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ORIGINAL RESEARCH

Financial and resource costs of transvenous lead extraction in a high-volume lead extraction centre

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ABSTRACT

Objectives Transvenous lead extraction (TLE) poses a significant economic and resource burden on healthcare systems; however, limited data exist on its true cost. We therefore estimate real-world healthcare reimbursement costs of TLE to the UK healthcare system at a single extraction centre.

Methods Consecutive admissions entailing TLE at a high-volume UK centre between April 2013 and March 2018 were prospectively recorded in a computer registry. In the hospital's National Health Service (NHS) clinical coding/reimbursement database, 447 cases were identified. Mean reimbursement cost (n=445) and length of stay (n=447) were calculated. Ordinary least squares regressions estimated the relationship between cost (bed days) and clinical factors.

Results Mean reimbursement cost per admission was £17 399.09±£13 966.49. Total reimbursement for all TLE admissions was £7 777 393.51. Mean length of stay was 16.3±15.16 days with a total of 7199 bed days. Implantable cardioverter-defibrillator and cardiac resynchronisation therapy defibrillator devices incurred higher reimbursement costs (70.5% and 68.7% higher, respectively, both p<0.001). Heart failure and prior valve surgery also incurred significantly higher reimbursement costs. Prior valve surgery and heart failure were associated with 8.3 (p=0.017) and 5.5 (p=0.021) additional days in hospital, respectively.

Conclusions Financial costs to the NHS from TLE are substantial. Consideration should therefore be given to cost/resource-sparing potential of leadless/extravascular cardiac devices that negate the need for TLE particularly in patients with prior valve surgery and/or heart failure. Additionally, use of antibiotic envelopes and other interventions that reduce infection risk in patients receiving transvenous leads should be considered.

INTRODUCTION

A growing number of cardiac implantable electronic devices (CIEDs) are implanted due to ageing populations, increased global healthcare spending and expanding CIED indications,[1] with a subsequent rise in the number of CIED complications[2–4] and corresponding greater need for transvenous lead extraction (TLE) procedures.[5 6] Globally, approximately 10 000–15 000 leads are extracted each year for CIED infections and/or lead malfunction,[3 7] and TLE is considered the first-line approach.[8] Despite significant advances in techniques and equipment improving procedural outcomes,[3 9 10] TLE remains associated with considerable morbidity, mortality[5 11] and a significant economic burden to healthcare systems.[1] Limited data exist on the true cost of TLE including significant procedural and consumables costs, in addition to the cost of prolonged hospital stays including critical care days. We analysed a prospectively collected TLE registry from April 2013 to March 2018 to estimate real-world healthcare reimbursement costs of TLE to the UK healthcare system.

METHODS

Details of consecutive admissions entailing TLE at a high-volume UK lead extraction centre were prospectively recorded on a computer registry from October 2000. Analyses were performed on discharge dates between April 2013 and March 2018 as cost data were not reliably available for admissions prior to April 2013. Cost and length of stay (LOS) data were extracted from the National Health Service (NHS) clinical coding and reimbursement database and applied to the TLE registry dataset.

Definitions

The 2017 Heart Rhythm Society consensus document[8] was used to define procedural techniques. LOS was calculated from time of admission to discharge at the TLE centre. UK public hospitals are reimbursed for admissions through a system of diagnosis-related groups (DRGs) that classify admissions into groups for the purpose of payment.[12] The particular DRGs used in the NHS are known as Health Resource Groups (HRGs). The HRG system identifies the 'dominant' episode of an admission assigning an HRG code based on that episode. An episode is defined as a period of care under a single consultant in a single hospital. This HRG code denotes the main activity during admission and is linked to a core HRG reimbursement amount paid by the NHS to the hospital trust[13] and is weighted according to a 'market forces factor' to reflect geographical cost variations. For this reason, UK public hospitals are generally only reimbursed for one episode per admission, even if the admission consists of multiple episodes. For example, a patient admitted for a TLE of an infected CIED who subsequently undergoes staged implantable cardioverter-defibrillator (ICD) reimplantation during the same admission would accrue two episodes during that

