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Real-world costs of transvenous lead extraction: the challenge for reimbursement

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Aims Transvenous lead extraction is challenging, often requiring specialist equipment and prolonged hospital admission. A single tariff or itemized costs may be available for reimbursement. Due to limited data relating to the costs of transvenous extraction, it is unclear whether either form of reimbursement is adequate. We aim to describe accurately the total real-world costs of managing patients undergoing transvenous extraction at a single, large centre. We further aim to consider the additional costs of device reimplantation.

Methods and results At a single UK extraction centre, a retrospective, patient level service line analysis was undertaken, during a complete financial year. Seventy-four patients required transvenous extraction (47 infected and 27 non-infected; 156 leads). Sixty-nine procedures (93%) were performed under general anaesthesia, with a median time in theatre of 95 min [interquartile range (IQR) 71–120]. Specialist extraction tools were required for 130 leads (83%). The median hospitalization duration was 3 days (IQR 1–8). The mean cost of extraction was £9228 (±4099); infected £10 727 (±4178) and non-infected £6619 (±2269). With the additional costs of device reimplantation, the overall mean cost rose to £17 574 (±12 882); infected £22 615 (±13 343) and non-infected £8801 (±5007). At the time of this study, the UK NHS tariff was £2530 for elective and £4764 for non-elective extraction, covering barely half of the real costs.

Conclusion We demonstrated a substantial difference between the real-world cost of extraction and the UK NHS tariff. Extracting centres should scrutinize their practice, including the timing of reimplantation.

Keywords Transvenous extraction • Cardiac device infection • Service line reporting • Cost analysis

Introduction

In Europe, the implantation rate of cardiac implantable electronic devices (CIED) is rising, driven by an aging population and broader indications supporting their use. In 2015, 528 441 (518 per million) new permanent pacemakers, 103 399 (102 per million) new implantable cardioverter-defibrillators (ICDs) and 84 205 (82 per million) new cardiac resynchronization therapy (CRT) devices were implanted across the continent.[1]

The predominant indication for CIED extraction is system infection, followed by lead failure and vascular access issues. Additional indications include radiotherapy in the vicinity of the system or the need for magnetic resonance imaging. During 2013, >2650 extraction procedures were reported to the European Heart Rhythm Association,[2] rising to >10 480 in 2014[3] and >8748 in 2015 (13 per million).[1] However, underreporting effects the reliability of this data (52% of EU countries reporting in 2013,[2] rising to 68% in 2014[3] and 2015[1]), as does the variation in clinical approach to lead recalls and advisories (e.g. Sprint Fidelis, Riata). Among countries with high implanting rates per head of population, with complete implantation and extraction data returns to EHRA for 2015; Germany implanted 106 700 (1320 per million) new pacemakers, 28 914 (358 per million) new ICDs, 21 139 (261 per million) new CRT devices, and extracted 2357 (29 per million) devices; Austria placed 7905 (912 per million) new pacemakers, 1393 (161 per million) new ICDs, 1364 (157 per million) new CRT devices, and extracted 250 (29 per million) devices;

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What's new?

- Tariff-based reimbursement for transvenous lead extraction is inadequate in the UK.
- European extracting centres with either tariff or diagnosis-related group reimbursement are also at financial risk.
- Extraction centres should consider their practice and reimbursement, especially in relation to the timing of device reimplant.
- The substantial cost of extraction and reimplantation should be considered in the context of CIED cost effectiveness.

and Poland inserted 30 494 (791 per million) new pacemakers, 8526 (221 per million) new ICDs, 3964 (103 per million) new CRT devices, and extracted 1050 (27 per million) devices.[1]

Transvenous extraction is a complex clinical procedure, with associated morbidity and mortality.[4,5] Although some economic analyses have been undertaken using a range of economic methodologies (cost benefit, cost effectiveness, cost utility, and cost of illness), the exact resource utilization of extraction has generally been excluded from consideration. The analyses that have evaluated extraction costs have been relatively small scale, incomplete, and frequently inconclusive.[6–8]

In the USA, the cost of managing Sprint Fidelis lead failures over a 5-year period was estimated to be $287 million, with an average of >$45 000 per patient. Although calculated from hospital records and incorporating the charge of patient monitoring, such figures are unlikely to be representative of European costs.[9]

This study aims to define the difference between the cost incurred and the reimbursement for transvenous extraction. We present a patient level cost analysis for the financial year 2013/2014, at a tertiary cardiac unit utilizing a detailed service line reporting system.

