

# Clinical and cost-effectiveness of left ventricular assist devices as destination therapy for people with end-stage heart failure: A systematic review and economic evaluation

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**Objectives:** The clinical and cost-effectiveness of left ventricular assist devices as destination therapy for people with end-stage heart failure is assessed through a systematic review and economic evaluation.

**Methods:** Systematic review was performed of randomized controlled trials, quasiexperimental studies, case series, and case studies identified through searching

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eighteen electronic databases, bibliographies, and consultation with experts and manufacturers. Studies assessed survival, functional capacity, and quality of life. Cost-effectiveness was assessed through a 5-year decision analytic model to estimate the incremental cost-effectiveness ratio for using left ventricular assist devices compared with usual care.

**Results:** Six studies met the inclusion criteria, showing that left ventricular assist devices appear beneficial, improving survival and quality of life. Adverse events are a serious concern. The economic evaluation showed that left ventricular assist devices had a cost per quality adjusted life year of £170,616. Sensitivity analysis showed that the cost-effectiveness was not sensitive to changes in costs or utility.

**Conclusions:** Although left ventricular assist devices appear clinically effective as destination therapy, it is unlikely they will be cost-effective unless costs decrease or the benefits of their use increase.

**Keywords:** Heart failure, Left ventricular assist devices, Systematic review, Economic evaluation, Health technology assessment

For people with severe or end-stage heart failure (ESHF), treatment options are limited. Heart transplantation has been the only treatment that has provided substantial benefit, improving the length and quality of life (3;18). Serious shortages in donor organs have restricted the use of heart transplantation to a few (11;12;19). As a result, increasing attention has focused on the role of mechanical circulatory support, either as a replacement for the natural heart (total artificial hearts) or as a support that works in parallel with the heart (ventricular assist device). Left ventricular assist devices (LVADs), originally developed to bridge people to heart transplantation, have continued to evolve. Miniaturization, low power use, and ease of implantation, allied with decreasing costs and advances in patient care, have made LVADs an acceptable treatment option (14). With the increasing scarcity of donor organs for transplantation, people have been supported for longer periods, extending to months or even years. Inevitably, this finding has raised the possibility of using LVADs as destination therapy, providing an alternative through long-term chronic support for those awaiting heart transplantation or those ineligible for transplantation. With the fast changing nature of the technology and more than twenty different devices having been developed, uncertainty remains as to the suitability of these devices as destination therapy. Before adopting new technologies, it is important to evaluate the evidence of their benefits, risks, and costs. This study summarizes the results of a systematic review and economic evaluation commissioned by the Department of Health's Health Technology Assessment Programme to assess the evidence of the clinical and cost-effectiveness of all available LVADs used as destination therapy for people with ESHF (2).

## METHODS

We searched for published and unpublished studies using eighteen electronic databases, including Medline, Cochrane Library, and Embase, from their inception to December 2004

with no language restrictions (details of search strategy available elsewhere) (2). Also, we searched through bibliographies of related publications and contacted relevant experts and manufacturers of LVADs to identify additional references. Studies reported as abstracts or conference presentations were only considered for inclusion if adequate details of their methodology and results were provided to judge the quality and rigor of the study.

We included randomized controlled trials (RCTs), controlled clinical trials, cohort studies, case series, and case studies that evaluated currently available LVADs used as destination therapy for people 16 years of age and older with ESHF. Natural history studies were sought as it was recognized that experimental studies of this rapidly evolving technology may be scarce. These studies may provide useful evidence of effectiveness where outcomes are poor and predictable without treatment (21). We placed an emphasis on including studies that used the most rigorous study designs and that included an appropriate comparator, whether another LVAD or optimal medical management. We excluded studies if LVADs were used during the perioperative period only or as an emergency rescue strategy during an operation. Studies were included if they assessed survival, functional capacity, or quality of life as primary outcome measures. Standard criteria were used to assess the quality of included studies (1;20). Two reviewers independently applied inclusion criteria, extracted data, and assessed quality. Any differences were resolved through independent assessment by a third reviewer. We extracted standard information on study characteristics, methods, and results wherever possible to allow comparison across different studies. Clinical effectiveness was assessed through a narrative comparison of different outcomes. Differences in, or insufficient details on, study designs, outcomes used, patient characteristics, or intervention used precluded meta-analysis.

