ESC European Society of Cardiology

Europace (2022) **24**, 1824–1833
https://doi.org/10.1093/europace/euac105

Iatrogenic cardiac perforation due to pacemaker and defibrillator leads: a contemporary multicentre experience

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Received 2 February 2022; editorial decision 25 May 2022; online publish-ahead-of-print 27 July 2022

Aims To determine the incidence, clinical features, management, and outcomes of pacemaker (PM) and implantable cardioverter-defibrillator (ICD) lead cardiac perforation. Cardiac perforations due to PM and ICD leads are rare but serious complications. Clinical features vary widely and may cause diagnostic delay. Management strategies are non-guideline based due to paucity of data.

Methods and results A multicentre retrospective series including 3 UK cardiac tertiary centres from 2016 to 2020. Patient, device, and lead characteristics were obtained including 6-month outcomes. Seventy cases of perforation were identified from 10 631 procedures; perforation rate was 0.50% for local implants. Thirty-nine (56%) patients were female, mean (± standard deviation) age 74 (± 13.8) years. Left ventricular ejection fraction 51 (± 13.2) %. Median time to diagnosis was 9 (range: 0–989) days. Computed tomography (CT) diagnosed perforation with 97% sensitivity. Lead parameter abnormalities were present in 86% (whole cohort) and 98.6% for perforations diagnosed >24 h. Chest pain was the commonest symptom, present in 46%. The management strategy was percutaneous in 98.6% with complete procedural success in 98.6%. Pericardial effusion with tamponade was present in 17% and was associated with significantly increased mortality and major complications. Anticoagulation status was associated with tamponade by multivariate analysis (odds ratio 21.7, 95% confidence interval: 1.7–275.5, $P = 0.018$).

Conclusions Perforation was rare (0.50%) and managed successfully by a percutaneous strategy with good outcomes. Tamponade was associated with increased mortality and major complications. Anticoagulation status was an independent predictor of tamponade. Case complexity is highly variable and requires skilled operators with a multi-disciplinary approach to achieve good outcomes.

Keywords Cardiac perforation • Pacemaker • Defibrillator • Lead • Pericardial effusion • Tamponade

Introduction

Cardiac perforation is a rare but potentially life-threatening complication of cardiac implantable electronic device (CIED) implantation with transvenous leads and is associated with increased mortality and morbidity.[1]

The incidence of clinically significant perforation due to a pacemaker (PM) or implantable cardioverter-defibrillator (ICD) lead is typically <1% in retrospective cohorts and randomized control trials.[2–4] A meta-analysis of 60 744 patients undergoing PM implantation reported a mean perforation incidence of 0.82% (range: 0–6.4%).[5]

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What's new?

- This study reports the largest series of lead-related cardiac perforation, including all timescales. This includes clinical characteristics, management strategy, and outcomes in 70 cases, 51 from locally implanted cases at 3 UK tertiary centres.
- Rate of perforation was 0.50% from 10 631 procedures. Ninety-eight percent were managed percutaneously with 98.6% procedural success.
- Pericardial effusion was common (59%), with tamponade in 17%. Tamponade was associated with higher all-cause mortality and complications.
- We describe best practice for the assessment of transvenous leads when suspecting perforation.

True prevalence may be underestimated due to asymptomatic, subclinical perforation reported in up to 5%, highest in non-septal active fixation right ventricular (RV) leads.[6,7] Studies typically involve small numbers and large national registry data sets have limited information regarding clinical characteristics, management strategies or patient outcomes.[1] No prospective randomized studies assessing management strategies exist; however retrospective studies advocate transvenous lead extraction (TLE) to improve outcomes.[8–10]

Presenting clinical features are influenced by perforation timing, location, extent, and sequelae which are influenced by patients' premorbid state, cardiac rhythm, and chance.[6,9]

Proposed procedure-related risk factors include apical RV lead positioning, over-torquing active fixation leads and excessive lead slack.[4,11–13] Low volume operators (<50 annual procedures) may also have higher rates of perforation.[3] Patient risk factors include female sex, advanced age, recent steroid use, non-single-chamber and temporary transvenous leads.[1,14,15] Risks for atrial vs. ventricular perforation and upgrade vs. *de novo* implants are similar.[5,16] The 2021 European Society of Cardiology pacing guidelines recommend (Class IIb, level of evidence C) lead placement at the mid-ventricular septum for patients with high perforation risk (elderly, previous perforation).[17]

This study aims to review the incidence, clinical features, management, and outcomes of patients with clinically significant lead-related cardiac perforation. We hypothesized that cardiac perforation can be managed safely by percutaneous TLE with good outcomes and that requirement for surgical intervention is rare.

Methods

Retrospective, multicentre cohort study including three United Kingdom (UK) tertiary referral centres: St Bartholomew's Hospital, Barts Health; Royal Brompton and Harefield; and University Hospital Southampton NHS Trusts. The data collection period included 4 years from 2016 to 2020.

