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Cost-effectiveness of the implantable HeartMate II left ventricular assist device for patients awaiting heart transplantation

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BACKGROUND: Left ventricular assist devices (LVADs) are being proposed as a life-saving therapeutic alternative to conventional medical management for people with end-stage heart failure awaiting transplantation. However, cost-effectiveness assessments of first-generation LVADs have not been encouraging. The cost-effectiveness of the enhanced second-generation LVAD HeartMate II (Thoratec, Pleasanton, CA) is estimated here.

METHODS: A probabilistic Markov model was developed to extrapolate survival, utility, and resource use over the total lifetime of a hypothetic cohort of patients with end-stage heart failure under the 2 competing therapeutic strategies, using the most robust and recently published evidence about their performance. Cost data are based on UK activity to consider reimbursement in the UK National Health Service setting.

RESULTS: HeartMate II had a mean cost per quality-adjusted life-year (QALY) of £258,922 ($414,275). The sensitivity analysis showed that 2 factors mainly explain why HeartMate II is not a cost-effectiveness strategy as a bridge-to-transplant: (1) the survival of heart transplant candidates treated conventionally while on the waiting list has significantly improved in recent years, and (2) the high acquisition cost of the device, £94,200 ($150,720).

CONCLUSIONS: Although HeartMate II LVAD implantation significantly increases survival compared with conventional medical management, it does not provide good value for the money spent according to established thresholds of cost-effectiveness in the UK. HeartMate II is unlikely to become cost-effective unless the additional survival gained by its use raises and/or the device is given free of charge. Therefore, its implantation to transplant candidates lacks justification in terms of cost-effectiveness.
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The steady decline in donor hearts observed over time in the United Kingdom (UK) means that patients often wait a long time for a heart transplant (HT).[1] As a result of the high mortality rate associated with conventional therapy while awaiting HT, which is mainly pharmacologic with intravenous inotropic agents, left ventricular assist devices (LVADs) have been proposed as a life-saving alternative for patients with hemodynamic decompensation.[2–4]

In 2008, the United States (US) Food and Drug Administration (FDA) approved the LVAD HeartMate II [5] (Thoratec Corp, Pleasanton, CA) for use as a bridge to HT (BTT) in candidates at risk of imminent death from non-reversible LV failure.[6,7] In 2010, the FDA extended the indication for use as destination therapy.[8] This economic evaluation focuses on the first approved indication commonly known as the BTT indication. This evaluation is important because the potential benefits provided by HeartMate II might be offset by its high acquisition cost of £94,200 ($150,720), which may partially explain the limited diffusion of an otherwise appealing technology.[9–11] However, evaluating low-volume, high-cost, but potentially life-saving technologies is difficult because randomized controlled trials of adequate size are scarce and not always relevant to the objectives of the evaluation.[12,13] Moreover, there have been

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no randomized comparisons between different types of implantable LVADs for the BTT indication,[14,15] which makes a direct comparison challenging.

It was anticipated 15 years ago that implantable LVAD therapy would become not only a cost-effective BTT strategy but even cost-saving.[16] However, cost-effectiveness assessments of first-generation LVAD have not been encouraging.[10] The HeartMate II is a second-generation continuous-flow LVAD that has been shown to be more beneficial than the previous generation of HeartMate with a pulsatile-flow design.[15,17] Similarly, survival of HT candidates treated conventionally while on the waiting list has significantly improved in recent years.[18] In consequence, results from earlier cost-effectiveness evaluations comparing LVADs against conventional therapy may have become obsolete. Hence, the aim of this work was to estimate the cost-effectiveness of the HeartMate II using the most robust and recently published evidence about its comparative performance vs conventional therapy for patients listed for HT.

Methods

Study outcomes measures

The driving outcome was survival while waiting for HT and subsequent post-HT survival. The benefits to patients were assessed in survival duration and associated quality of life measured in life-years gained (LYG) and quality-adjusted life-years (QALYs), respectively.

For the LVAD-implanted group, estimates of survival while listed for HT were obtained from Pagani et al.[14] This uncontrolled multicenter study published in 2009 monitored for 18 months 281 patients (mean age, 50 years) who were urgently listed for HT (United Network of Organ Sharing [UNOS] status 1A + 1B) and underwent implantation of HeartMate II as a BTT. Overall survival rates (95% confidence interval [CI]) for the patients on LVAD support were 92% (94%–90%) at 1 month, 82% (77%–87%) at 6 months, 73% (66%–80%) at 1 year, and 72% (65%– 79%) at 18 months.