The economic evaluation developed for this study was a cost utility analysis using a decision analytic model based on a Markov approach. A detailed discussion of the

methodology used to develop the evaluation is available elsewhere (2). It compared the benefits and costs of the use of LVADs with that of usual medical care as destination therapy for people with ESHF through calculation of an incremental cost-effectiveness ratio (ICER) (6). The evaluation adopted an National Health Service and Personal Social Services perspective for costs and benefits for 2003 (UK prices). The base case focused on devices that were considered to be the most clinically effective in the systematic review. Benefits were assessed in terms of changes in patient survival and quality of life. The Randomized Evaluation of Mechanical Assistance for the Treatment of Congestive Heart Failure (REMATCH) study (15), which compared the HeartMate Vented Electric (VE) LVAD with optimal medical management, provided the only source of data measuring patient survival with an indication of time to an event through Kaplan–Meier survival curves. Although these survival curves were censored at 30 months, we extended these through survival analysis until all patients had died (60 months) to ensure all survival benefits were accounted for in the model. No studies reporting utility values for destination therapy were identified by the systematic review. Instead, we obtained utility values using a panel-based approach, mapping the Minnesota Living with Heart Failure questionnaire to utilities using different scenarios from data reported in the REMATCH study (2; 15). Costs reflected current clinical practice in the United Kingdom and originate from the systematic review, expert clinical advice, UK hospitals, and device manufacturers (Table 1) (2). Benefits were discounted at 1.5 percent and costs at 6 percent. Results were presented as incremental cost per quality-adjusted

life-years (QALYs) gained (6). One-way and multiway sensitivity analyses examining different devices, costs, utilities, efficacy, and discounting were carried out.

## RESULTS

### Systematic Review of Clinical Effectiveness

Six studies assessing the clinical effectiveness of LVADs as destination therapy for ESHF met the inclusion criteria, with studies of the HeartMate VE LVAD (15), LionHeart LVAD (7), Novacor LVAD (4;5), Toyobo LVAD (16), and Jarvik 2000 LVAD (8;10;17;22;24). Only the RCT assessing the HeartMate VE LVAD included a comparator (15), that of optimal medical management, with the remaining studies being either case studies (4;5;7;9;16) or case series (8;10;17;22;24).

### Quantity and Quality of Evidence

The methodological quality and the quality of reporting of the case series and case studies were judged to be weak. The five studies lacked rigorous study designs and allocation process, as well as providing limited information on the selection of participants, blinding, and methods of data collection (Table 2) (4;5;7;10;16;17;22;24). In contrast, the RCT comparing the use of the HeartMate VE LVAD with optimal medical management was judged to be moderate in its methodological quality and quality of reporting (15). Although it had a strong study design and appeared to use appropriate methods of allocation, it lacked an adequate description of the actual methods of randomization. The RCT was judged to be weak in its selection of a representative patient group, a consequence of changes to the a priori selection criteria to ensure adequate enrollment. The risk of confounding was considered low as the study demonstrated that there were no significant differences between groups. Blinding of patients and treating surgeons to interventions was impossible and, despite efforts to limit the effects of observational bias through the use of independent blinded observers to judge outcomes, was judged to be methodologically weak. The validity and reliability of data collection tools was considered weak due to the limited discussion in the trial report. Reporting of withdrawals and drop-outs was thought to be methodologically strong, identifying numbers of, and reasons for, withdrawal as well as undertaking an intention to treat analysis. The external validity of the studies was assessed through a comparison of the characteristics of the different patient groups (2). Although limited information was provided, studies tend to focus on male patients 60 years of age and older who had suffered ischemic or dilated cardiomyopathy and were ineligible for heart transplantation.

### Survival

Studies showed that people supported with an LVAD had a survival benefit when compared with those on optimal

**Table 1.** Component Costs Used in the Economic Evaluation

Component	Cost (unit in £)	Event rate per patient	Total cost per patient (£)
LVAD costs			
Pre-LVAD implant assessments <sup>a</sup>	2,202	1.3125	2,891
Implant operation <sup>a</sup>	36,986	1	36,986
Follow-up outpatient visit <sup>a</sup>	99	6	595
Readmissions <sup>a</sup>	5,391	3	16,174
Total charge excluding device			56,645
HeartMate/Novacor devices <sup>b</sup>			48,000
MicroMed DeBakey device <sup>b</sup>			35,000
Jarvik device <sup>c</sup>			40,948 <sup>d</sup>
LVAD ongoing management costs <sup>a</sup>	Quarterly		4,192
Medical management <sup>a</sup>	Quarterly		1,382

<sup>a</sup> Caine N, Papworth Hospital NHS Trust, unpublished data, 2004.

