et al.* (2017)[9]. QALY, Quality-Adjusted Life Years. full color online

Probabilistic Sensitivity Analysis

Default inputs were varied ±25%. 1,000 simulations were run for BTT and DT. Probabilistic BTT ICER equated $70,018/QALY (95% CI $45,361 to $94,676/QALY) and DT $104,927/QALY (95% CI $64,211 to $145,643/QALY). BTT ICERs were < $50,000/QALY in 3.8% of simulations and in 98.8% <$100,000/QALY. DT ICERs were 44.1% <$100,000/QALY, 76.8% <$120,000/QALY, and 97.3% <$150,000/QALY (**Figure 4**).

Discussion

This analysis used trial data[17–19,28] to estimate the contemporary cost-effectiveness of LVAD therapy in the BTT and DT indications. Implants rates have risen substantially over the last years,[22] emphasizing the need to assess the extent these devices represent good use of healthcare resources. In line with U.S. guidelines,[29] the perspective of the most common payer was employed and the model compared offering LVAD technology to the scenario of the technology not being available at all. Therefore, results are reported as the incremental cost to offer an additional quality-adjusted year of life using LVAD, in each indication, against simply leaving patients on medical therapy. Traditionally, ICERs below $50,000/QALY gained were considered cost-effective in the U.S.[30] However, given the dramatic growth in GDP per capita of the U.S. economy, thresholds between $100,000 and $120,000/QALY have been deemed more appropriate.[30]

Previously conducted analyses[9–12] have attempted to answer the question of LVAD cost-effectiveness in various populations, using different methodological approaches. Long *et al.*[9] reported $206,300/QALY for BTT patients; while destination

therapy ranged widely from $198,184 to $802,700/QALY[9–12] with Rogers *et al*.[9] reporting an ICER of $198,184/QALY for a 5-year time horizon.[10] This analysis found $69,768/QALY for BTT and $102,587/QALY for DT, bringing LVAD therapy drastically closer to the traditional acceptability threshold previously described (**Figure 5**). This result is important since it validates that as LVAD technology evolves, patient selection improves, adoption rises, and cost decreases.

It is important to contrast our reported values with the ones previously published. Technological advances and improved understanding of patient selection and postimplant management have positively affected outcomes. The principal driver of the results is increased survival of patients that receive an LVAD. Patient survival from contemporary trials of currently marketed devices in patients implanted as recently as late 2015 were used. Long *et al*. used INTERMACS data from 2006 to 2012,[9] whereas prior DT analysis used data from patients implanted in 2005-2007.[10] Second, this analysis used quality of life data directly derived by the underlying clinical trials, making it the first to truly employ VAD-specific utilities assessing the benefit of implantation and the severity of adverse events. Third, using current trial data allowed improved LVAD safety profiles to inform results. Fourth, functional outcomes post-ischemic/hemorrhagic stroke accurately portrayed stroke severity. This allowed more accurate accounting of stroke severity in the model. Finally, for BTT specifically, the model explicitly accounts for improved survival posttransplant along with costs and benefits.

There are no randomized clinical trials comparing continuous-flow LVADs to medical therapy. The model examines survival of medically managed patients by adjusting a HR derived from the SHFM. SHFM has been widely used to estimate survival of hypothetical HF patient cohorts. A potential downside is its reliance on somewhat dated cohorts, without including all contemporary medications and interventions. SHFM has been updated to account for angiotensin-converting-enzyme inhibitors/angiotensin II receptor blockers, β-blockers, implantable cardioverter-defibrillator, and cardiac resynchronization therapy defibrillator/cardiac resynchronization therapy pacemaker. Sacubitril/valsartan is not yet included but its inclusion will make the data increasingly compelling, *via* increased medication costs. Alternatives exist. When comparing Metabolic Exercise test data combined with Cardiac and Kidney Indexes to SHFM, the former may be superior in prognostic value for HF patients.[31,32] Later studies showed SHFM particularly more accurate in predicting survival, whilst other HF models tend to overestimate mortality.[33] Given the validation and regionalization of SHFM internationally,[34] it may be the most appropriate for this analysis, notwithstanding cardiopulmonary exercise testing-based score advantages.[35] The latest U.S. randomized study comparing VAD to MM, REMATCH, enrolled during 1998–2001 when therapies were less advanced.[27] This makes REMATCH HRs largely inapplicable.