In the absence of randomized evidence comparing conventional therapy vs HeartMate II as BTT, the comparative survival data for the conventionally treated patients was taken from the USA U.S. government-sponsored Scientific Registry of Transplant Recipients (www.srtr.org) 2000 to 2005 registry of 7,376 patients in the HT waiting list (UNOS status 1A + 1B). The latest published rates of survival were 76%, 69%, and 63% at 6, 12, and 18 months, respectively.[18] These estimates should be interpreted with caution due to the limitations associated with the retrospective analysis of a registry database.

Specifically, 1,682 patients (22.8%) had "mechanical circulatory support," defined as temporary or permanent circulatory support devices on the day of listing, including right, left, or biventricular support devices or a total artificial heart device. Information about use of "mechanical circulatory support" was not reported to the registry after the day of listing. Therefore, the registry-derived survival estimate may overestimate the true survival of patients treated conventionally due to the presence of some LVAD-implanted patients. According to the Interagency Registry For Mechanical Circulatory Support (INTERMACS), 123 patients listed for HT were bridged with LVAD in the USA during an 18-month period starting in June 2006 (earliest date available in INTERMACS).[19] Hence, for the 6-year period in the 2000 to 2005 registry, we can expect 6.7% of the 7,376 patients had a LVAD.

The base-case scenario considers that the average waiting time to receive a HT in the UK is 6 months.[20] Pagani et al[14] reported a median time of 118 days (range, 10–545 days) in their USA study, where 50% of patients listed for HT (remained alive with ongoing LVAD support) received a donor heart within 12 months. In a climate of availability decline of donor hearts, the sensitivity analysis considers a bridging interval of 1 year, and an extended interval of 18 months, corresponding to the longest interval for which there is survival data of implanted HeartMate II patients.[14]

John et al[21] published in 2010 the post-HT survival rates after support with the HeartMate II by monitoring the same cohort of patients as Pagani et al.[14] Of 250 patients (mean age, 51) who underwent HT, 190 patients completed a 1-year follow-up. The average 1-year post-HT survival of 87% (95% CI, 81%–91%) coincides with the survival reported in 2009 by Russo et al[22] for 1,680 patients previously bridged with a range of implantable LVADs, including the HeartMate II. Aside from monitoring a considerably larger number of LVAD-implanted patients than John et al,[21] the observational study of Russo et al[22] also monitored 8,346 patients treated conventionally before HT. Data collected for a 7-year period did not find differences in post-HT (unadjusted) survival between the 2 strategies, and so an identical risk of death was assumed in both groups. The average post-HT survival of conventionally treated patients at 3 months and from 1 to 7 years was 93%, 89%, 84%, 81%, 77%, 74%, 69% and 65%, respectively.[22] Because the post-HT survival estimates of conventionally treated patients were derived from a larger number of patients, they are used indistinctly for both treatment groups.

Survival was weighted by the average utility (from 1 = full health to 0 = death) to estimate QALYs for each group. According to Sharples et al,[23] reported utility values (95% CI) were 0.50 (0.32–0.68) for conventionally treated patients, 0.51 (0.40–0.62) during the first month for LVAD implanted patients and 0.66 (0.63–0.69) thereafter, and 0.76 (0.73–0.79) for post-HT patients.

Economic analysis methods

To allow comparability with the most recently published economic evaluation of LVAD use in the UK setting,[23] this evaluation makes use of the same cost data, except for the purchase of the HeartMate II device, which was not considered in the original analysis. Sharples et al[23] collected resource use data charged at 2005 prices adopting the UK NHS perspective. Costs have been inflated to 2011 prices by applying the projected health service cost index (HSCI) of 15%.[24]

A detailed description of resource use data and unit cost estimates can be found in the original article[23] and associated Health Technology Assessment report.[1] Briefly, data were collected for surgical procedure and subsequent stay in the intensive care unit (ICU) and cardiac ward, HT assessment, HT procedure and associated ICU and ward stay, follow-up readmissions to the ICU or ward, outpatient visits, investigations, blood tests, and drugs. Resource use data were also collected for all adverse events. Key cost results were converted to US $ using an exchange rate of £1 = $1.60.