<sup>b</sup> MicroMed Technology, Inc., unpublished data, 2003.

<sup>c</sup> Jarvik Heart, Inc., unpublished data, 2003.

<sup>d</sup> U.S. costs converted to UK£ at \$1.8316 = £1 (*Wall Street Journal Europe*, 9 January 2004).

LVAD, left ventricular assist device.

**Table 2.** Methodological Quality and Quality of Reporting of Studies

Study	Study design & comparator	Design & allocation	Selection	Confounding	Blinding	Data collection	Withdrawals	Intention to treat
HeartMate LVAD Rose et al. (15)	RCT (Optimal medical management)	Moderate	Weak	Strong	Weak	Weak	Strong	Yes
LionHeart LVAD El Banayosy et al. (7)	Case reports (No comparator)	Weak	Weak	Not applicable	Weak	Weak	Not applicable	Not applicable
Novacor LVAD Dohmen et al. (4;5)	Case report (No comparator)	Weak	Weak	Not applicable	Weak	Weak	Not applicable	Not applicable
Toyobo LVAD Seki et al. (16)	Case report (No comparator)	Weak	Weak	Not applicable	Weak	Weak	Not applicable	Not applicable
Jarvik 2000 LVAD Frazier et al. (9)	Case report (No comparator)	Weak	Weak	Not applicable	Weak	Weak	Not applicable	Not applicable
Frazier et al. (10)	Case series (No comparator)	Weak	Weak	Not applicable	Weak	Weak	Not applicable	Not applicable

*Note.* The different criteria were rated following the guidelines provided by Thomas and colleagues (20), with some adaptations. Where criteria are rated as weak, moderate, or strong, it relates to the study's methodological control of the criteria. As such, if a study is rated as strong, it indicates that there is a low risk of bias for the particular criteria. Where a component is considered not to be relevant to a study design, it is referred to as not applicable. LVAD, left ventricular assist device; RCT, randomized controlled trial.

medical management or to the natural history of ESHF (Table 3). The REMATCH trial reported that the HeartMate VE LVAD provided a statistically significant 48 percent reduction in the risk of death from any cause at 30 months compared with optimal medical management (15). Actuarial survival was significantly higher for people with the HeartMate VE LVAD compared with optimal medical management at 1 year (survival difference 27 percent) and 2 years (survival difference 15 percent) follow-up. Survival benefits from the HeartMate LVAD were evident for people 60 years of age and younger and those 60 to 69 years of age at 1-year follow-up. Studies of other devices were limited to case studies or case series with no comparator, providing only an indication of any additional benefit gained when compared with the natural history of the ESHF. A series of six case studies of the LionHeart LVAD showed all survived implantation of the device and that 50 percent survived to 18 months postimplantation (7). Case studies of the Novacor and Toyobo LVADs reported that a patient receiving a Novacor LVAD survived for over 4 years before dying (4;5) and a patient receiving a Toyobo LVAD was still alive after 6 months (16). A case series of seven patients who received a Jarvik 2000 LVAD reported that five continued to undergo support (8;10;17;22;24). Mean survival for the four patients at the UK center was 502 days (range, 95 to 889 days) and for the 3 patients at the German center was 93 days (range, 66 days to 145 days). A separate case report of the Jarvik 2000 LVAD reported survival of a patient until discharge 6 weeks after implantation (9).

### Functional Status

Changes to functional status were assessed in the REMATCH trial and a case series (15;23). The REMATCH trial showed that significantly more patients surviving on the HeartMate LVAD experienced improvement in their functional status on the New York Heart Association (NYHA) functional classification (baseline 100 percent NYHA IV; 12 months 100 percent NYHA II) compared with those on optimal medical management (baseline 100 percent NYHA IV; 12 months 64 percent NYHA IV) (15). Similar improvements on NYHA functional classification were reported in a case series for three patients with Jarvik 2000 LVAD (baseline 100 percent NYHA IV; 4 weeks postimplantation 66 percent NYHA I, 33 percent NYHA II) (23).