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admission: one for the TLE and another for ICD implantation; however, only one episode would be assigned as the dominant episode and linked to a base cost. The HRG system also assigns additional funding based on factors, such as number of bed days in excess of the threshold specified for the HRG code ('excess bed days'), number of days spent in critical care ('critical care days'), a more complex case mix ('specialist uplift') and the use of high-cost medical devices or medicines such as replacement cardiac devices ('high-cost value').[14]

We were principally concerned with the total cost to the NHS of admissions entailing TLE, which is the total reimbursement paid to the hospital trust. This is equal to the sum of the core HRG cost and all other elements of top-up reimbursement. It was not possible to identify a reimbursement cost of TLE procedures in isolation because admissions are reimbursed based on the dominant episode that may have entailed other procedures in addition to TLE or may not have entailed TLE at all (the TLE being included in a different, non-dominant episode).

Extraction procedure

TLEs were performed by experienced operators in a cardiac catheter laboratory, hybrid cardiac theatre or cardiac theatre with immediate onsite cardiothoracic surgical cover. Our extraction methods have been detailed previously.[4 6]

Cost and LOS estimation

Of the 455 TLE admissions in the registry during the 5-year study period, 447 were identified in the NHS clinical coding and reimbursement database. The cost data consisted of the core HRG reimbursement cost, including the market forces factor weighting and additional top-up reimbursement costs associated with excess bed days, critical care days, specialist uplift and high-cost medical devices and medicines. The total reimbursement amount for each admission had already been computed in the NHS clinical coding and reimbursement database as the sum of these cost variables. Of the 447 admissions for which cost and LOS data were available, two were identified as having been assigned an HRG code corresponding to a coding error and therefore had invalid reimbursement cost data. These observations were discarded for the purpose of cost analysis but retained for the LOS analysis since the LOS data remained valid. Using this complete case analysis approach, mean reimbursement cost (n=445) and LOS (n=447) were calculated.

Statistical analysis

Ordinary least squares (OLS) regressions were performed using complete case analysis. Outcome variables were log reimbursement cost and LOS. Reimbursement cost was log transformed to account for right-skew of the data. Patient-level explanatory variables were selected based on clinical experience as to those factors thought likely to be strongly correlated with the outcome variables. These included: binary variables for original pacing indications, common comorbidities (as listed in table 1), indication(s) for lead extraction, presence of positive microbiology, single/dual coil ICD leads, dummy variables for type of CIED in situ, left ventricular ejection fraction and number of patient episodes during admission. Patient age, male gender and year of discharge were included as additional control variables.

RESULTS

Overviews of outcome and explanatory variables with their respective summary descriptive statistics are shown in table 1. The 447 admissions used in the analysis consisted of 155 (34.68%) dual-chamber pacemakers, 130 (29.08%) ICDs, 106 (23.71%) cardiac resynchronisation therapy defibrillators (CRT-Ds), 29 (6.49%) CRT pacemakers (CRT-Ps) and 28 (6.26%) single-chamber pacemakers. Of the 447 TLEs, 163 (36.47%) were performed for local infection, 57 (12.75%) for systemic infection and the remainder for non-infectious indications including lead malfunction, system upgrades and venous stenosis. High-cost medical device and/or medicine costs were incurred for 305 (68.23%) admissions. Critical care day costs were incurred for 58 (12.98%) admissions.

Between April 2013 and March 2018, the mean reimbursement cost per admission was £17 399.09±£13 966.49 (median: £15 899.32), and the overall reimbursement cost to the NHS for all TLE admissions was £7 777 393.51. High-cost medical device and medicine costs accounted for £3 508 859.00 (45.12%) of the overall costs. Critical care day costs accounted for £807 365.00 (10.38%) of the overall costs. Mean LOS was 16.30±15.16 days (median: 13 days), accounting for a total of 7199 bed days. Figures 1 and 2 show histograms of reimbursement cost and LOS.