Methods

Study centre

Liverpool Heart and Chest Hospital (LHCH) provides a comprehensive transvenous and open surgical extraction service for the North West of England and North Wales, with an estimated population of 3 million. Two full-time device sub-specialists jointly perform all transvenous extraction procedures in a dedicated pacing theatre. Most procedures are performed under general anaesthesia, with arterial access and trans-oesophageal echocardiography. Surgical and perfusion support are requested on an individual patient basis, according to clinical complexity and potential risk. Extraction techniques and tools are utilized in a stepwise fashion (traction alone, locking stylet, polypropylene sheath, laser sheath, femoral conversion, and surgical referral). Underlying rhythm directs, the requirement for temporary or semi-permanent pacing[10] and intra-operative microbial sampling is under the discretion of the operating physician.

Following extraction, four options exist regarding the timing of device reimplantation according to infection status, device dependency, and a multidisciplinary team (including microbiologist) review:

(1) *Reimplantation at time of extraction*: non-infected,
(2) *Inpatient delayed reimplantation*: infected device dependent patient or a secondary prevention defibrillator,
(3) *Outpatient reimplantation*: infected non-dependent device patient or a primary prevention defibrillator, and
(4) *Inpatient reimplantation at referring centre after repatriation*: infected device dependent patient or a secondary prevention defibrillator from a referring centre.

In 2008, the hospital introduced service line management, with separate business units identified to enable assessment of their individual contributions to resource use, cost, productivity, and financial performance. Service line reporting for device extraction ensured that no costs were excluded and was dependent on length of stay, procedure duration, salary-based clinical activity, and itemization of every single consumable.

Study design

A retrospective, observational cohort study was performed for all transvenous extractions during 2013/2014. Service line reporting cost drivers were revised by deconstructing the inpatient journey and standardizing care whenever possible (i.e. generic consumables). Fifteen cost drivers were redefined to enhance data consistency, accuracy, and reproducibility (*Table 1*).

All patient and procedural details were obtained from electronic health records and theatre logbooks. Overheads were calculated as a 10% supplement of the total hospital costs to cover management, capital maintenance, and amenities. Reimplant costs were calculated using the same methodology as shown in *Table 2*.

Study endpoints

The primary endpoint was the inpatient extraction cost in pounds sterling. At the time of the study, the exchange rate for the Euro was 1.21 (31 March 2013). The secondary endpoint was the total cost including new device reimplantation. Subgroup analysis was performed according to extraction indication.

Statistical analysis

Categorical variables were summarized by percentages and continuous variables by mean (±standard deviation) or median [interquartile range (IQR)]. The χ^2 and Mann–Whitney *U* tests were used in categorical variable and continuous variable subgroup comparison. All analyses for significance were two-tailed and performed using StatsDirect (version 2.8.0) software. *P*-values of <0.05 were considered statistically significant.

Costs were summarized by mean and median to demonstrate the influence of outliers, as recommended by Reed.[11]

Results

Seventy-four transvenous extraction procedures were performed, representing 25 per million of the catchment population. The majority of patients ($n = 49$, 66%) were referred from external hospitals and 35 (47%) were acute admissions. Infection was the most frequent indication for extraction ($n = 47$, 64%). Patients within the infected subgroup were significantly older, median age 74 years (IQR 65–80) vs. 50 years (IQR 44–74) [$P < 0.0001$, confidence interval (CI) 12–28] and had significantly more valvular heart disease, hypertension, and anti-platelet therapy than the non-infected group. In comparison, congenital heart disease was significantly more frequent in the non-infected subgroup vs. infected subgroup (7/27, 25.9% vs. 4/47, 8.5%, $P < 0.05$, 95% CI 0–0.37). Within the non-infected subgroup, 18