### Quality of Life

The REMATCH trial and a case series of the Jarvik 2000 LVAD provided the only evidence on changes in quality of life following LVAD implantation (Table 4) (15;23). Patients with the HeartMate LVAD reported a significantly better quality of life at 12 months after device implantation on the physical function and emotional role subscales of the thirty-six item Medical Outcomes Study Short-Form General Health Survey and on the Beck Depression Inventory when compared with patients on optimal medical management (15). Similar improvements were shown on the Minnesota Living with Heart Failure questionnaire, although differences were not statistically significant. A case series of

**Table 3.** Summary of Evidence of the Effect of LVADs on Patient Survival

Study	Outcomes	LVAD	Comparison	<i>p</i> value
<b>HeartMate LVAD</b>				
Rose et al. (15)	Survival at 1 year (actuarial)	52%	25%	=.002
	Survival at 2 years (actuarial)	23%	8%	=.09
	Median survival	408 days	150 days	
	Death from any cause (Kaplan–Meier analysis over 30 months)	RR, .52; 95% CI, .34–.78; <i>p</i> = .001		
	1-year survival in patients 60 years old and younger	74% ( <i>n</i> = 13)	33% ( <i>n</i> = 9)	=.05
	1-year survival inpatients 60 to 69 years old	47% ( <i>n</i> = 29)	15% ( <i>n</i> = 20)	=.009
<b>LionHeart LVAD</b>				
El Banayosy et al. (7)	Operative mortality	100% survived implantation ( <i>n</i> = 6)	No comparator	Not applicable
	Survival at 18 months postimplantation	50% survived ( <i>n</i> = 6). 3 patients died at 17, 31, and 112 days	No comparator	Not applicable
<b>Novacor LVAD</b>				
Dohmen et al. (4;5)	Survival	Patient survived 1,514 days and died of causes unrelated to the pump	No comparator	Not applicable
<b>Toyobo LVAD</b>				
Seki et al. (16)	Survival	Patient died 190 days after surgery	No comparator	Not applicable
<b>Jarvik 2000 LVAD</b>				
Frazier et al. (9)	Survival postimplantation	Patient survived for 6 weeks until discharged	No comparator	Not applicable
Westaby et al. (23) and Frazier et al. (10)	Survival	UK study ( <i>n</i> = 4): 3 patients left hospital within 4 weeks (one report states that 3 patients left hospital within 3–8 weeks), 2 patients died at 95 days and 382 days; the surviving 2 patients were still supported after 642 and 889 days. German study ( <i>n</i> = 3): 3 patients surviving at follow-up	No comparator	Not applicable

LVAD, left ventricular assist device; RR, relative risk; CI, confidence interval.

**Table 4.** Summary of Evidence of Quality of Life of Patients

Outcomes	Intervention	Comparison	<i>p</i> value
Rose et al. (15)			
Quality of life/function at 12 months			
Physical function	No. assessed: 23/24 (96%) Score: 46 (SD 19)	No. assessed: 6/11 (55%) Score: 21 (SD 21)	=.01
Emotional role	No. assessed: 23/24 (96%) Score: 64 (SD 45)	No. assessed: 6/11 (55%) Score: 17 (SD 28)	=.03
Minnesota Living with Heart Failure score	No. assessed: 23/24 (96%) Score: 41 (SD 22)	No. assessed: 6/11 (55%) Score: 58 (SD 21)	=.11
Beck Depression Inventory	No. assessed: 22/24 (92%) Score: 8 (SD 7)	No. assessed: 5/11 (45%) Score: 13 (SD 7)	=.04
Westaby et al. (23)			
Minnesota Living with Heart Failure score	UK study ( <i>n</i> = 4) Patient 1: Pre-LVAD 89, Post-LVAD 24 Patient 2: Pre-LVAD 76, Post-LVAD died Patient 3: Pre-LVAD 83, Post-LVAD 38 Patient 4: Pre-LVAD 87, Post-LVAD 45 German study ( <i>n</i> = 3) Pre-LVAD 75.2 (SD 11.4), Postimplant (2 months) 30.0 (SD 18.6)	Not applicable	Not applicable
		Not applicable	Not applicable

LVAD, left ventricular assist device.

seven patients with the Jarvik 2000 LVAD showed that quality of life of the surviving patients improved following implantation of the device (23).