Cost-effectiveness model

A multistate probabilistic model was used to extrapolate survival, utility, and resource use over the total lifetime of 100 hypothetical patients (UNOS status 1A + 1B: urgent listed cardiac transplant candidates at risk of imminent death from non-reversible left ventricular failure). We adopted an existing natural history model developed by Sharples et al[1,23] (Figure 1). The same structure depicted in Figure 1 was used for conventionally treated patients, with LVAD replaced by conventional therapy.

The inputs to the cost-effectiveness model for survival and utilities are summarized in Table 1. Probability distributions for the survival rates of BTT patients were parameterized as beta distributions using the number of deaths and survivals at each point in time. Mean survival rates for the conventionally treated patients[18] and post-HT survival rates[22] are assumed not to vary, reflecting the large sample size from which these estimates were derived. Monthly transition probabilities were derived from the survival rates reported in Table 1. Transition probabilities are not constant but dependent on the time spent in the previous health state. Time-dependent transition probabilities are modelled as piecewise constant probabilities (based on the exponential distribution) between the intervals indicated in Table 1.[1,25]

Survival data of patients while implanted with HeartMate II are available for up to 18 months, and so this becomes the maximum waiting time for HT in our model. Post-HT estimates are available for up to 7 years, and so extrapolation beyond is done assuming a constant hazard rate for the remaining lifetime of the Markov model. The effect of this extrapolation on the incremental cost-effectiveness ratio (ICER) is investigated by exploring different time-horizons in the sensitivity analysis.

Each month, a given state—alive with LVAD, alive with conventional therapy, or alive with HT—was associated with a utility value, resource use, and costs components. Utility parameters are modelled as beta distributions.[26] The cost inputs to the cost-effectiveness model are summarized in Table 2, as originally reported by Sharples et al.[23] Gamma distributions are used to model uncertainty around the mean cost for those costs inputs assumed to vary according to Sharples et al.[23] The LVAD device cost is considered fixed because its price is determined by the manufacturer.[27] Probabilistic distributions were fitted by method of moments, where the mean and standard errors reported[23] are equated to the estimates of mean and standard error of the given distribution, and these equations are then solved to give the appropriate distribution parameters.[27]

To estimate the present value of future costs and benefits, an annual discount rate of 3.5% was adopted for both costs and benefits. Results are presented as total lifetime, QALYs, and costs with their associated 95% CIs. Comparisons between the 2 treatment strategies were made by means of the ICER for both LYGs and QALYs.

Table 1 Survival and Utilities Inputs to the Cost-Effectiveness Model

Variable	Mean (%)	SE	Beta distribution: Parameter α	Beta distribution: Parameter β
Survival rates[a]				
ConvT				
6 months	76	N/A	N/A	N/A
1 year	69	N/A	N/A	N/A
18 months	63	N/A	N/A	N/A
LVAD implant				
1 month	92	0.016	258	23
6 months	82	0.033	109	24
18 months	72	0.059	42	16
Post-HT				
3 months	93	N/A	N/A	N/A
7 years	65	N/A	N/A	N/A
Utility values				
ConvT	0.500	0.092	6.5	6.5
LVAD implant				
Month 1	0.510	0.056	35.7	34.3
Month 2+	0.660	0.015	46.2	23.8
Post-HT	0.760	0.015	58.5	18.5

ConvT, conventional therapy; HT, heart transplant; LVAD, left ventricular assist device; N/A, not applicable; SE, standard error.

[a]Monthly transition probabilities were derived from these survival rates.

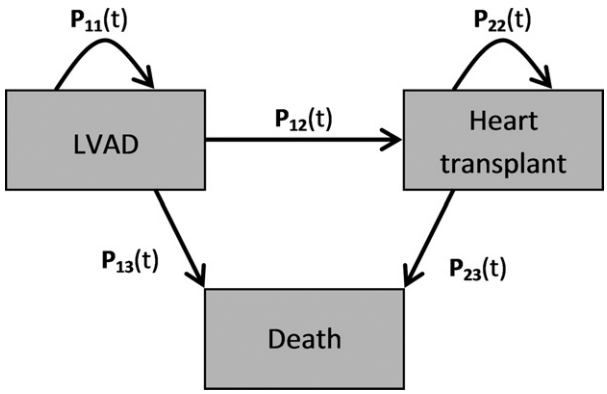

Figure 1 Semi-Markov discrete-time (monthly cycles) multistate model for left ventricular assist device (LVAD) patients. P_{11}, probability of a LVAD patient surviving *t* months after LVAD implant; P_{12}: all patients undergo transplantation after a pre-specified *t* months after LVAD implant; P_{13}, probability of a LVAD patient dying *t* months after LVAD implant, before heart transplantation (HT); P_{22}, probability of a transplant recipient surviving *t* months after HT; P_{23}: probability of a transplant recipient dying *t* months after HT.