Table 1 Cost drivers

Number	Cost driver	Inclusion criteria	Cost unit
1	Admission	Admission and capacity team	E
2	Bed cost	Cleaning, laundry, management and bed space (itemized per day per care level)	D + I
3	Theatre	Personnel, sterilization, maintenance, and capital depreciation	T
4	Anaesthetist	Consultant anaesthetist	T
5	Physician	Two consultant cardiologists trained in extraction	T
6	Physiology	Clinical physiologist and intra-operative TOE	S
7	Surgeon	Consultant surgeon on standby	T
8	Perfusion department	Perfusionist and primed equipment on standby	S
9	Theatre consumables	Standard and itemized consumables	S + I
10	Extraction consumables	Itemized extraction equipment	I
11	Radiology	Intra-operative radiology and itemized investigations throughout hospital episode	T + I
12	Laboratory	Itemized haematology, biochemistry, microbiology, pathology, and transfusion investigations during the hospital episode	I
13	Pharmacy	Pharmacy support and itemized intra-operative drugs[a]	D + I
14	CRM specialist nurse	Specialist nurse review	E
15	Ward care	Physician ward care and secretarial support	D

CRM, cardiac rhythm management; D, duration of episode (£/day); E, hospital episode (£/admission); I, itemized consumables, investigations/blood product unit or bed space care level (£/day by day ward, Level 1, Level 2, and Level 3); S, standard per procedure (£/procedure); T, operation length of time (£/min, calculated proportionate to salary and job plan).
[a]Medication administered external to theatre environment excluded.

Table 2 Reimplant cost drivers

Reimplantation at extraction[a]	Inpatient reimplantation	Outpatient day-case reimplantation	Inpatient reimplantation after repatriation
Standard implant set for infected patients	Theatre	Admission	Admission
Device	Physician	Bed cost	Bed cost
	Physiology	Theatre	Theatre
	Theatre consumables	Physician	Physician
	Standard implant set	Physiology	Physiology
	Radiology	Theatre consumables	Theatre consumables
	Device	Standard implant set	Standard implant set
	Pharmacy	Radiology	Radiology
		Device	Device
		Pharmacy	Pharmacy
		CRM specialist nurse	CRM specialist nurse
		Ward care	Ward care

CRM, cardiac rhythm management.
[a]Admission, bed, theatre, physician, physiology, theatre consumables, radiology, pharmacy, CRM specialist nurse, and ward care encompassed in the extraction episode cost, see *Table 1*.

(67%) were single lead extractions and 9 (33%) multiple leads. Overall 46% of the CIEDs extracted were pacemakers, 23% ICDs, and 31% CRTs.

Device implant duration ranged between 0 and 26 completed years, with 47 (64%) devices implanted >5 years. Infected systems had been implanted for a significantly greater duration prior to extraction (median 9 years, IQR 5–13 vs. median 5 years, IQR 3–9, $P < 0.02$, CI 1–5). In the 12 months prior to extraction, 26 (35%) patients had undergone ≥1 CIED-related operation, significantly more frequently in the infected group (49% vs. 11%).

Procedures were performed under general anaesthesia in 69 (93%) cases, with a median time in theatre (defined as door to door time) of 95 min (IQR 71–120). There was no significant difference in the operative duration between the two subgroups. Procedure characteristics are described in *Table 3*. Complete clinical success (removal of all target leads and lead material from the vascular space, or