### Adverse Events

Serious adverse events were common among people with ESHF who received either an LVAD or optimal medical therapy. People receiving a HeartMate LVAD were twice as likely to suffer a serious adverse event as those on optimal medical management (rate ratio [RR], 2.35; 95 percent confidence interval [CI], 1.86–2.95), with significantly higher rates of non-neurological bleeding (RR, 9.47; 95 percent CI, 2.30–38.90) and neurologic dysfunction (RR, 4.35; 95 percent CI, 1.31–14.50) (15). Also those with a HeartMate LVAD had higher rates of supraventricular arrhythmias (RR, 3.92; 95 percent CI, .47–32.40), sepsis (RR, 2.03; 95 percent CI, .99–4.13), local infection (RR, 1.63; 95 percent CI, .72–3.70), renal failure (RR, 1.42; 95 percent CI, .54–3.71), miscellaneous adverse events (RR, 1.41; 95 percent CI, .93–2.12), syncope (RR, 1.31; 95 percent CI, .12–14.40), and serious psychiatric disease (RR, 1.31; 95 percent CI, .12–14.30) than patients receiving optimal medical management. In contrast, people receiving optimal medical management had higher rates of ventricular arrhythmias (RR, .45; 95 percent CI, .22–.90), cardiac arrest (RR, .65; 95 percent CI, .21–2.00), and nonperioperative myocardial infarction (RR, .65; 95 percent CI, .04–10.30). Of the patients who died while supported by a HeartMate LVAD, 41 percent were due to sepsis, 17 percent to LVAD failure, and 10 percent to cerebrovascular disease. Some 93 percent of the deaths among optimal medical management patients were due to left ventricular dysfunction. A series of six case reports of the LionHeart LVAD showed that patients suffered from temporary hemolysis (50 percent), bleeding (50 percent), early arrhythmia (40 percent), and other adverse events (7). It was reported that none of the patients with the LionHeart LVAD were readmitted with infection, thromboembolic complications, or arrhythmias. Case studies of the Novacor (4;5) and Toyobo (16) LVADs reported that a patient with the Novacor device suffered from transient renal failure, bronchopneumonia, and febrile episodes due to device-related infection, whereas a patient with a Toyobo LVAD suffered from multiple cerebral embolisms and thrombi within the pump. The case series of seven patients with Jarvik 2000 LVADs reported a case of dyspnea, ventricular tachycardia, power supply problems, and infection (8;10;17;22;24). No other device-related malfunctions or infections were reported.

### Cost-Effectiveness of LVADs as Destination Therapy for ESHF

With no relevant cost-effectiveness studies available (2), we developed an economic evaluation to assess the cost-effectiveness of LVADs as destination therapy within the UK setting. A base case comparison of the use of the HeartMate LVAD with optimal medical management showed that

the LVAD offered an additional .6 quality-adjusted life-years (QALYs) per patient over the 5-year duration of the model at an additional cost of £102,000, producing an incremental cost per QALY of £170,616 (Table 5).

One-way sensitivity analysis has shown that the model was not sensitive to changes in costs, discount rates, or changes in utility (Table 5). Only when survival improves by 60 percent and device costs are reduced by 60 percent compared with the base case scenario does the incremental cost-effectiveness ratio approach the generally accepted cost-effectiveness thresholds for the United Kingdom (cost per QALY, £30,000) (13).

### DISCUSSION

The systematic review has revealed the lack of good quality evidence assessing the clinical effectiveness of LVADs as destination therapy for people with ESHF. Despite these limitations, it appears that LVADs are beneficial when compared with optimal medical management or to the natural history of ESHF, improving the length and quality of life of patients. However, it is evident that adverse events were associated with their use, including device malfunctions, infections, and bleeding. When comparing the various devices, the evidence was less clear due to the scarcity and poor quality of the studies available, as well as the lack of direct comparisons. Only the REMATCH trial comparing the HeartMate VE LVAD with optimal medical management had sufficient rigor to judge efficacy, showing benefit for patients with an LVAD on measures of survival, functional status, and quality of life. Studies of the Novacor, LionHeart, Toyobo, and Jarvik 2000 were of poor methodological quality with no comparator, limiting any comparison. Further investigations are needed to adequately compare the different devices, taking into account the developments in devices, implantation techniques, and patient care.

Limited evidence on the cost-effectiveness of LVADs as destination therapy necessitated the development of a *de novo* economic evaluation for the United Kingdom (2). The analysis showed that LVADs are not a cost-effective option with a cost per QALY of £170,616, which lies outside the threshold for acceptability in the United Kingdom of £30,000 per QALY (13). One-way sensitivity analysis showed that cost-effectiveness was not sensitive to changes in the costs associated with care, discount rates, or measures of utility. In fact, multiway sensitivity analysis showed that there would need to be reductions of over 60 percent in the cost of the devices as well as substantial improvements of over 60 percent in the length and quality of life of the patient for cost-effectiveness to reach a cost per QALY of £30,000. Although it is likely that the cost of devices will decline as the technology develops and diffuses, doubts remain as to the extent to which additional benefits can be achieved. Some of the uncertainty reflects limitations in the evidence on benefits and costs available, particularly for the new axial flow devices.