Case identification

Prospectively collated NHS Trust CIED databases maintained at each institution were searched to identify confirmed cardiac perforation secondary to any procedure involving CIED lead interventions.

Clinically significant lead perforation was defined by the fulfilment of one or more of the following criteria, in agreement with previous publications:[8,18]

(1) Acute chest pain with or without hypotension and the finding of a significant pericardial effusion during CIED implant procedure.
(2) Suggestive clinical symptoms and significant pericardial effusion acutely following implant procedure with haemorrhagic fluid at pericardiocentesis.
(3) Suggestive clinical symptoms or the incidental finding of significant lead parameter changes occurring post-CIED implant associated with definite lead perforation on imaging.
(4) The finding of RV lead non-capture associated with diaphragmatic or chest wall stimulation during RV bipolar pacing.

Lead dislodgement in the absence of perforation may produce non-capture of right atrial (RA) or coronary sinus leads with phrenic nerve stimulation; therefore these were excluded.

Case note review was undertaken with collection of demographics, cardiac history, comorbidities, lead and implant data, clinical course including time to diagnosis, presenting complaint, lead parameters, management, and outcomes at 6 months following diagnosis of perforation. Imaging was reviewed including echocardiography, chest radiography (CXR), fluoroscopy and thoracic computed tomography (CT) where available. Perforation extent beyond the epicardium was ascertained and defined as either beyond the visceral pericardium but within the pericardial space (visceral) or also beyond the parietal pericardium (parietal). An example of a case perforating the visceral but not parietal pericardium is illustrated by CT in *Figure 1*.

Acuity of diagnosis was classified as follows:

(i) Acute, during the implant procedure or within 24 h,
(ii) Sub-acute, within 1–30 days post-implant,
(iii) Chronic, >30 days post-implant.

Procedural success and complications were defined according to the 2017 Heart Rhythm Society consensus statement on lead extraction.[19] Lead parameters were assessed serially at the time of perforation diagnosis and then 1- and 6-months post-diagnosis where available.

Significant lead parameter changes were recognized by marked changes in pacing threshold (capture threshold ≥3V at 0.5 ms), abrupt lead sensing decrease (R wave ≤5 mV or P wave ≤1.5 mV) or change of lead impedance (<300 or >1000 Ohms) when compared with measurements at the time of implant.

Leadless PMs, temporary pacing wires and TLE cases for alternative indications were excluded. The study was approved by local institutional review boards.

Statistical analysis

IBM SPSS Statistics, version 25.0 (IBM Corp. Armonk, NY) was used for statistical analysis. Results are expressed as mean (± standard deviation) for normally distributed continuous variables and median (± range or interquartile range, [IQR] as specified) for non-parametric continuous data. Categorical variables are presented as frequency (%). Continuous non-parametric variables were analysed using 2-tailed *t*-tests, and categorical variables using Fisher's exact test. Multivariable analysis with logistic regression was performed to identify predictors of pericardial effusion with tamponade: sex, age (years), LV ejection fraction (EF) category (0 = ≥50%, 1 = 36–49%, 2 = ≤35%), diabetes mellitus, chronic kidney disease, hypertension, ischaemic heart disease, anticoagulation, antiplatelet use, and extent of perforation. Confidence intervals of 95% were used, and $P < 0.05$ was considered significant.

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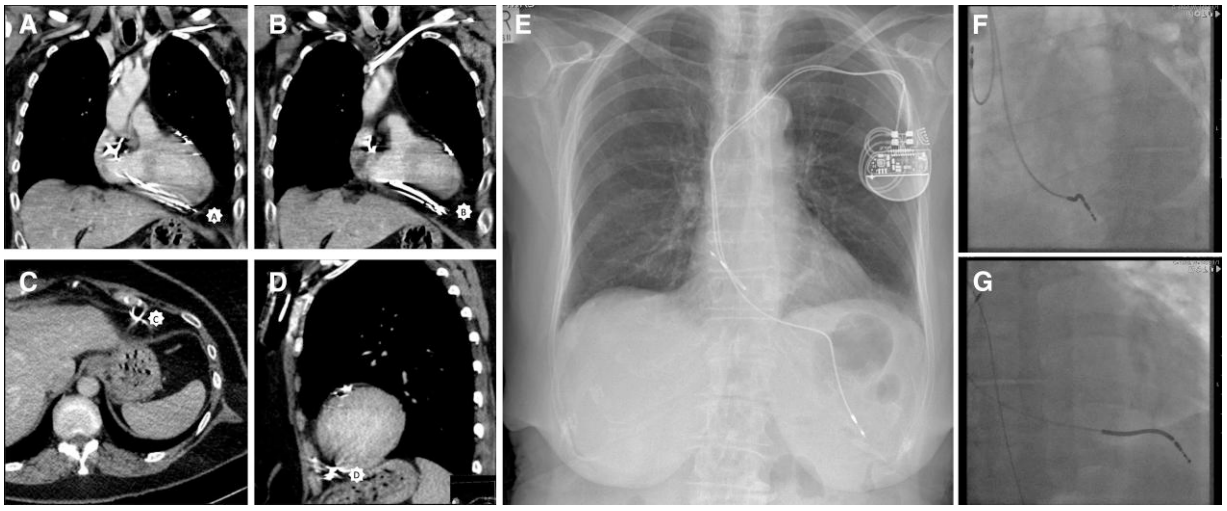