Table 3 Procedure characteristics

	Total ($n = 74$)	Infected ($n = 47$)	Non-infected ($n = 27$)
Hospital admission priority*, *n* (%)			
Acute	35 (47)	29 (62)*	6 (22)*
Elective	39 (53)	18 (38)*	21 (78)*
Number of leads to remove	156	119	37
Number of leads procedural success, *n* (%)	148 (95)	113 (95)	35 (95)
General anaesthesia, *n* (%)	69 (93)	45 (96)	24 (89)
Theatre duration (min), median (range)	95 (20–205)	95 (45–205)	95 (20–157)
Perfusionist standby or required, *n* (%)	15 (20)	12 (26)	3 (11)
Surgeon standby or required, *n* (%)	16 (22)	13 (28)	3 (11)
Complications, *n* (%)			
Major	2 (3)	2 (4)	0 (0)
Minor	2 (3)	2 (4)	0 (0)
Timing of device or lead reimplant, *n* (%)			
Contra-lateral system already *in situ*	2 (3)	2 (4)	0 (0)
At extraction*	24 (32)	1 (2)*	23 (85)*
Delayed inpatient*	15 (20)	15 (32)*	0 (0)*
Delayed outpatient	3 (4)	3 (6)	0 (0)
Repatriated*	19 (26)	18 (38)*	1 (4)*
No reimplant	11 (15)	8 (17)	3 (11)

*$P<0.05$.