In 2017 (the most recent full calendar year data were available), mean reimbursement cost per admission was £16 270.71±£11 418.47 (median: £12 713.63) and mean LOS was 18.88±16.70 days (median: 16 days). Mean and total reimbursement cost, and mean and total LOS, are summarised by full calendar year in tables 2 and 3. Due to interval changes in HRG systems and reimbursement rates, like-for-like comparisons between years was not possible.

Regression analysis on cost

Table 4 summarises OLS regression results using log reimbursement cost as the outcome variable. Coefficients represent the percentage change in reimbursement cost associated with a one unit increase in value of the explanatory variable. The distribution of model residuals was consistent with normality. Presence of an ICD or CRT-D, prior valve surgery and heart failure were all positively and significantly correlated with reimbursement cost ($p<0.05$). All other explanatory variables were not significantly correlated with reimbursement cost.

Notably, presence of an ICD or CRT-D were associated with increased reimbursement costs of 70.5% ($p<0.001$) and 68.7% ($p<0.001$), respectively. Since ICD and CRT-Ds are the most expensive CIEDs, large coefficients on these variables might be explained by their high replacement costs when necessary. Therefore, further regression analysis was performed using reimbursement cost as the outcome variable, excluding top-up reimbursement for high-cost devices and medicines to remove differences in cost caused by the reimbursement of high-cost devices and/or medicines. In this analysis, ICD and CRT-D devices were no longer significantly correlated with reimbursement cost, indicating that correlation of these variables with reimbursement was entirely through the mechanism of high-cost device and medicine reimbursement. Since the use of high-cost medicines is rare in TLE patients, this effect is likely to be almost entirely from replacement of high-cost CIEDs. Of the 130 patients with ICDs and 106 patients with CRT-Ds, 108 (83.08%) and 86 (81.13%), respectively, incurred a high-cost medical device and/or medicine. Without controlling for other factors, the mean reimbursement cost of admissions for patients with ICDs and CRT-Ds was £21 483.38 and £24 181.28, respectively, compared with a mean cost of £10 989.75 of admissions for patients with other kinds of devices. Prior valve surgery and heart failure were also associated with an increased

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Table 1 Summary descriptive statistics

Variable	Mean	SD	Minimum	Maximum	Observed
Outcome variables					
Reimbursement cost	£17 399.09	£13 966.49	£1262.98	£141 196.20	445
Length of stay	16.29	15.16	1	95	447
Comorbidities					
CABG	0.12	0.32	0	1	445
Valve surgery and CABG	0.01	0.11	0	1	445
Cerebrovascular disease	0.10	0.31	0	1	445
Ischaemic heart disease	0.38	0.49	0	1	444
Valve surgery	0.08	0.27	0	1	445
Heart failure	0.41	0.49	0	1	445
Diabetes mellitus	0.19	0.39	0	1	445
High blood pressure	0.51	0.50	0	1	445
Respiratory	0.13	0.34	0	1	444
Peripheral vascular disease	0.04	0.19	0	1	445
Renal failure	0.23	0.42	0	1	445
≥2 comorbidities	0.58	0.49	0	1	446
≥3 comorbidities	0.40	0.49	0	1	446
Device type					
Single chamber pacemaker	0.06	0.24	0	1	445
ICD	0.29	0.46	0	1	445
CRT-P	0.07	0.25	0	1	445
CRT-D	0.24	0.43	0	1	445
Number of ICD coils					
Single coil	0.26	0.46	0	1	444
Dual coil	0.24	0.46	0	1	444
Indication for pacing					
Sinus node dysfunction	0.19	0.39	0	1	438
Sinus node dysfunction with AV block	0.01	0.10	0	1	439
Atrial fibrillation/atrial flutter	0.11	0.32	0	1	439
Second or third degree AV block	0.21	0.41	0	1	439
Congenital	0.03	0.16	0	1	439
VT or VF	0.24	0.43	0	1	439
Indication for lead extraction					
Local infection	0.36	0.48	0	1	445
Systemic infection	0.13	0.33	0	1	445
Non-infective indication	0.24	0.43	0	1	439
Other variables					
Male	0.72	0.45	0	1	446
Vegetation	0.10	0.30	0	1	320
LVEF	46.18	14.96	0	71	313
Age of patient at extraction	64.80	14.74	0.16	94.84	446
Positive microbiology	0.45	0.50	0	1	437
Number of episodes of care	1.56	0.95	1	7	447