Specifically, for the utility scores, values were sourced from the included trials for the basecase. The needed values included data on how well people live compared to full health with the various treatment options (LVAD, Transplant, MM) and how much HRQOL is reduced when an AE happens. There is literature paucity for the latter and thus uncertainty was examined within the PSA. For the utility of the actual state data from large VAD patient registries were used to test uncertainty. Despite absolute values varying from this model, the actual impact on the ICERs did not change the directionality of the analysis.

Estimates of the utility decrements associated with AEs may be biased by factors besides the event itself (e.g., medical intervention, incapacitation, *etc.*) and influence patient utility following an AE. The calculated utility decrements will likely be underestimated when some time has elapsed since the AE occurred and patients have time to recover from the acuity of the event. As a result, although decrements estimated from HVAD trial data add to the understanding of the negative impact of AEs within this specific HF population, they are likely underestimating the severity of events. Ultimately, this translates into the ICER being calculated to be higher than what they actually are. More importantly, the "Living-on-MM" healthcare state, the main driver of QALY accumulation in the comparator arm, is informed by utilities collected pre-implant in patients who proceed to receive an LVAD. This method likely overestimated the quality of life, since patients prepared for a procedure are receiving more support than "real-world" standard of care. Indeed, the difference in utility reported[25] is larger than the one in this study.

The model used a payer perspective and more specifically the CMS perspective. To account for variations in cost between CMS and private payers two scenarios were run with higher cost for LVAD implantation and heart transplantation. This resulted in higher ICERs, as expected, (BTT, 20%—$79,997/QALY and 25%—$82,554/QALY; DT, 20%—$114,752/QALY and 25%—$117,793/QALY) but still supported the results by showing large improvements in LVAD cost-effectiveness compared to older studies. Even under higher costs, the ICERs were much lower than past studies in both BTT and DT indication, with BTT being under the $100,000/QALY threshold and DT being under $120,000/QALY.

Finally, the model did not include any inputs from the period after the new UNOS heart donor allocation changes (October 2018) because of lack of longitudinal data at the time of the study. The basecase value for heart transplantation was sourced from the INTERMACS BTT rate (34% annually).[22] Newer criteria from October 2018 onwards suggest BTT patients would remain longer on the transplant list. Use of durable LVADs in listed patients after the UNOS changes has been found on a first analysis, to have marginally decreased at the time of listing and largely decreased at the time of transplant.[36] We tested sensitivity analyses with lower transplant rates (25% and 15%) than the basecase (34%); this resulted in higher ICERs (25%—$71,167/QALY; 15%—$75,695/QALY), but the direction of the results remained unchanged. ICERs were between $50 and $100,000/QALY demonstrating consistency of the improvement in cost-effectiveness of LVADs. Early analyses of outcomes post October 2018 show that the new UNOS donor allocation criteria do not have an impact on LVAD outcomes but seem to have a negative impact on transplant outcomes because of a higher number of patients bridged with temporary MCS devices.[36,37]

Limitations of this study included first that survival of the comparator arm on MM was derived from a modelled cohort and not from a randomized clinical trial. Second, regarding utilities, the MM utility was based on preimplant values of LVAD patients rather than MM patients not undergoing LVAD as treatment. Third, costs included in the model were derived from a single payer (CMS). Finally, the timing of the study did not allow for inclusion in the BTT model of any post-UNOS 2018 allocation change data.

In conclusion, this study demonstrated the cost-effectiveness of LVAD therapy to be dramatically improved compared to older estimates. Estimated ICER reductions exceeded 50% and approached the $50,000/QALY threshold for BTT patients that makes technologies formally cost-effective. On a Life-Year basis, BTT reached $56,538/LY, essentially guaranteeing threshold crossing within 1–2 years driven by LVAD cost declines. These values can already be considered cost-effective, when adjusting thresholds for advances in the U.S. economy. Given the widespread adoption of LVAD as a therapy for advanced HF, the improvement is timely and notable. Sensitivity analyses showed modest variance in our results without directional change, which strengthens the validity of our conclusions. More research is needed on whether targeted advancements can be made to further improve cost-effectiveness of LVAD therapy.

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