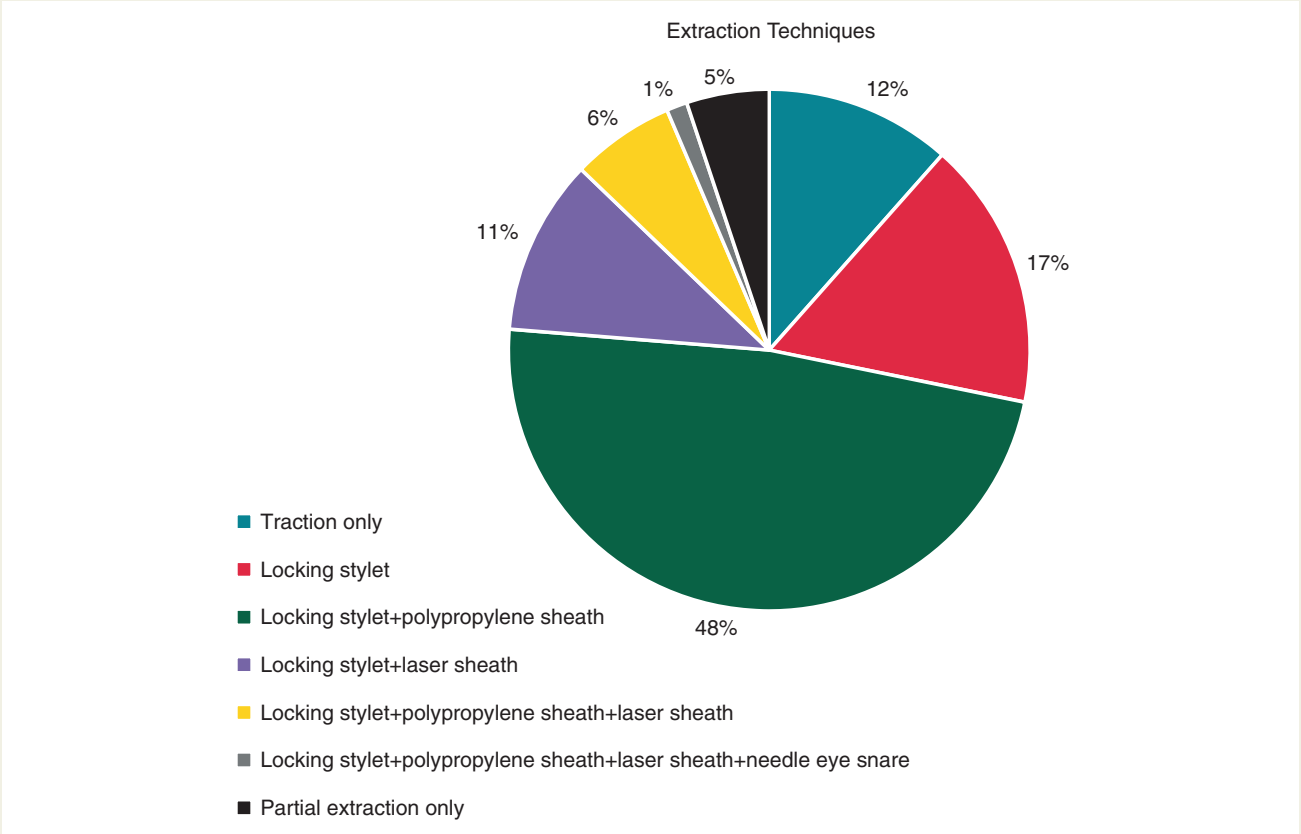

Figure 1 Extraction techniques per lead.

retention of a small portion of the lead that does not negatively impact on the outcome goals of the procedure) was achieved with 148 (95%) leads. The techniques used per lead are shown in *Figure 1*.

Emergency conversion to an open extraction with perfusion support was necessary for one (1%) patient and surgical oversewing of the vascular access site in another. Complications as defined by Wilkoff *et al.*,[12] were only encountered within the infected group; two (3%) major complications (two cardiac avulsions, only one requiring intervention with 26 min on cardio-pulmonary bypass and subsequent haemofiltration) and two (3%) minor (one subclavian vein thrombosis and one blood transfusion). There were no perioperative deaths.

The inpatient extraction cost was £682 892 (mean patient cost £9228 ± 4099, median £7772, IQR £5958–11 178); the infected subgroup £504 182 (mean £10 727 ± 4178) and the non-infected £178 710 (mean £6619 ± 2269). *Table 4* demonstrates the costs for each driver according to the infected and non-infected grouping, and *Figure 2* demonstrates the range of costs.

Extraction consumables (£163 488), bed cost (£162 485), and physician cost (£90 724) were the principle cost drivers, accounting for 61% of total costs. The median length of hospital admission was 3 days (IQR 1–8); 7 days (IQR 3–9) in the infected subgroup, and 1 day (IQR 1–2) in the non-infected group. Bed and ward care costs contributed 31% (£155 271) of the infected group cost and 23% (£40 535) of the non-infected group.

The total cost including reimplant was £1 300 509 (mean £17 574 ± 12 882, median £12 814, IQR £7179–24 239). For the infected subgroup, the cost was £1 062 892 (mean £22 615 ± 13 343, median £17 597, IQR £11 321–34 103). For the non-infected group, the cost was £237 617 (mean £8801 ± 5007, median £6828, IQR £6114–9332). Device or lead reimplantation occurred in 63 (85%) patients. Thirty-seven reimplants post-extraction were in infected patients and 24 non-infected patients, with associated costs of £558 710 and £58 907, respectively. The remaining two reimplants were performed prior to extraction at referring centres. Reimplantation at extraction was significantly less frequent in patients with infection (2% vs. 85%), who usually received a delayed reimplant, either during the index admission (32%), after discharge at the extracting centre (6%) or after repatriation to the referring centre (38%).

Just one non-infected patient was repatriated to their referring hospital for further medical care. The length of hospital stay for those patients repatriated was obtainable for 14 (74%) patients and the median episode was 18 days (14–56). The cost associated with repatriated hospital stay was £154 392 in the infected subgroup and £5201 in the non-infected subgroup (*Tables 5 and 6*).

Within 30 days of hospital discharge, six patients were readmitted, four patients from the infected group (three for delayed outpatient device reimplantation and one wound concern requiring pressure dressing application) and two in the non-infected group (one decompensated cardiac failure and one wound concern requiring no intervention).

The mortality within the year post-extraction was 8%. Among the patients who died within 30 days of extraction ($n = 3$, 4%), two patients were receiving treatment for endocarditis and one for localized infection. None of these individuals had undergone reimplantation at the time of their death.