Figure 1 A–D: computed tomography post-contrast displaying lead tip perforation localization with review in three orthogonal views: A + B: coronal planes, C: axial plane and D: sagittal plane. All demonstrating the lead tip (denoted by *) traversing beyond the visceral pericardium and likely abutting but not extending beyond the parietal pericardium, visible even with some motion artefact. E: plain chest radiograph posteroanterior projection displaying perforation of right ventricular pace-sense lead beyond the parietal pericardium. F (left anterior oblique projection) and G (right anterior oblique projection): fluoroscopy images displaying inferior angulation of the right ventricular defibrillator coil extending beyond the cardiac contour, below the diaphragm.

Table 1 Patient demographics

Characteristics	N = 70
Age (years)	74 (±13.8)
Female, *n* (%)	39 (56%)
LV EF (%)	51 (±13.2)
Diabetes mellitus, *n* (%)	15 (21%)
Hypertension, *n* (%)	32 (46%)
Chronic kidney disease (Creatinine > 200/dialysis) *n*, (%)	9 (13%)
Anticoagulation	16 (23%)
Apixaban	7 (10%)
Rivaroxaban	2 (3%)
Warfarin	4 (6%)
Fondaparinux	1 (1%)
Antiplatelets	18 (26%)
Steroids	1 (1%)
Cardiomyopathy	
Nil, good LV function	43 (61%)
Ischaemic cardiomyopathy	7 (10%)
Dilated/idiopathic	7 (10%)
Hypertrophic cardiomyopathy	2 (3%)
Valvular heart disease	6 (9%)
Other	5 (7%)

Other = cardiac sarcoid, long QT syndrome, congenital heart disease and myocarditis. LV = left ventricle, EF = ejection fraction.

Results

Demographics and prevalence

A total of 10 631 procedures involving CIED lead intervention occurred during the search period. Seventy cases of lead-related cardiac perforation were identified, involving 71 leads. Fifty-three cases involved implants at included centres, 17 cases involved leads implanted at alternative centres transferred for tertiary centre management. The prevalence of cardiac perforation was therefore 0.50%.

Thirty-nine (56%) patients were female, median age 77 (range: 32–95) years. Median LV EF was 55% (range: 20–74%), echocardiographic data were available in 56 (82%) patients at the time of perforation diagnosis. *Table 1* displays the patient demographics for cases of perforation.

Clinical characteristics

Symptoms related to cardiac perforation were present in 60 (86%) patients, of which 10 (14%) were asymptomatic and identified by abnormal lead parameters prompting further investigation. Chest pain was the most common symptom, present in 46% of patients. This was typically pleuritic, localized, sharp or electrical sometimes with a pulsatile component including positional or respiratory variability. Symptomatic bradycardia was present in 17%, symptomatic tamponade in 14%, dyspnoea in 13%, phrenic nerve stimulation in 10%, and abdominal pain in 3%. *Figure 2* displays the presenting complaint data, and *Figure 3* displays these data stratified by acuity of presentation. Chest pain was the most frequent symptom for both sub-acute and chronic perforations (69% and 32%, respectively); however, symptomatic tamponade and phrenic nerve stimulation were more common in acute presentations of perforation (44% and 25%, respectively). Asymptomatic

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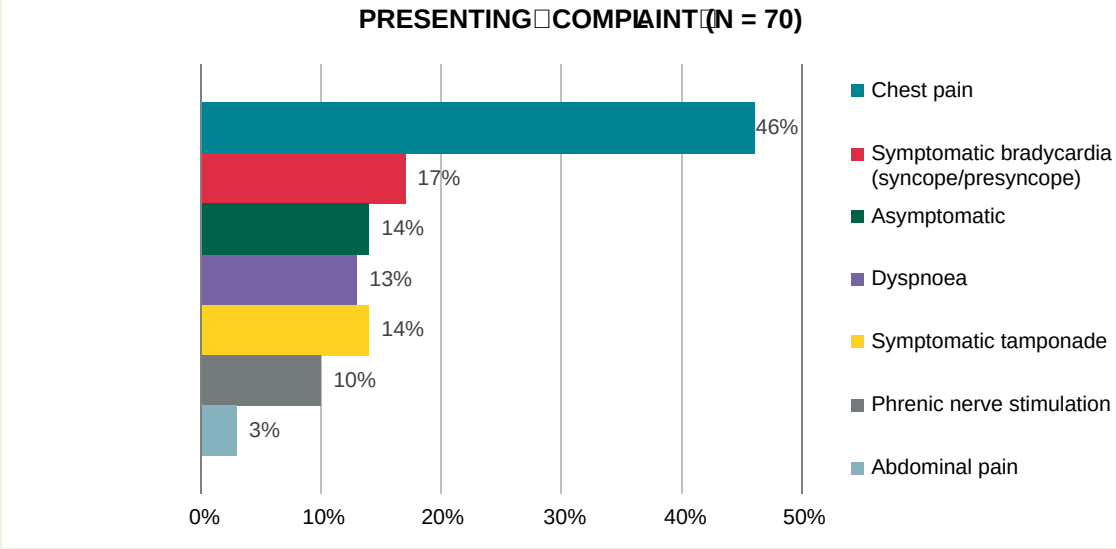

