

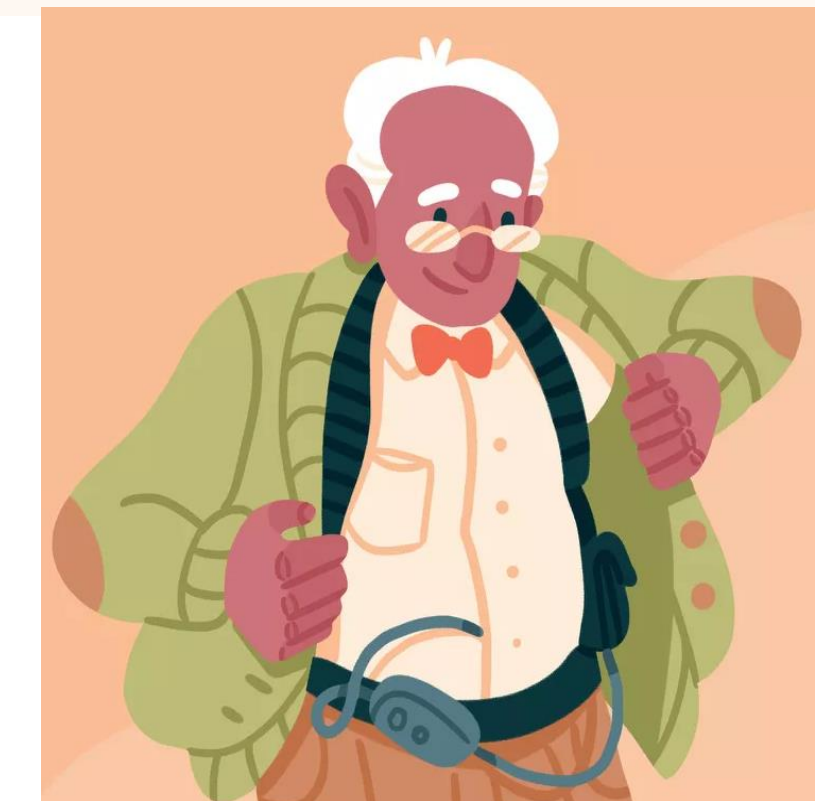
**Saygın Avşar T, Jackson L, Barton P, Beese S, Lim S, Quinn D, Price M, Moore D.**

**University of Birmingham, University of Birmingham Hospitals, University College London**



## Introduction

In the UK, Left Ventricular Assist Devices (LVADs) are not commissioned by the NHS for use in patients with advanced heart failure who are ineligible for heart transplantation (as destination therapy - DT). A systematic review of the economic evaluations of LVAD in DT patients found two recent studies that suggested LVADs were cost-effective as DT in the UK[1-3]. However, the review identified important limitations in the previous studies and concluded that it was necessary to conduct a novel evaluation. Thus, this study aimed to estimate the cost-effectiveness of LVADs as DT in the UK compared to optimal medical management (OMM).