Discussion

The lack of accurate cost data on transvenous extraction impedes clinical and executive decision-making. We present comprehensive clinical cost data generated through service line methodology at a single large extraction centre and make comparison to reimbursement through the NHS UK national tariff. The extraction rate, case mix, practices, and outcomes at the centre under evaluation were representative of practice across Europe at the time of the study.[13] Total annual expenditure on transvenous extractions was £682 892, with a mean per patient cost of £9228. When reimplant procedure costs and transfer back to the referring centres were included, the expense escalated to £1 300 509 (mean £17 574). Infection was the most frequent indication for extraction, with a mean cost per extraction of £10 727, increasing to £22 615 when including device reimplantation. During the study period, the UK national tariff for extraction was £4764 for an acute admission and £2530 for an elective episode, equating to a reimbursement of £265 410. This provided a deficit of £417 482 even before considering the cost of reimplantation. If a patient was repatriated to a referring hospital, reimplant charges could be recouped through creation of a new hospital episode. However, reimplantation at the extracting centre was restricted to a single tariff payment. The hospital thus lost a further £201 366 on device reimplants performed during the same admission, creating a total loss of £618 848 during 1 year. The failure of a single tariff to adequately reimburse the costs incurred in managing CIED infections has also been described by Clémenty *et al.*[14] Among 687 patients in France, the mean cost of treating infection following a *de novo* implant procedure was €23 237 and €20 211 following a replacement operation. Diagnosis-related group (DRG) tariff repayment met just 63% (€14 612) and 71% (€14 299) of costs, respectively, with reliance on supplementary payments to recoup the total cost (prolonged hospital stay, physician fees, medication, and system reimplant). This study, like ours, reported costs from the hospital perspective but mean costs were slightly lower potentially explained by only 72% of the cohort requiring a system explant. Most other European countries have moved to adopt a DRG-based reimbursement system but significant variation exist in terms of the actual values.[15]

Very few other studies have reported on the financial impact of CIED extraction. Ahsan *et al.*[7] described higher mean costs for extraction alone of £16 207, rising to £30 958 with additional device reimplantation. This represented a single-centre experience for transvenous extraction of 30 infected CIEDs, with costs calculated by incorporating the local tariff for extraction, bed days, antibiotic therapy, and replacement devices.[7] Their mean length of hospital admission was 30 days, which was significantly longer than our 7 days for infected systems alone. This was sufficient to explain the difference in costs and highlights the importance to health care organizations of minimizing patient length of stay, especially when there is a fixed tariff.

A more in-depth approach to costing the extraction of infected pacemakers and defibrillators was employed by Kuehn *et al.*,[6] who quantified the cost of bed days, the operation, anaesthesia, blood products, and laboratory services in the treatment of seven patients. However, the cohort studied were undergoing open surgical extraction, thus making the procedures and related costs non-comparable to transvenous extraction.

Table 4 Inpatient extraction episode costs by cost driver (£, £:€ 1:1.21)

	Total ($n = 74$), (£)	Infected ($n = 47$), (£)	Non-infected ($n = 27$), (£)
Admission	5323	3381	1942
Bed cost	162 485	127 866	34 619
Theatre	54 882	36 066	18 816
Anaesthetist	29 495	19 383	10 112
Physician	90 724	59 620	31 104
Physiology	12 432	7896	4536
Surgeon	5814	4531	1284
Perfusion department	8753	7078	1675
Theatre consumables	12 476	8038	4438
Extraction consumables	163 488	127 147	36 341
Radiology	16 472	10 606	5867
Laboratory	8548	7686	862
Pharmacy	6608	5300	1308
CRM specialist nurse	9990	6345	3645
Ward care	33 321	27 405	5916
Trust overheads	62 081	45 835	16 246
Total, mean ± SD	682 892 (9228 ± 4099)	504 182 (10 727 ± 4178)	178 710 (6619 ± 2269)

CRM, cardiac rhythm management; SD, standard deviation.