Overviews of the outcome and explanatory variables with their respective summary descriptive statistics.
AV, atrioventricular; CABG, coronary artery bypass graft surgery; CRT-D, cardiac resynchronisation therapy defibrillator; CRT-P, cardiac resynchronisation therapy pacemaker; ICD, implantable cardioverter-defibrillator; LVEF, left ventricular ejection fraction; VF, ventricular fibrillation; VT, ventricular tachycardia.

reimbursement cost of 36.0% (p=0.015) and 28.4% (p=0.012), respectively.

Regression analysis on LOS

Table 5 summarises the OLS regression results using LOS as the outcome variable. Coefficients represent absolute change in number of bed days associated with one unit increase in value of the explanatory variable. Prior valve surgery and heart failure were both positively and significantly correlated with reimbursement cost (p<0.05). All other explanatory variables were not significantly correlated with LOS.

Prior valve surgery was associated with an increase of 8.26 bed days (p=0.017). Without controlling for other factors, mean LOS was higher for patients with prior valve surgery versus those without (27.11 vs 15.18 days). Heart failure was associated with an increase LOS of 5.5 bed days (p=0.021).

DISCUSSION

Reimbursement of lead extraction

We have identified a significant financial burden to the NHS of £7 777 393.51 associated with TLE admissions from a single

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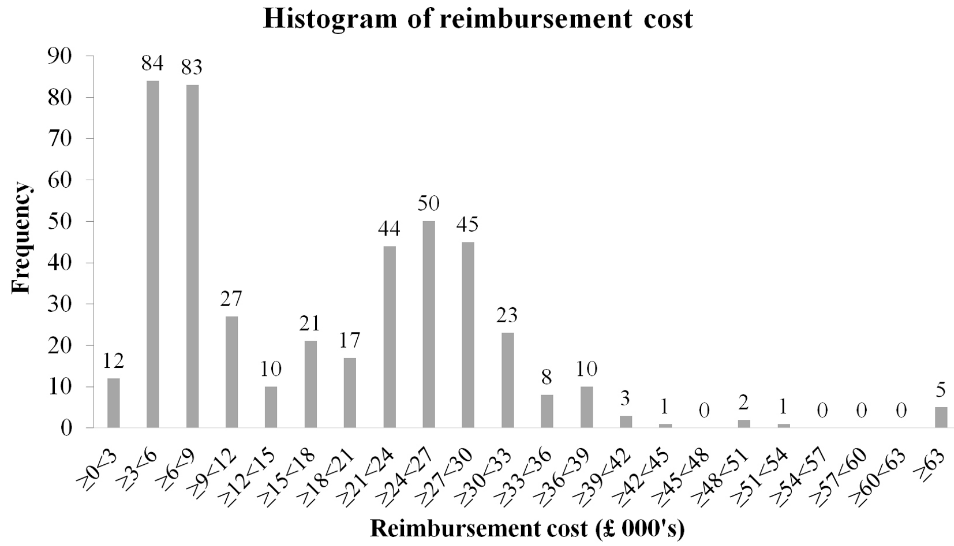

Figure 1 Histogram of reimbursement cost.

centre and a considerable resource burden on the hospital with prolonged admissions.

Drivers of reimbursement cost and LOS

ICD and CRT-Ds were associated with significantly higher reimbursement costs than other CIEDs manifested entirely through increased replacement CIED costs. Similarly, patients requiring ICD and CRT-D replacement had significantly higher overall costs than patients with other CIED types, explained by their high cost. Thus, higher costs are incurred when these devices require replacement due to infection or age of the device; however, TLE of these devices was not in itself associated with a significantly increased LOS.