Sensitivity analysis

A sensitivity analysis was designed to investigate how parameters uncertainty and model assumptions influence results and their generalizability. A probabilistic model provides an ideal framework for a probabilistic sensitivity analysis by incorporating the uncertainty in the model parameters where it still remains. The sensitivity of conclusions relative to the model assumptions are assessed by means of the following one-way sensitivity analyses:

1. Because donor hearts are expected to become scarcer in the future, this analysis assesses the sensitivity of conclusions to an extension in the waiting time for a HT from 6 to 12 and 18 months.

Table 2 Cost Inputs to the Cost-Effectiveness Model (£ Sterling)

			Gamma distribution	
Event	Mean (£)	SE (£)	Parameter α	Parameter β
HeartMate II device	94,200	N/A	N/A	N/A
LVAD implant procedure	19,628	2,120	85.7	229.1
Post-LVAD implant				
Month 1	25,601	1,669	235.3	108.8
Month 2	13,348	1,297	106.0	126.0
Month 3	5,075	759	44.7	113.5
Month 4	3,810	602	40.0	95.2
Month 5	3,226	457	49.9	64.6
Month 6	2,310	354	42.7	54.1
Month 7+	1,880	901	4.4	432.0
ConvT				
HT assessment	1,621	N/A	N/A	N/A
Treated Month 1	12,133	2,526	23.1	525.9
Treated Month 2	6,350	1,320	23.1	274.5
Treated Month 3+	5,925	423	196.6	30.1
HT surgery (both groups)				
Peri-op/post-op	16,933	N/A	N/A	N/A
Theater for HT				
LVAD patient	16,550	N/A	N/A	N/A
ConvT patient	11,317	N/A	N/A	N/A
Post-HT patients				
LVAD Month 1	15,471	1,667	86.1	179.6
ConvT Month 1	13,120	969	183.5	71.5
Post-HT, both groups				
Month 2	4,301	694	38.4	112.1
Month 3	2,591	407	40.4	64.1
Month 4	2,808	226	154.9	18.1
Month 5	2,164	374	33.4	64.8
Month 6	1,634	119	187.6	8.7
Month 7+	1,401	154	82.7	16.9

ConvT, conventional therapy; HT, heart transplant, LVAD, left ventricular assist device; N/A, not applicable, SE standard error.

2. The base-case considers the complete lifetime of the simulated cohort. Shorter time-horizons are expected to result in less favorable ICERs for the LVAD strategy.[1] This analysis investigates the sensitivity of conclusions to a time-horizon of 10 years to better reflect the data collection period.
3. The high acquisition cost of HeartMate II is one of the major causes for the elevated cost associated to the BTT strategy: £78,500 in all European Union countries +20% UK value added tax = £94,200 ($150,720; personal communication in October 2011 by Thoratec Europe Ltd).
4. To assess the sensitivity of the cost-effectiveness conclusions to future device price fluctuations,[28] we did a threshold analysis to identify the price at which the HeartMate II would be cost-effective, starting with a hypothetical scenario where the device is free of charge.[29]

Results

For the base-case scenario with a bridging interval of 6 months (Table 3), the average HeartMate II patient had a mean survival of 9.19 years and 6.93 QALYs. For conventionally treated patients, the corresponding values were 8.54 years and 6.38 QALYs. Thus, the mean survival gained by HeartMate II was 0.65 life-years and 0.55 QALYs.

The average lifetime cost for a LVAD implanted patient was £350,939, whereas the cost for managing a conventionally treated patient was £208,444, resulting in a difference of £142,495. Thus, the average ICER for a LYG is £219,705, whereas the average ICER for a QALY is £258,922 ($414,275). Table 3 also presents results when the bridging interval is extended from 6 to 12 and 18 months, which inflated the survival gained by HeartMate II and therefore reduced the ICER for a QALY from £258,922 ($414,275) to £178,829 ($286,126) and £133,860 ($214,176), respectively.