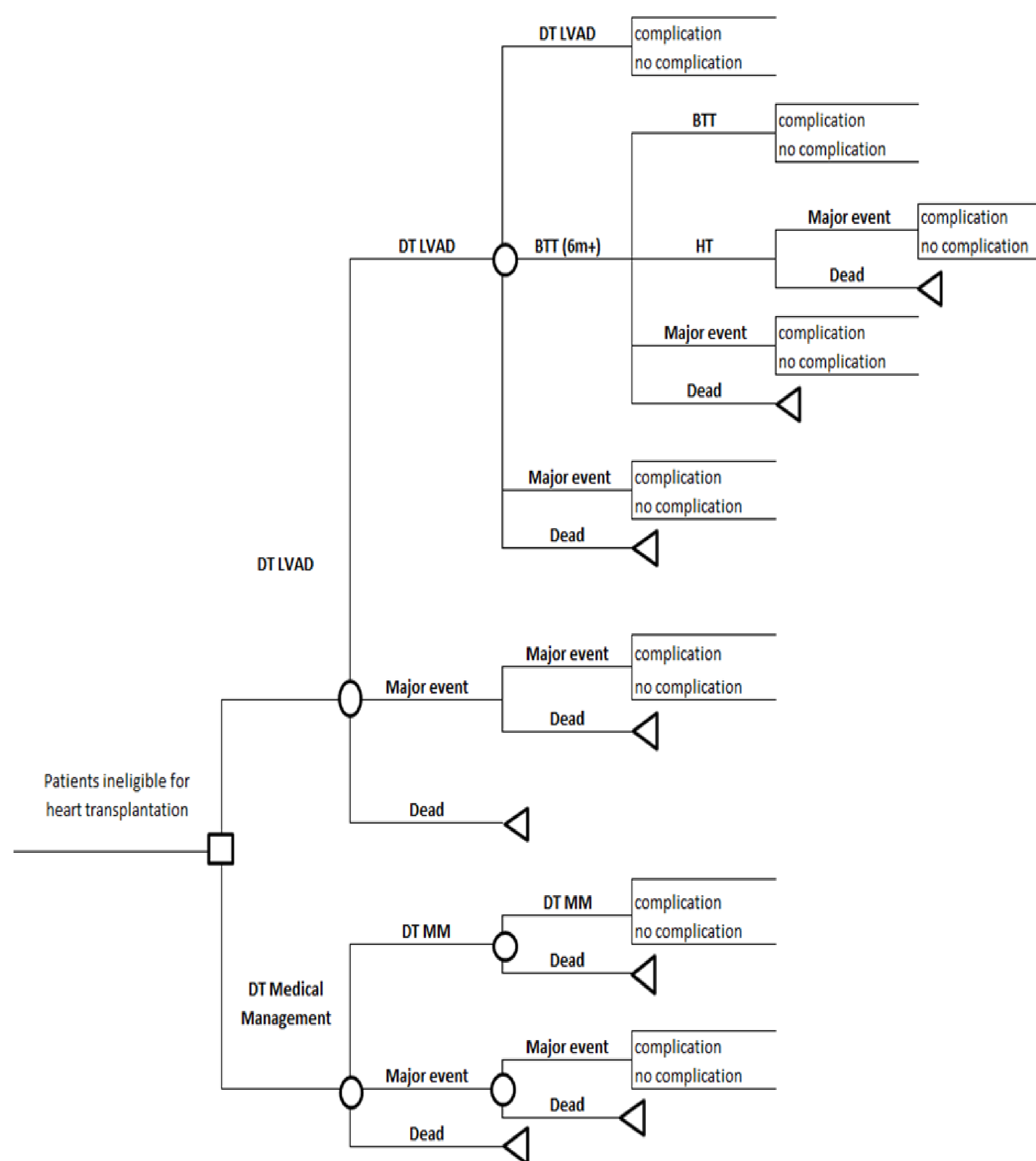


## Methods

A cost-utility analysis from an NHS perspective was conducted, using a novel Markov model with a lifetime horizon and monthly cycles. The model development was informed by systematic reviews and guidance from clinicians, patients and commissioners. The study population was a hypothetical cohort of 1,000 patients with advanced heart failure who were deemed ineligible for a heart transplantation or to be future candidates for a heart transplant. The mean age was 65 years and 50% were female. Unlike previous models, both major events and complications experienced by patients were included. A major event was defined here as any health condition which increased the long-term mortality risk substantially, and these were modelled as separate health states.

The major events identified for patients receiving LVAD were stroke, right heart failure (RHF), and aortic regurgitation (AR) and stroke for patients in the OMM group. A complication was defined as an LVAD-related health condition with no or limited impact on long-term mortality and these were incorporated given the impacts on quality-of-life and the costs.