Patients with heart failure had significantly longer admissions and higher reimbursement costs. Heart failure may be considered a marker of morbidity and even patients with well-controlled heart failure may decompensate during a hospital admission for lead extraction thus requiring a longer LOS. Additionally, patients with heart failure frequently require careful balance of fluid status, renal impairment and optimisation of heart failure pharmacotherapy. Furthermore, patients with heart failure are more likely to have a high-cost device extracted and/or reimplanted explaining the significantly higher reimbursement costs in such patients together with a longer LOS.

Patients with prior valve surgery incurred significantly higher reimbursement costs and spent longer in hospital than those without. Such patients were more likely to require TLE for systemic infection; however, the association with higher reimbursement cost persisted even when controlling for the incidence of systemic infection suggesting that patients undergoing TLE for systemic infection tend to be costlier if they had prior valve surgery. In cases where infection of a prosthetic heart valve or repair is identified, prolonged antibiotic treatment and/or redo valve surgery may be required, entailing an increased LOS and associated cost. Moreover, patients with mechanical valves usually require careful periprocedural anticoagulation management to minimise bleeding and thrombotic complications entailing longer LOS. Given the associated cost, usage of CIEDs that do not employ transvenous leads may be considered appropriate for patients with prior valve surgery or who are likely to undergo future valve surgery/intervention.

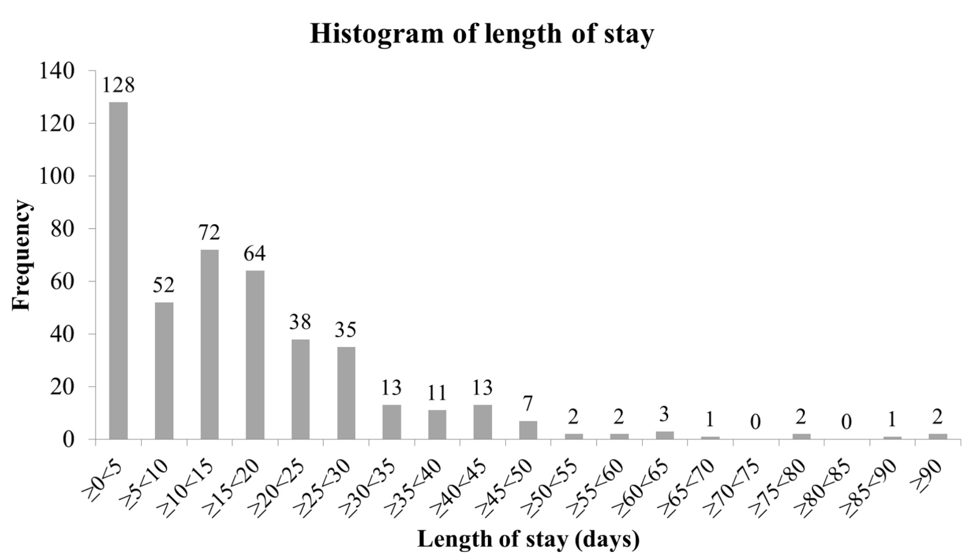

Figure 2 Histogram of length of stay.

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Table 2 Reimbursement cost and admissions by period

	2014	2015	2016	2017	April 2013–March 2018
Mean cost	£16518.42	£18769.73	£18301.23	£16270.71	£17399.09
Median cost	£15845.95	£19785.85	£17041.25	£12713.63	£15899.32
Total cost	£1 486 657.79	£1 914 512.41	£1 445 797.01	£1 610 800.72	£7 777 393.51
Admissions	89	102	79	99	447

Mean and total reimbursement cost are summarised by full calendar year. All values are presented as Great British pounds (GBP).