Figure 2 Frequency of presenting complaint.

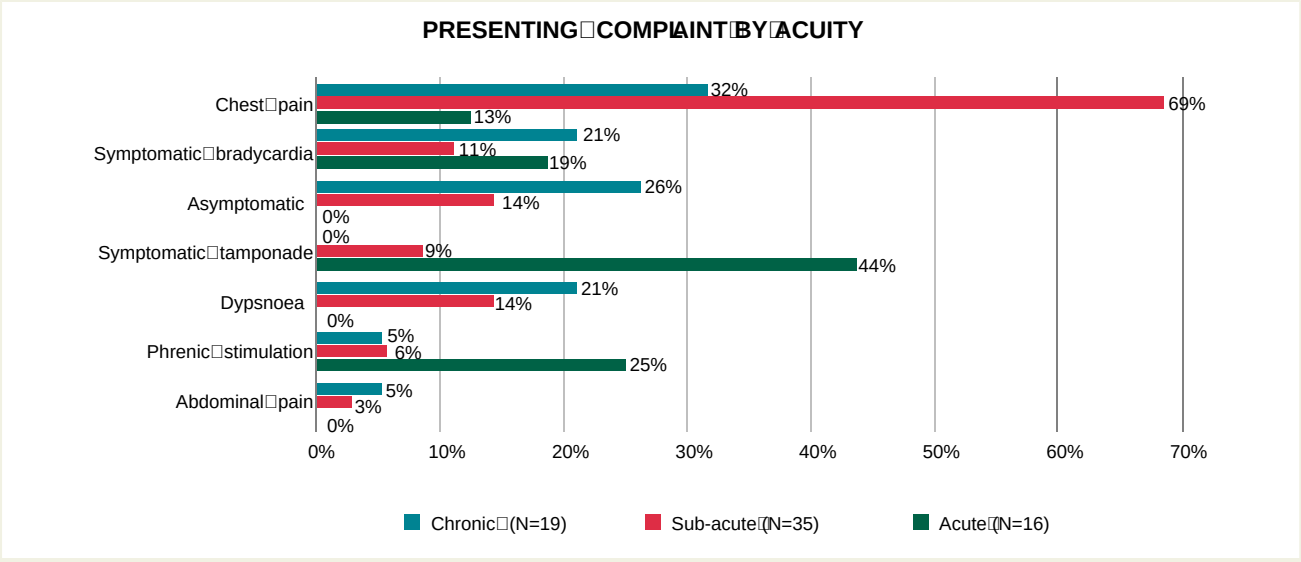

Figure 3 Frequency of presenting complaint by acuity.

presentations were most frequently identified within chronic and sub-acute presentations (26% and 14%, respectively).

Diagnosis and diagnostic timescale

Diagnostic timescale, from index procedure to perforation diagnosis was available in all cases, data are displayed in *Figure 4*. The median time from implant procedure to perforation diagnosis was 9 (range: 0–989) days for all cases and 16 (1–989) days for sub-acute and chronic cases. Sixteen (23%) cases were diagnosed acutely, (<24 h), 35 (50%) sub-acutely (1–30 days), and 19 (27%) chronically (>30 days). Of the chronic cases, 11 (58%) were diagnosed at 1–3 months, 6 (32%) between 3 and 12 months, and 2 (11%) at >12 months post-implant.