**Figure 1.** Structure of the Bham LVAD model



Complications considered were gastrointestinal bleeding (GIB), driveline infection (DI), pump infection (PI), pump exchange (PE), and arrhythmia. Patients in the OMM group also had the risk of experiencing hospitalisation due to any reason other than stroke.

The costs were presented in UK£ at 2019 prices, and a discount rate of 3.5% was employed. The analysis was repeated incorporating the probability of transition to heart transplant (HT) for a small number of LVAD receiving patients. Exploratory sub-group analyses estimated the impact of severity of heart failure (in terms of INTERMACS profiles). Uncertainty was assessed in deterministic and probabilistic sensitivity analyses.

**Table 1.** Transitions within the Bham LVAD model

Starting state	Jump to state	Complications
<b>DT (LVAD)</b>	Death Non-disabling stroke, disabling stroke, RHF, AR, DT (LVAD)	GIB, DI, PE, AF and VF
<b>Non-disabling stroke</b>	Death Non-disabling stroke, disabling stroke, AR, RHF	GIB, DF, DI, PE, AF and VF
<b>Disabling stroke</b>	Death, disabling stroke	GIB, DF, DI, PE, AF and VF
<b>RHF</b>	Death Disabling stroke, RHF	GIB, DF, DI, PE, AF and VF
<b>AR</b>	Death RHF, disabling stroke, AR	GIB, DF, DI, PE, AF and VF
<b>OMM</b>	Death, Non-disabling stroke, disabling stroke	Re-admission for any reason

DT: destination therapy, RHF: right heart failure, AR: aortic regurgitation, GIB: gastrointestinal bleeding, DI: driveline infection, PE: pump exchange, AF: atrial fibrillation, VF: ventricular fibrillation, OMM: optimal medical management

## Results

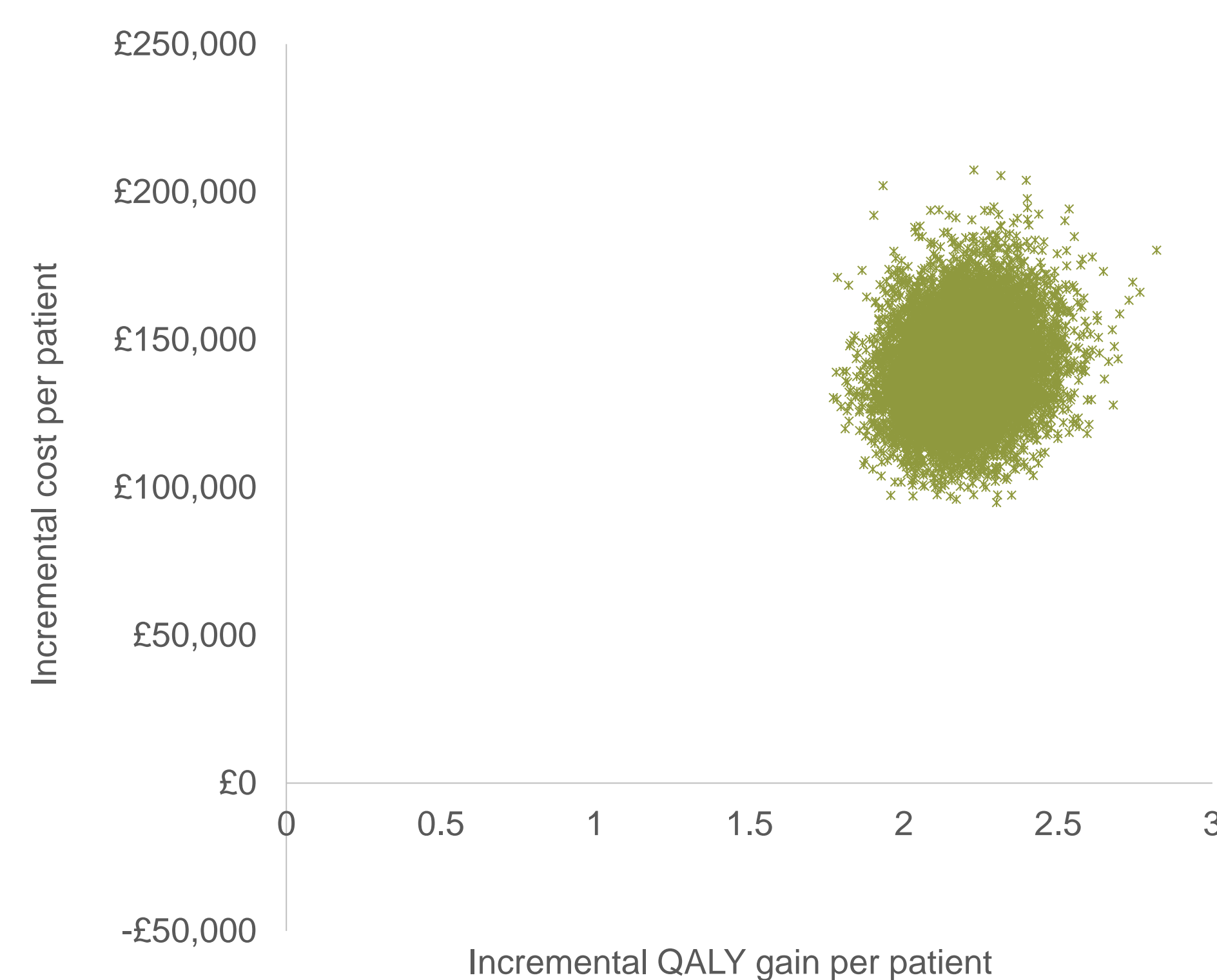
LVAD produced an additional 2.20 (95% CI 1.99 – 2.42) QALYs at an incremental cost of £140,375 (95% CI £116,889 - £166,018) compared to OMM, giving an incremental cost-effectiveness ratio (ICER) of £63,870 per QALY gained. The probability of cost-effectiveness was 2% at a threshold of £50,000 per QALY gained, reaching 100% at a threshold of £90,000.