To overcome the problems faced when estimating the CI of a ratio,[30] ICER results are presented on the cost-effectiveness plane. Figure 2 displays 1,000 replications of the ICER results derived from 100 hypothetical patients for the 3 bridging intervals. Threshold lines are added to show the proportion of replications below a specified threshold. These thresholds represent the maximum willingness to pay (eg, £30,000) by the decision maker for an additional QALY.[30]

Table 3 Results From the Cost-Effectiveness Model for the Base-Case and Sensitivity Analyses on the Waiting Time to Receive a Heart Transplant

	Base-case	Sensitivity analyses	
Waiting time for HT	6-month interval	12-month interval	18-month interval
(Time horizon; device cost)	(Lifetime horizon; £94,200)	(Lifetime horizon; £94,200)	(Lifetime horizon; £94,200)
	Mean (95% CI)	Mean (95% CI)	Mean (95% CI)
Survival (LYs)			
LVAD	9.19 (8.48–9.91)	8.99 (8.34–9.65)	8.87 (7.84–9.91)
ConvT	8.54	8.19	7.95
Diff. survival (LYG)	0.65 (–0.06 to 1.36)	0.80 (0.15–1.46)	0.92 (–0.11 to 1.96)
QALYs			
LVAD	6.93 (5.94–7.93)	6.76 (5.84–7.69)	6.62 (5.54–7.69)
ConvT	6.38 (5.61–7.16)	6.04 (5.31–6.78)	5.76 (5.04–6.48)
Diff QALYs	0.55 (-0.01–1.11)	0.72 (0.16–1.28)	0.86 (0.02–1.69)
Costs (£)			
LVAD	350,939 (311,726–390,151)	347,216 (313,018–381,414)	344,170 (303,118–385,222)
ConvT	208,444 (178,835–238,053)	218,630 (190,796–246,464)	229,638 (198,472–260,804)
Diff. Costs	142,495 (116,413–168,578)	128,586 (108,801–148,371)	114,532 (80,689–148,376)
	£ (US$)	£ (US$)	£ (US$)
Mean ICER			
For a LYG	219,705 (351,528)	160,388 ($256,621)	124,066 (198,506)
For a QALY	258,922 (414,275)	178,829 ($286,126)	133,860 (214,176)

CI, confidence interval; ConvT, conventional therapy; Diff, difference; HT, heart transplant; ICER, incremental cost-effectiveness ratio; LVAD, left ventricular assist device; LYG, life-year gained; QALY, quality-adjusted life-year.

The probability that an acceptability criterion threshold is met by HeartMate II can be calculated based on the proportion of replications falling below the specified threshold (Figure 3). Figure 3 indicates that for the base-case scenario (a 6-month bridging interval), the 95% CI of the ICER can be found between £140,000 and £980,000 per QALY (2-sided $p = 0.05$). Likewise, 95% of the replications fall below the £670,000/QALY threshold (1-sided $p = 0.05$). When the bridging interval is extended from 6 to 12 months, the 95% CI becomes £108,000 to £640,000/QALY, with 95% of the replications falling below the £440,000/QALY threshold. For an 18-month interval, the 95% CI is £65,000 to £780,000/QALY, with 95% of the replications falling below the £440,000/QALY threshold.

Table 4 presents the cost-effectiveness results obtained when the HeartMate II is given free of charge. In such an implausible scenario, the average ICER per QALY would decrease from £258,922 ($414,275) to £85,897 ($137,435). When the bridging interval is extended from 6 to 12 and 18 months, the average ICER per QALY is reduced from £85,897 $137,435) to £47,140 ($75,424) and £24,063 ($38,501), respectively. Unsurprisingly, when shrinking the time-horizon from lifetime to 10 years, the ICER increases substantially (Table 4). On the whole, results show that the ICER is largely driven by the incremental LYG while implanted with the LVAD and its acquisition cost.

Discussion

According to a 2008 review[10] on the cost-effectiveness of LVADs as BTT or destination therapy, only 4 studies reported results in cost-effectiveness terms. We add to these data by providing a cost-effectiveness evaluation specific to the HeartMate II, reporting costs per LYG and QALY in a probabilistic manner. Ultimately, this analysis intends to aid decision making regarding reimbursement of the LVAD by the public health service.[11]

One limitation of this study is that the model does not incorporate the potential benefit of LVAD after HT. Some have argued that LVAD not only increases patient survival while implanted but that the benefit (in form of less deteriorated organs function vs conventionally treated patients) is also carried forward once the patient receives a donor heart.[31] We decided that this hypothesis was not corroborated by sufficiently compelling scientific evidence[22,23] and did not include it in the analysis. Another limitation is that the survival estimate applied to patients treated conventionally while listed for HT may slightly overestimate the true survival due to the presence of a small proportion of LVAD-implanted patients in the registry database form where it was derived. Therefore, results of this study should be interpreted with caution.