Of the 16 cases diagnosed acutely, 13 (81%) were diagnosed during the index procedure and managed by immediate lead revision with or without pericardiocentesis as required. Two cases (12%) were diagnosed post-implantation due to significant lead parameter change identified at device interrogation, and both cases were managed by lead revision on the same day. One case (6%) was diagnosed following identification of a small pericardial effusion without tamponade identified due to symptoms of chest pain post-implantation of a dual-chamber PM. This case involved a 72-year-old male, anticoagulated with apixaban for paroxysmal atrial fibrillation. Lead parameters were stable, and the patient was discharged with a plan for interval echocardiography to monitor the pericardial effusion which progressed to show features of tamponade at Day 9. Lead parameters also changed with loss of capture at maximum output on

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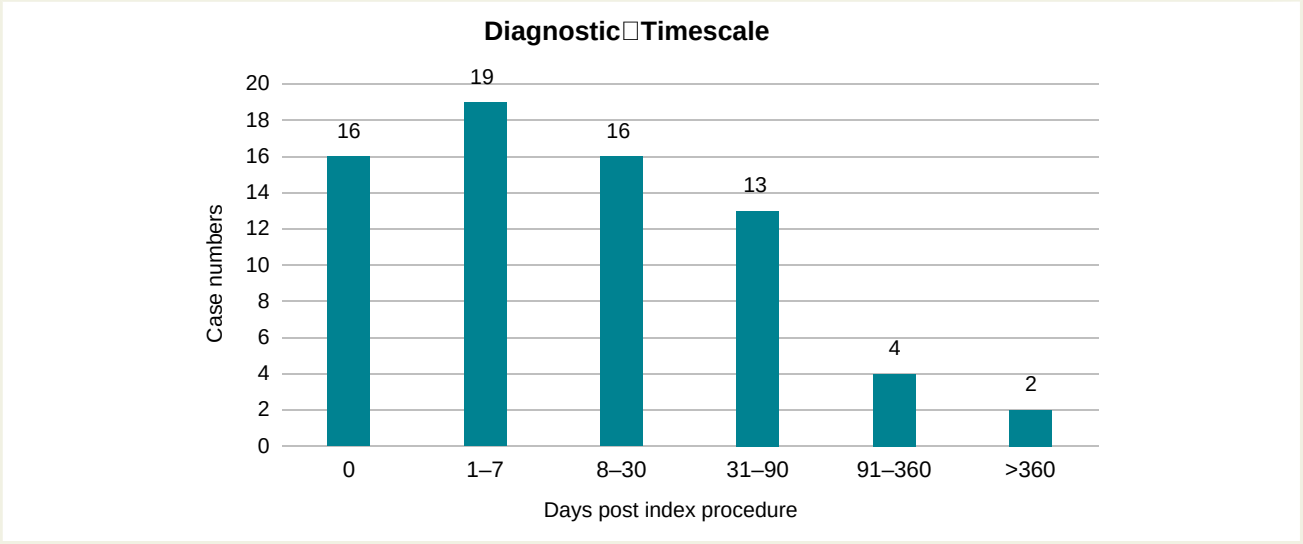

Figure 4 Timescale from lead implantation to perforation diagnosis (days).

Table 2 Perforation location and extent

Perforated chamber	n = 71 (leads)
RA, *n* (%)	4 (5.6%)
RV, *n* (%)	63 (88.7%)
Other/unknown, *n* (%)	4 (5.6%)
Perforation extent	
Visceral pericardium, *n* (%)	52 (74%)
Parietal pericardium, *n* (%)	18 (26%)
Perforation location	
RV apex, *n* (%)	46 (64.8%)
RV free wall, *n* (%)	17 (23.9%)
RA appendage, *n* (%)	2 (2.8%)
RA lateral, *n* (%)	2 (2.8%)
Other/unknown, *s* (%)	4 (5.6%)

RA = right atrium, RV = right ventricle

Table 3 Device and lead characteristics

Device type	*n* = 70
PM single-chamber	4 (5.7%)
PM dual-chamber	45 (64.3%)
ICD single-chamber	3 (4.3%)
ICD dual-chamber	7 (10%)
CRT-D	8 (11.3%)
CRT-P	3 (4.3%)
Perforating lead type	***n* = 71**
RA pace-sense, active fixation	5 (7%)
RV pace-sense, active fixation	44 (62%)
RV pace-sense, passive fixation	4 (6%)
RV defib, active fixation	14 (20%)
Unknown/wire	4 (6%)

PM = pacemaker, ICD = implantable cardioverter defibrillator, CRT = cardiac resynchronization therapy P = pacemaker, D = defibrillator, RA = right atrium, RV = right ventricle.

the RV pace-sense lead. The RV lead was therefore revised, and pericardial drain was inserted.

Computed tomography imaging was performed in 36 of 70 (51%) of the whole cohort and 34 of 54 (63%) of non-acute cases diagnosed >24 h post-lead implantation. Computed tomographies were diagnostic for perforation in 35 of 36 cases, indicating a sensitivity 97.2% in cases of suspected perforation. The single non-diagnostic CT was performed as a non-gated CT pulmonary angiogram to investigate suspected pulmonary embolism. Cases without CT were those in which diagnostic uncertainty was low and perforation extent was clear from alternative imaging. One example of which is displayed in *Figure 1E* showing a CXR with RV apical perforation beyond the parietal pericardium, a second example is displayed in *Figure 1 F* and *G* with fluoroscopy displaying an active fixation defibrillator coil extending beyond the cardiac contour with an inferior orientation at the RV apex.