Comparison with previous studies

Few studies have focused on the economic effects of TLE. Ahsan *et al*[15] studied 30 patients undergoing TLE for CIED infection in the UK reporting a mean cost of £30958.40 for TLE and CIED replacement costs and a mean of 29.9±28.8 bed days per admission. In our cohort of patients undergoing TLE for infection (n=218), mean reimbursement cost was £18 963.89±£13685.22 and mean LOS was 22.76±14.73 days. Our findings suggest a substantially lower figure for both cost and LOS despite including the cost of the entire admission. The reason for this disparity is unclear but may relate to differences between included centres and time periods with the oldest admission data in the present study being approximately 4 years more recent. Furthermore, our study included a larger sample of patients with infection (n=218 vs n=30). Ahmed *et al*[16] assessed the average treatment cost of CIED infection for 84 patients undergoing TLE at a large UK tertiary referral centre, identifying an average cost of £5139 for patients with a pacemaker compared with £24318 for CRT-D. Additionally, the total cost was similar for both early and delayed reimplantation strategies (median £14241.48 vs £14 741.70) including wearable external cardioverter-defibrillators and outpatient antibiotics.[16] Brough *et al*[17] estimated costs to a single UK extraction centre of 74 TLE procedures over the financial year 2013/2014, using a microcosting approach and reported a mean cost to the hospital of £17 574±£12882. This estimate must be distinguished from our own cost findings, which identify the cost to the NHS rather than the hospital and is, therefore, not directly comparable ith our own. However, if Brough *et al*'s findings are generalised to the present study or vice versa, they suggest TLE admissions are not adequately reimbursed by the NHS. If TLE procedures and device replacement alone cost the hospital an average of £17574[17] and the average hospital reimbursement for these admissions is £17399 (present study), this leaves virtually no reimbursement to cover other elements of the admission. Importantly, the current study is the largest study to date addressing the cost to the NHS rather than the individual institution. Additionally, the present study is the first to look at drivers of reimbursement and LOS associated with TLE and the findings in this regard in prior valve surgery patients has not previously been reported.

Clinical implications

The risk profile of lead failure and CIED-related infection is believed to be higher in patients with indwelling transvenous leads compared with leadless or extravascular CIED systems. There is a trend in moving to 'leadless' endocardial CIEDs with American Heart Association and American College of Cardiology guidelines advocating subcutaneous ICDs as a class I recommendation for some patient populations.[18] Leadless right atrial pacing electrodes are also in development and entirely extravascular/subcutaneous ICD systems are available.[19–21] The common denominator with these 'leadless' or subcutaneous systems is that they do not contain indwelling transvenous leads connected to a subcutaneous or submuscular generator. When CIED-related systemic infection occurs, it is likely to arise due to the presence of transvenous leads. Given the large costs and bed stays associated with TLE, one could argue that using devices that reduce the need for future TLE may offer both clinical and economic benefits that may be particularly relevant in patients with prior valve surgery and heart failure in whom TLE is particularly costly. Furthermore, the The Worldwide Randomized Antibiotic Envelope Infection Prevention Trial (WRAP-IT) reported significantly lower incidences of infection using antibiotic envelopes compared with standard of care.[22] Burnhope *et al*[23] performed retrospective cost analyses of the antibiotic envelope in the heart failure population and identified an estimated cost saving of £624 per patient. Such strategies should be used as an adjunct to preprocedure intravenous antibiotics, strict aseptic technique and good surgical technique with careful haemostasis for all CIED procedures.

Table 3 Length of stay by period

	2014	2015	2016	2017	April 2013–March 2018
Mean	12.81	15.62	19.43	18.88	16.30
Median	9.00	13.00	19.00	16.00	13.00
Total	1153	1593	1535	1869	7199

Mean and total length of stay are summarised by full calendar year. All values are presented as length of stay (days).