A recent study[15] reports an improvement in survival in HeartMate II patients compared with the survival estimate used here.[14] The authors suggest that the observed improve-

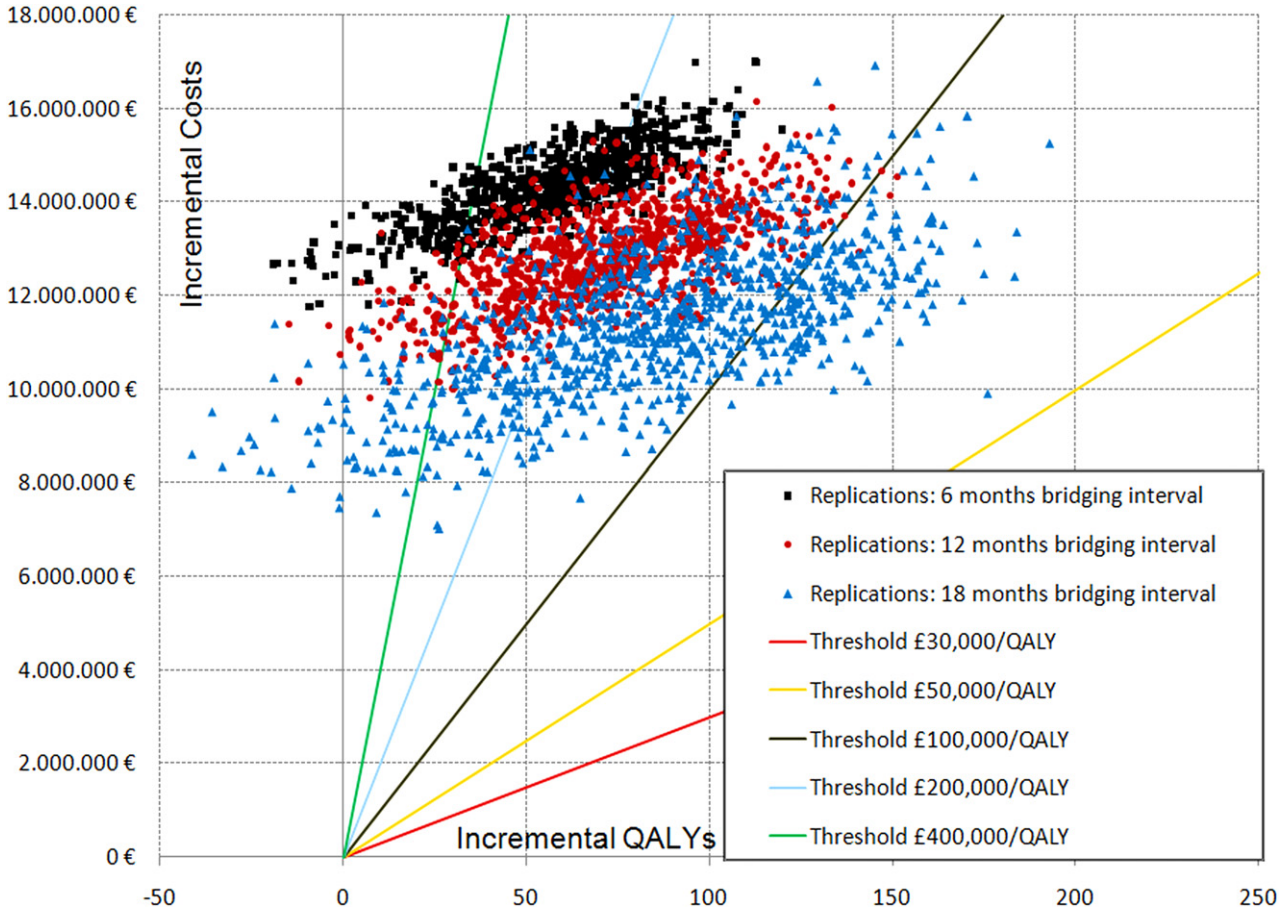

Figure 2 Cost-effectiveness plane displays 1,000 replications of the incremental cost-effectiveness ratio per quality-adjusted life-year (QALY) for each bridging interval (6, 12 and 18 months), based on 100 hypothetical patients.