Chest radiographies were performed in 58 of 70 (83%) patients, 51 of 54 of non-acute cases (94%), and images were diagnostic for perforation in 33 of 58 (57%) cases.

Perforating chamber and extent

The perforated cardiac chamber was the RV in 63 (90%) cases, RA in four (5%) cases, and unknown in four (5%) cases; one case involved both RV and RA lead perforation. Of the sub-acute and chronic perforations, the extent of perforation was limited to the visceral

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pericardium only in 52 (74%) cases and included the parietal pericardium in 18 (26%) cases. There was no significant difference in the rate of pericardial effusion by extent of perforation, present in 31 of 52 (60%) and 10 of 18 (56%) of visceral and parietal perforations, respectively ($P = 0.7874$). *Table 2* displays perforation location and extent data.

Perforating lead characteristics

Perforating leads were PM pace-sense leads in 48 of 71 (68%), RV ICD leads in 14 of 71 (20%), RA pace-sense leads in 4 of 71 (6%), and unknown in 4 of 71 (6%) cases. 'Unknown' cases all involved acute peri-procedural tamponade, 3 of 4 were considered likely to be RV lead-related and 1 of 4 was RV-lead or J-wire related. Lead fixation type was active in 63 of 71 (88%) cases, passive in 4 of 71 (6%) cases, and unknown for 4 of 71 (6%) cases. Device and lead data are presented in *Table 3*. The Ingevity 7742 MRI (Boston Scientific, Marlborough, MN) active fixation pace-sense lead was the most numerous perforating lead ($n = 28$), followed by the Durata 7122Q, active fixation, ICD coil ($n = 8$) (Abbott, St Paul, MN), and CapsureFixNovus 5076 (Medtronic, Minneapolis, MN) pace-sense lead ($n = 7$).

Lead parameters

Significant change in lead parameters were present in 60 of 70 (86%), including 53 of 54 (98.1%) of sub-acute and chronic perforations. In acute perforations, 7 of 16 (44%) had lead parameter abnormalities including phrenic nerve stimulation (1/6), abnormal injury current (3/6) (biphasic, negative, or absent), and capture threshold rise (3/6). Most frequent abnormalities at follow-up device interrogation included: significant capture threshold rise 52 of 60 (87%), reduction in sensing amplitude 8 of 60 (30%), change in impedance 6 of 60 (10%), and abnormal injury current 4 of 60 (7%).

Table 4 Multivariate analysis assessing variables contributing to the finding of tamponade requiring pericardial drainage

Variables	*P*-value	Odds ratio (Exp(B))	95% confidence intervals
Sex	0.561	1.901	0.218–16.579
Age	0.999	1.00	0.929–1.076
Hypertension	0.998	0.997	0.072–13.725
Ischaemic heart disease	0.579	2.271	0.234–22.033
Chronic kidney disease	0.998	0.00	0.000–0.000
Diabetes mellitus	0.404	2.758	0.254–29.937
LV EF category			
0, 50% or more	0.238		
1, 36–49%	0.122	12.715	0.506–319.464
2, 35% or less	0.443	0.318	0.017–5.948
Anticoagulation	**0.018**	**21.679**	**1.706–275.495**
Antiplatelets	0.512	0.299	0.008–11.023
Extent of perforation (visceral vs. parietal)	0.193	0.148	0.008–2.629

LV EF = left ventricle ejection fraction, bold text indicates statistical significance ($p < 0.05$).

Management

Acute perforations occurring were managed by urgent lead revision and pericardial drainage, where necessary during the index procedure. No acute perforations required surgical intervention.

All patients except one (98.6%) were managed by a percutaneous strategy; one (1.4%) patient required cardiac surgical intervention with sternotomy, relief of pericardial effusion, right haemothorax, and repair of a RA tear, diagnosed at Day 19 after dual-chamber PM implantation for complete heart block. The patient was an 83-year-old female with no relevant medical history, steroid use, or anticoagulation. The perforating lead was an Ingevity 7742 MRI, 5Fr active fixation RA pace-sense lead (Boston Scientific, Marlborough, MA) placed on the lateral RA due to difficulty finding acceptable sensing and pacing parameters. The patient made a complete recovery despite requiring prolonged inpatient stay.

Transvenous lead extraction and reimplantation was performed in 41 of 70 (58.6%) cases, all achieved by simple manual traction. Lead repositioning was performed in 28 of 70 (40.0%) patients. One (1.4%) patient also required surgical intercostal drain insertion for treatment of haemopneumothorax.