**Table 5.** Baseline Results and Sensitivity Analyses

Baseline results					
	LVAD	Optimal medical management		Increment	
<i>Costs per patient per 3 months</i>					
Initial 3 months (£)	87,877	1,382		86,495	
Each subsequent 3 months (6–63 months) (£)	4,192	1,382		2,811	
Utility per patient	.93	.70		.23	
<i>Cohort (100 patients)</i>					
Total cost, undiscounted (£)	11,033,131	562,991		10,470,141	
Total QALYs, undiscounted	114.60	50.07		64.53	
Total cost, discounted (£)	10,675,641	475,807		10,199,835	
Total QALYs, discounted	104.19	44.41		59.78	
Incremental cost-effectiveness ratio				£170,616	
One-way and multiway sensitivity analyses					
Parameter varied	Base case	Range of values tested		Cost per QALY (£) (range)	
Baseline	—	—	—	170,616	
Upper and lower estimates of costs	—	–20%	+20%	136,597	190,283
LVAD operation cost (£)	36,986	29,589	44,383	158,242	182,989
LVAD management cost (£)	16,769	13,415	20,123	164,300	176,932
Medical management cost (£)	5,526	4,421	16,769	154,423	172,207
HeartMate/Novacor LVADs cost (£)	48,000	38,400	57,600	154,557	186,674
MicroMed DeBakey LVAD cost (£)	48,000	28,000	42,000	137,161	160,579
Jarvik 2000 LVAD cost (£)	48,000	32,758	49,137	145,120	172,518
Improvement over REMATCH survival	Not applicable	60%	40%	49,120	61,154
Improvement over REMATCH survival/ MicroMed DeBakey VAD device cost	Not applicable	+60%/–60%	+40%/–40%	44,339	54,692
Costs discount rate	6%	3%	9%	169,638	171,656
Benefits discount rate	1.5%	0%	6%	167,059	181,491
Mean expert-based utilities					
• Baseline (pretrial)	.55	.45			
• On LVAD support	.925	.84		178,426	
• On drug therapy	.7	.57			

LVAD, Left ventricular assist device; QALY, quality-adjusted life-years; REMATCH, Randomized Evaluation of Mechanical Assistance for the Treatment of Congestive Heart Failure.

Consistent methods for undertaking systematic reviews and economic evaluations were applied, with support throughout the process from an expert advisory group of clinicians, academics, and health professionals from the United States and United Kingdom. Contact was made with manufacturers, the major specialist centers implanting LVADs in the United Kingdom, and authors of studies to try and obtain additional information, with varying success. The economic evaluation used the most up to date data available, with evidence from our systematic review of clinical effectiveness, patient utility data from on-going primary research using a panel-based approach, and cost data from specialist centers in the United Kingdom and device manufacturers.

Although the evaluation included different types of devices, the evidence on benefits and costs tended to focus on the more established displacement pulsatile devices, particularly the HeartMate LVAD. With the emergence of the new axial flow devices and their increasing use in clinical practice, it is inevitable that the evidence base will continue to

improve. It will be important to incorporate any emerging evidence into our systematic review and economic evaluation to ensure it accurately assesses their benefits, risks, and costs.

Several areas for research have emerged, including the epidemiology of ESHF to assess incidence, prevalence, and characteristics of sufferers; long-term (at least 5 years follow-up) RCTs focusing on head to head comparisons of different devices and optimal medical management that encompass a broad range of patient groups and assess patient survival, functional ability, quality of life, and adverse events; and economic evaluations as part of clinical trials with prospective collection of data on quality of life, utilities, resources, and costs.

## POLICY IMPLICATIONS

New developments in LVADs and the management of patients have brought optimism concerning the permanent use of LVADs for people with ESHF. The lack of alternative treatment options has increased attention on the possibility

of developing a specialist service within the United Kingdom. Despite the limited evidence assessing the effectiveness of LVADs as destination therapy, our study has shown that LVADs appear to be clinically effective, improving survival and quality of life. However, currently they are not a cost-effective option. As a consequence, it is unlikely that funding of a service within the UK National Health Service would be justified at present. Despite this outlook, it will be important to continue to fund further good quality comparative research to assess the benefits, risks, and costs of this rapidly developing technology. This research should be undertaken as part of a nationally coordinated and funded formal research program allowing the research objectives to be progressed while maintaining the skills and structure of the current service.

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