Study limitations

As a single-centre, observational study, our results do not necessarily represent the overall burden across the NHS. Our findings are dependent on the hospital reimbursement system in question and, while they are broadly generalisable to any DRG-based/similar system, there may be important differences, for example,

Table 4 Ordinary least squares regression results (log reimbursement cost)

Log reimbursement cost (n=291)	Coefficient	SE	P value
Device type			
ICD	0.705**	0.165	<0.001
CRT-D	0.687**	0.179	<0.001
Comorbidities			
Prior valve surgery	0.360*	0.148	0.015
Heart failure	0.284*	0.112	0.012
Other variables			
Total number of episodes	0.125**	0.037	0.001

Ordinary least squares regression using log reimbursement cost as the outcome variable. Coefficients should be interpreted as the percentage change in reimbursement cost associated with a one unit increase in the value of the explanatory variable.

*P<0.05; **p<0.01; only variables that were significant at the 5% significance level are included.

CRT-D, cardiac resynchronisation defibrillator; ICD, implantable cardioverter-defibrillator.

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Table 5 Ordinary least squares (OLS) regression results (length of stay)

Length of stay (n=291)	Coefficient	SE	P value
Comorbidities			
Prior valve surgery	8.260*	3.442	0.017
Heart failure	5.500*	2.368	0.021
Other variables			
Total number of episodes	6.219**	0.897	<0.001

OLS regression using length of stay as the outcome variable. The results of the OLS regression using length of stay as the outcome variable are summarised in table 5. Coefficients should be interpreted as the absolute change in the number of bed days associated with a one unit increase in the value of the explanatory variable. *P<0.05; **p<0.01; only variables that were significant at the 5% significance level are included.

lower weighting factors based on local purchasing power or lack of top-up funding for expensive devices in certain countries. Since the registry included no control group and the administrative data used for our analyses included the cost and bed days associated with the entire admission, we were unable to estimate the extent to which the use of transvenous leads specifically contributed to financial and resource burdens. The costs and number of bed days incurred during the recorded admission did not include any costs or bed days incurred at referring hospitals prior to the recorded admission or at destination hospitals to which patients were transferred after the recorded admission. Therefore, although the complete LOS during the recorded admission was captured, the overall number of bed days incurred is likely to be higher than that reported. The HRG system and reimbursement rates have changed over time, and therefore costs incurred in different years are not directly comparable. Furthermore, costs recorded in a given calendar year reflect admissions both before and after changes to the HRG system and reimbursement rates. The data are therefore not instructive in relation to NHS reimbursement rates over time but rather reflect the actual costs incurred during a given period.

Key messages

What is already known on this subject?

- Transvenous lead extraction (TLE) poses a significant economic and resource burden on healthcare systems; however, limited data exist on its true cost.

What might this study add?

- To our knowledge, this is the first study to look at drivers of reimbursement and length of stay associated with TLE. Financial costs to the National Health Services (NHS) from TLE are substantial, and a considerable number of bed days are associated with these admissions representing a considerable resource burden for the hospital and the NHS.

How might this impact on clinical practice?

- Transvenous leads are associated with systemic infection. This paper suggests they are also associated with increased costs for the healthcare system. Given the large costs and bed stays associated with TLE, devices that reduce the need for TLE in the future may offer clinical and economic benefits.

CONCLUSION

We have identified a substantial financial cost to the NHS from a single high-volume UK lead extraction centre and a considerable number of bed days associated with these admissions, representing a considerable resource burden for the hospital. ICD and CRT-D devices were associated with significantly higher reimbursement cost than other device types that manifested entirely through increased replacement device costs. Notably, patients with prior valve surgery incurred significantly higher reimbursement costs and longer LOS than patients with native heart valves. Heart failure was also associated with significantly longer stays in hospital and significantly increased reimbursement costs. Given the significant cost associated with TLE, consideration should be given to the cost/resource-sparing potential of leadless/extravascular cardiac devices (including those employing subcutaneous leads) that negate the need for TLE particularly in patients with prior valve surgery and/or heart failure. In addition, use of antibiotic envelopes and other interventions that reduce infection risk in patients receiving transvenous leads should be considered.

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