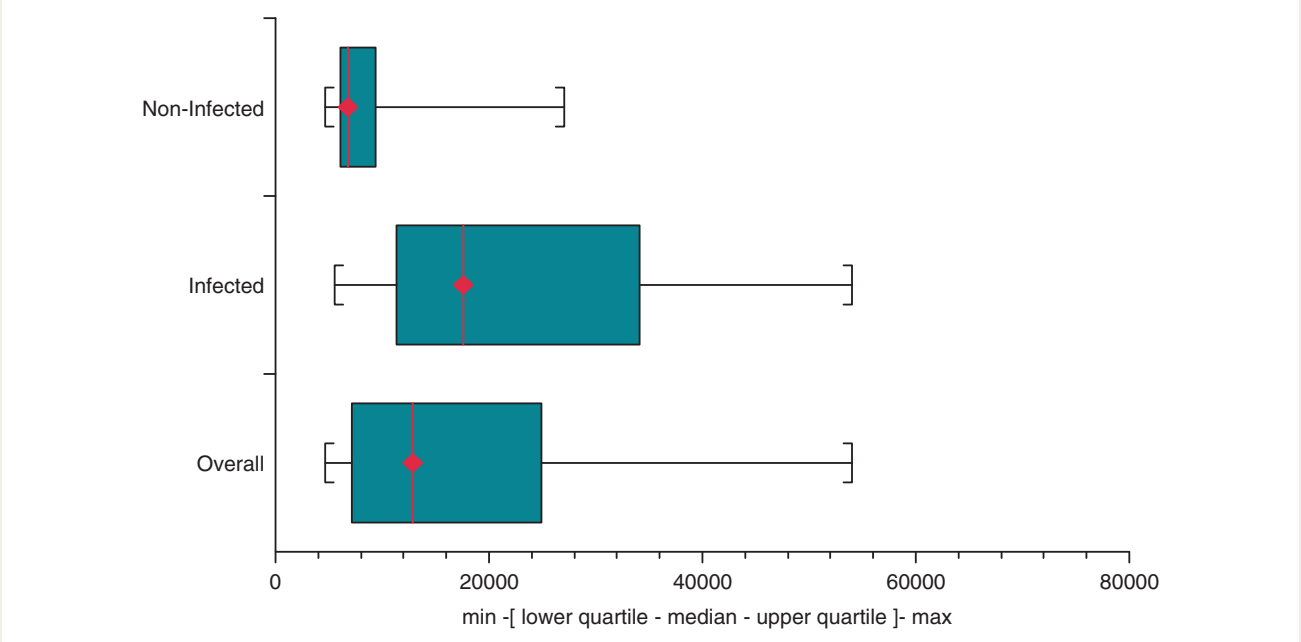

Figure 2 Total cost in managing extraction patients (excluding reimplantation, £).

Among our non-infected group, 81% of extractions were due to non-functional leads and of those 27% had a lead under an advisory. This group of patients were significantly younger than those with infection. They had potentially favourable cost implications due to the elective nature of most admissions and the fact that reimplantation could be safely performed at the same time as the extraction. A retrospective cohort study reported by Groarke *et al.*[8] investigated the cost of managing failing defibrillator leads in 23 patients in Ireland.[8] However, only nine out of 23 patients (39%) underwent extraction and with traction alone. The median cost of extraction at lead replacement was €4922 per patient, representing a significant under estimation.

Table 5 Reimplantation costs (£, £:€ 1:1.21)

	Total ($n = 61$), (£)	Infected ($n = 37$), (£)	Non-infected ($n = 24$), (£)
Reimplantation at extraction	38 693	1416	37 277
Inpatient reimplantation	162 673	162 673	
Outpatient reimplantation	35 755	35 755	
Inpatient reimplantation after repatriation	380 495	358 865	21 630
Total, mean ± SD	617 616 (8346 ± 11 174)	558 710 (11 887 ± 12 252)	58 907 (2182 ± 4782)

SD, standard deviation.