Pericardial effusion

Pericardial effusion at perforation diagnosis was identified in 41 of 70 (58.6%) patients. Pericardial drain insertion for tamponade was performed in 12 of 70 (17.1%) cases, and cardiac surgical relief of pericardial effusion in 1 of 70 (1.4%) cases. Of those with pericardial effusion, 13 of 41 (31.7%) required intervention. Pericardial drain insertion was required in 5 of 16 (31.2%) for acute, 6 of 35 (17.1%) for sub-acute, and 2 of 19 (10.5%) cases for chronic perforations ($P = 0.2544$ for acute vs. sub-acute, $P = 0.1061$ acute vs. chronic). Pericardial drain insertion was performed during the percutaneous lead revision procedure in 11 of 12 cases with one case requiring pericardial drainage 9 days after the identification of a moderate pericardial effusion diagnosed due to chest pain after dual-chamber PM implantation, as described previously in the 'diagnosis and diagnostic timescale' section.

Diagnostic timescale differed without significance ($P = 0.2777$) for cases with tamponade median (IQR) 8 (2–33) days vs. no-tamponade 7 (0–34) days.

Of those with sub-acute and chronic perforation diagnoses, repeat echocardiography following intervention revealed new or enlarged pericardial effusion in 2 of 54 patients (3.8%), 1 of 54 (1.9%) required repeat pericardiocentesis 7 days following TLE.

Patient outcomes

Complications

Major complications due to intervention for cardiac perforation occurred in 5 of 70 (7.1%) including one (1.4%) loose header requiring re-intervention, one (1.4%) enlarged pericardial effusion requiring pericardiocentesis, one (1.4%) pneumothorax requiring surgical

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intercostal drainage, and one (1.4%) case of pocket infection (despite using a TYRX antibacterial envelope) requiring system explant.

One (1.4%) patient died <24 h of acute perforation which occurred during dual-chamber PM implantation for symptomatic high degree AV block. This patient was an 81-year-old woman with a history of heart failure, LV ejection fraction 35%, end-stage renal failure requiring dialysis secondary to Goodpasture's syndrome, paroxysmal atrial fibrillation, anticoagulated with apixaban, hypertension, and previous stroke. Tamponade was identified shortly after the placement of a passive fixation pace-sense lead at the RV apex. The lead was immediately repositioned to the RV septum and a pericardial drain was inserted with aspiration of 150 mL of blood and subsequent improvement in haemodynamics. The pericardial drain was removed 20 h post-insertion; however, recurrent tamponade occurred requiring further pericardiocentesis and subsequently multi-organ failure culminating in a cardiac arrest with pulseless electrical activity.

Major complications occurred in 2 of 16 (12.5%) acute, 2 of 35 (5.7%) sub-acute, and 1 of 19 (5.3%) chronic perforation ($P = 0.5810$ acute vs sub-acute, $P = 0.5820$ acute vs. chronic). Minor complications occurred in one (1.4%) patient diagnosed with Dressler's pericarditis.

Grouping patients by the presence tamponade requiring drainage, the complication rate was significantly higher in the tamponade group, 3 of 12 (25%), vs. the non-tamponade group, 2 of 58 (3.4%) ($P = 0.0325$). A greater proportion of patients with perforations limited to the visceral pericardium experienced tamponade (35% vs. 10%); however, this was not statistically significant ($P = 0.1661$) nor was the rate of major complications ($P = 1.0$).

Multivariate analysis assessing predictors of tamponade requiring pericardial drainage at diagnosis is displayed in *Table 4*. Anticoagulation was significantly associated with tamponade (odds ratio: 21.7, 95% confidence interval: 1.7–275.5, $P = 0.018$).

Procedural success

Procedural success was achieved in 69 of 70 (98.6%) cases because one (1.4%) procedure-related death happened, and there was no permanently disabling procedure-related complications.[19]

Follow-up and mortality

Six months of follow-up including lead parameters and patient condition was available in 66 patients (94%). Complete follow-up data were lacking in four patients who were all confirmed to be still alive. Lead parameters at 6 months were stable in all surviving patients with no recurrent perforation or lead dislodgement.

All-cause mortality rate at 30 days and 6 months post-perforation diagnosis was 4.3% (3/70). One patient died from COVID pneumonia at Day 4 post-lead repositioning for chronic perforation, one from aspiration pneumonia at Day 30 post-lead repositioning for chronic perforation, and one died acutely due to tamponade (as previously described in the complications).

All deceased patients had been treated for pericardial effusion with tamponade. Grouping patients into those treated for tamponade and no-tamponade, 30-day all-cause mortality was significantly higher for the tamponade group 3/12 (25%), vs. non-tamponade group 0/58 (0%), ($P = 0.004$).

Discussion

The rate of PM/ICD lead-related cardiac perforation was 0.50%, including 70 cases with 53 implanted within our centres. To our knowledge this is the largest published cohort providing detailed clinical characteristics and management of clinically significant lead-related perforation across all timescales. Importantly, this study includes the 14% who were asymptomatic with clinically significant perforation. These data add to the body of knowledge regarding contemporary management and outcomes for patients with perforation.