ment is due to the better management practices for LVAD gained from experience with the device. In our opinion, the survival improvement could be also explained by the inclusion in their study of less ill patients compared with Pagani et al.[14] Although Pagani et al[14] only included HeartMate II patients urgently listed for HT UNOS as status 1(1A + 1B), Starling et al[15] additionally included patients not yet listed for HT as well as patients in UNOS status 2 (not inotrope dependent; INTERMACS profiles 4–7).[32]

A common concern in health technology assessment regarding simulation studies is the insufficient generalizability of their results to real life. We have tried to increase generalizability by taking into consideration (1) the uncertainty in model parameters though a probabilistic analysis, and (2) a sensitivity analysis on model assumptions. Despite this, limitations in the quality of the evidence base limit the extent to which the findings of this evaluation can be generalized.

The latest economic evaluation of LVADs [23] reported a negative ICER because LVAD implantation was more expensive and provided less survival than conventional therapy. Our findings are not encouraging either, because HeartMate II implantation is only cost-effective at the generally accepted threshold for the UK of £30,000 ($48,000) per QALY[33] in one extreme scenario; that is, only when the device is implanted for at least 18 months before HT and is given free of charge, whereas the average waiting time to receive a HT is 6 months at present and the purchase price of the device in the UK is £94,200 ($150,720). Thus, we can conclude that small increases in the average waiting time to receive a HT and/or device price reductions are not expected to make HeartMate II a cost-effective strategy. For all other scenarios investigated, the probability that HeartMate II implantation is a cost-effective strategy is negligible. These results indicate that use of HeartMate II as a BTT does not represent an efficient use of resources for the UK NHS.

The National Institute for Health and Clinical Excellence (NICE) would only justify increasing this established threshold when all the criteria referred to next is satisfied[34]:

1. The treatment is indicated for patients with a short life expectancy, normally less than 24 months.
2. There is sufficient evidence to indicate that the treatment offers an extension to life, normally of at least an additional 3 months, compared with current UK NHS treatment.
3. The treatment is licensed or otherwise indicated for small patient populations.

Robust clinical evidence satisfies the first 2 criteria but not the last one because end-stage heart failure is a prevalent disease. Moreover, it is difficult to recommend HeartMate II