Table 6 Cumulative extraction and reimplant costs (£, £:€ 1:1.21)

	Total ($n = 74$), (£)	Infected ($n = 47$), (£)	Non-infected ($n = 27$), (£)
Total, mean ± SD	1 300 509 (17 574 ± 12 882)	1 062 892 (22 615 ± 13 343)	237 617 (8801 ± 5007)

SD, standard deviation.

In our practice, we achieved complete procedural success in 95% of operations, which is comparable to other series exceeding 94% when advanced modern techniques are applied.[13,16] Specialist equipment was required for 83% of leads, and our patients had mean implant dwell times consistent with those reported in the meta-analysis by Di Monaco *et al.*[17] The risk benefit ratio of lead extraction vs. abandonment is not only challenging from a clinical perspective but consideration might also be given to the financial implications especially as a redundant lead may not represent a significant risk even in the long term.

Extraction provides an opportunity to reassess the continuing clinical need for device therapy based upon clinical status, contemporary evidence-based guidelines, and patient wishes. Observational studies have demonstrated replacement systems may not be required in approximately one-third of patients,[18,19] however, in our experience 82% of all patients post-extraction were deemed appropriate for lead or system reimplantation. Eighty-five percent of the non-infected subgroup underwent reimplantation at the time of extraction, whereas 70% of the infected patient group required reimplantation as a delayed inpatient or following repatriation. Our mean cost for lead or system reimplant was £11 887 ± 12 252 for infected and £2182 ± 4782 for non-infected extractions, dependent on the device implanted.

To mitigate the cost of extraction, our centre has a short hospital stay policy with early repatriation to referring centres or utilization of community antibiotics in non-pacing dependent and primary prevention cases if a prolonged course is required. Subsequent reimplantation at the referring centre was through a day-case admission. The operative procedure has also been reviewed and designed to limit risk and cost alike, with extraction tools used in a stepwise approach. Further cost efficiency measures may look at; conservatively, managing non-infected systems when simple traction fails, placement of a new lead alongside redundant leads, or due to the low complication rates less intense monitoring using Level 1 beds and reducing peri-procedure investigation/eliminating aspects of aftercare (arrhythmia nurse care) as safe clinical limits allow.

The societal cost of extraction procedures is an important consideration as our 30-day readmission rate was 8% and mortality at 1 year also 8%, although studies have reported mortality as high as 20.3%.[20] Through establishing national databases for CIED extraction procedures and collaboration on the costs incurred, more representative reimbursement for transvenous extraction procedures is likely to follow. Without empiric data, the renegotiation of tariffs is unlikely to take place. However, primary prevention against infection and reoperation (consideration of novel antibiotic delivery systems, extravascular devices, leadless systems, MR compatible systems, lead reliability, and generator longevity) is imperative to reduce this financial burden and positively influence the quality adjusted life year calculations for the benefits of device therapy.

Limitations

Limitations are inherent from the retrospective cohort design and the single-centre nature of this study within the UK national healthcare system. Applicability to other European hospitals will depend on the case mix, clinician technical expertise, variation of non-consumable cost drivers (salaries, buildings, and overheads), and method of reimbursement. As a high volume implanting centre, economies of scale will have influenced procurement of consumables in this study.

Costs incurred in patient management prior to the extraction centre admission, pharmaceutical agent use outside of the extraction theatre, surgical intervention costs, the unknown length of hospital stay post-extraction for five repatriated patients, and hospital attendances post-extraction have not been included, resulting in an underestimation of the total cost in this cohort.

Conclusion

In a single UK hospital, the mean expenditure on transvenous extraction and reimplantation of CIEDs was £17 574 increasing to £22 615

for infected patients. The hospital experienced a deficit of over £600 000 based upon the national tariff repayment for extraction.

Transvenous extraction services in public and private hospitals across Europe should consider their repayment systems, ensuring tariffs based upon DRG activities are representative of actual expenditure. Institutions reimbursed through itemized budget allocations must also account for all costs incurred or face potential financial loss. Where concern regarding the adequacy of repayment exists, a micro-cost analysis of practice is recommended.

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