The ICER remained above £50,000 if a small proportion of patients receiving LVAD become eligible for a heart transplant and in sub-group analyses based on INTERMACS profiles. The deterministic sensitivity analyses indicated that two parameters had substantial impacts on the model outcomes: ongoing costs for LVAD and OMM patients.

**Table 2.** Outputs of the Bham LVAD model

	OMM		LVAD		Incremental	
per patient	Mean	95% CI	Mean	95% CI	Mean	95% CI
<b>LYs</b>	0.93	0.80-1.07	3.78	3.49-4.10	2.85	2.53-3.20
<b>QALYs</b>	0.48	0.41-0.55	2.68	2.48-2.88	2.19	1.99-2.42
<b>Cost</b>	£18,925	£17,125-£20,966	£159,299	£135,929-£184,974	£140,375	£116,889-£166,018
<b>Incremental cost per QALY</b>					<b>£63,870</b>	
<b>Probability of cost-effectiveness at 50,000</b>					<b>2%</b>	

**Figure 2.** Probabilistic sensitivity analysis



## Discussion

This study overcomes many limitations of previous evaluations and provides a more extensive and robust analysis. However, it cannot overcome the major limitation of the field in that there is no head-to-head comparison between currently available LVAD and optimal medical management; and that indirect comparisons are limited due to heterogeneity between studies. Furthermore, whilst key model parameters were defined from studies involving the current device where possible, some parameters needed to be used from previous versions. However, the deterministic sensitivity analysis showed that these parameters did not have a substantial impact on the model outcomes.

## Conclusion

This study found that at a threshold of £50,000 per QALY gained LVADs as destination therapy would not be cost-effective. This is in contrast to two recent analyses. Robust data on ongoing costs for medical management are needed.