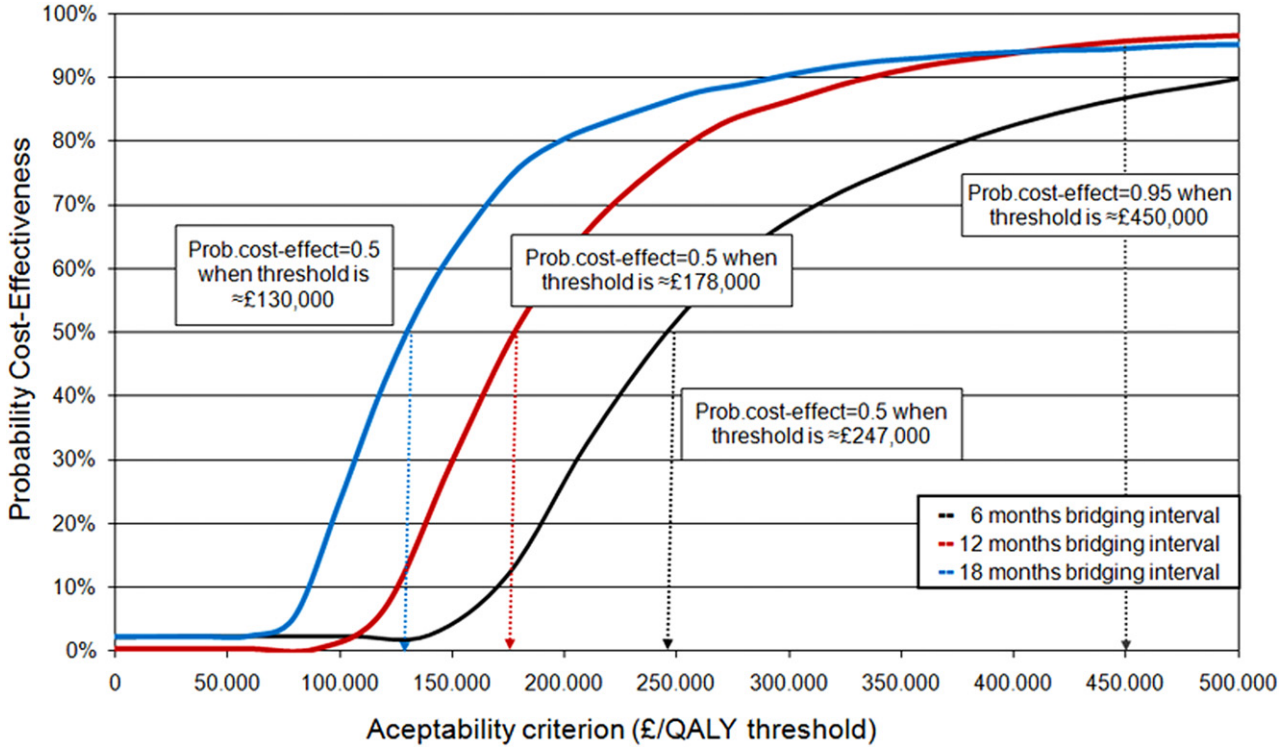

Figure 3 Cost-effectiveness acceptability curve derived from data on Figure 2.

over other LVADs owing to the lack of randomized evidence from head-to-head studies.[15]

The ever-decreasing availability of donor hearts will force doctors prioritize donor hearts even further. In our opinion, when doctors face the decision to initiate transplantation in a patient at risk of imminent death or a patient who is receiving LVAD support and is no longer at imminent risk, doctors will be reluctant to proceed with the latter

Table 4 Results from the Cost-Effectiveness Model for the Sensitivity Analyses on the Time Horizon and Device Cost Over Different Heart Transplant Waiting Times

Waiting time for HT (time horizon; device cost)	6-month interval (10 years horizon; £94,200)	6-month interval (Lifetime horizon; £0)	12-month interval (Lifetime horizon; £0)	18-month interval (Lifetime horizon; £0)
	Mean (95% CI)	Mean (95% CI)	Mean (95% CI)	Mean (95% CI)
Survival (LYs)				
LVAD	5.35 (5.01–5.70)	9.22 (8.52–9.91)	9.01 (8.19–9.83)	8.91 (7.92–9.90)
ConvT	4.98	8.54	8.19	7.95
Diff. survival (LYG)	0.37 (0.02–0.72)	0.68 (−0.02–1.37)	0.82 (0.00–1.64)	0.95 (−0.05–1.97)
QALYs				
LVAD	4.03 (3.50–4.56)	6.96 (5.96–7.96)	6.76 (5.75–7.77)	6.62 (5.57–7.67)
ConvT	3.69 (3.25–4.13)	6.39 (5.60–7.18)	6.03 (5.28–6.79)	5.74 (5.03–6.45)
Diff. QALYs	0.34 (0.05–0.62)	0.57 (0.04–1.11)	0.73 (0.09–1.37)	0.88 (0.06–1.71)
Costs (£)				
LVAD	286,599 (266,975–306,224)	258,047 (221,961–294,132)	253,187 (216,329–290,044)	251,650 (212,869–290,430)
ConvT	148,352 (132,461–164,243)	208,884 (179,394–238,375)	218,815 (191,315–246,314)	230,459 (202,503–258,415)
Diff. Costs	138,247 (125,673–150,822)	49,162 (29,423–68,902)	34,372 (10,000–58,744)	21,191 (−10,620 to 53,002)
	£ ($)	£ ($)	£ ($)	£ ($)
Mean ICER				
For a LYG	372,553 (596,084)	72,687 (116,299)	42,013 (67,220)	22,102 (35,364)
For a QALY	411,227 (657,962)	85,897 (137,435)	47,140 (75,424)	24,063 (38,501)

CI, confidence interval; ConvT, conventional therapy; Diff, difference; HT, heart transplant; ICER, incremental cost-effectiveness ratio; LVAD, left ventricular assist device; LYG, life-year gained; QALY, quality-adjusted life-year.

one. Consequently, originally intended BTT therapy will tend to become destination therapy. In this sense, the use of LVADs as destination therapy has been reported not to be more cost-effective than for BTT.[10,29,35] Despite this, we recommend to update the evaluation of LVAD for destination therapy, where we hope to invest future efforts.

In summary, we conclude from the results of a cost-effectiveness model populated with the latest survival data available for HeartMate II patients that its implantation as a BTT does not offer better value for money than conventional medical management. The implication from this analysis is that the recommendation for HeartMate II LVAD implantation to transplant candidates lacks justification in terms of cost-effectiveness.

Disclosure statement

None of the authors has a financial relationship with a commercial entity that has an interest in the subject of the presented manuscript or other conflicts of interest to disclose.

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