The management strategy was predominantly percutaneous (98.6%) with only one patient requiring cardiac surgical intervention due to complexity of perforation extent; no cases were managed conservatively. Percutaneous management was associated with a low rate (1.4%) of progressive pericardial effusion requiring drainage and device-related infection.

Major complications due to intervention (7.1%) for perforations are significant and include one procedure-related death (1.4%) within 24 h of intervention; this is in keeping with previously published data (complication rate range: 4–13%).[9,20,21] The complications in part reflect the underlying patient population which includes elderly, frail, and comorbid patients with additional risk factors including uninterrupted anticoagulation. This is reflected in the two additional cases of death within 30 days of re-intervention due to perforation, both of which occurred in frail elderly patients, one with COVID pneumonitis and the other with a hospital-acquired pneumonia.

Although none of the cases included within this study were managed conservatively, such a strategy may be appropriate in selected cases. The absence of conservative management in part relates to the criteria used for case identification and the definitions chosen for clinically significant cardiac perforation, as outlined in the methods. *Rav-Acha et al.*[8] previously compared conservative management vs. early lead revision ($n = 22$ vs. 26, respectively) with a follow-up period of 18 ($\pm$ 9) months. This study described the feasibility of a conservative management strategy; however, complication rates, in particular late presentations of tamponade, and symptom recurrence were higher compared with those managed by early lead revision.

Cases where a conservative strategy may be appropriate include those in which perforation-related symptoms have resolved without significant pericardial effusion or in which a pericardial effusion has been drained without recurrence. In addition, the culprit lead's electrical parameters must be preserved and show no signs of deterioration. When planning a conservative strategy, the patient's wishes must be considered through an open discussion regarding the potential future risk of complications requiring re-intervention vs. the up-front risks of lead revision. A further consideration should include anticoagulant use due to the strong association displayed in our data between anticoagulation and the development of tamponade. Accordingly, lead revision may be more appropriate when indications for continued anticoagulation exist.

In our cohort, cases for whom a conservative management was favoured were rare, only one case within this study involved delayed intervention following the identification of a moderate pericardial effusion occurring with chest pain during dual-chamber PPM as previously described. A cohort of patients not addressed by our study includes incidentally identified perforation with stable lead parameters, diagnosed by cross-sectional imaging without sequalae. In these cases, a conservative strategy will be preferable in the absence of symptoms.

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The presence of tamponade was associated with a significantly increased risk of complications ($P = 0.01$) and all-cause mortality ($P = 0.004$). As expected, anticoagulation status at diagnosis was associated with tamponade by multivariate analysis. These data do not however inform regarding the risk of cardiac perforation in general and anticoagulant use which would require a propensity matched cohort to compare to. Additional adverse clinical outcomes of particular concern to operators including recurrent tamponade, device infection or recurrent perforation were rare within this cohort.

Clinical features and perforation characteristics varied widely as displayed in *Figure 2*; acute chest pain was the commonest presenting symptom described in 46%. As displayed in *Figure 3*, chest pain was present at all timescales however was commonest in the sub-acute cohort. Asymptomatic presentations were most frequent in the chronic cohort and symptomatic tamponade followed by phrenic nerve stimulation were commonest within acute presentations.

This confirms that chest pain with indwelling PM/ICD leads should alert clinicians to the possibility of lead perforation at any timescale post-implant. Non-anginal chest pain should be treated with a high index of suspicion for perforation, particularly with lead parameter changes and diagnostic uncertainty can be clarified by a gated cardiac CT. This study corroborates others describing the utility and accuracy of cardiac CT in this context.[7,9] Image quality may be limited by pacing lead artefact however gated CT effectively confirmed presence, location, and extent of perforation in our cohort. Surgical consultation and standby should be sought for leads perforating into the thoracic or abdominal cavity.

Although lead parameter changes varied widely, the presence of *any* significant lead parameter abnormality was almost universal. Excluding acute peri-procedural perforations, all but one patient had significant lead parameter abnormalities, confirming that abrupt deviation of sensing, pacing or impedance, either individually or in combination without clear cause should prompt thorough investigation for evidence of lead perforation, regardless of the lead dwell time.

Best practice for electrical assessment of leads

As described in these results, there are several electrical characteristics commonly seen with clinically significant perforated leads. However, in subclinical and asymptomatic perforations, detailed electrical assessment is not uniformly performed and thus the specificity from electrical testing is less well described in this context. The literature describes incidental findings of RV and RA lead perforation in greater than 5% and 10%, respectively, from CT scans.[6,7] Detailed electrical assessment via the company specific programmer can be a safe, quick, and cost-effective investigation to diagnose perforation despite there currently being no well-defined diagnostic criteria. The clinical context should always be taken into consideration when diagnosing lead perforations, but we highlight some electrical characteristics below not described by quantitative change in lead parameters.

High output pacing

Pacing at maximum outputs can be useful in the presence of ventricular capture. Assessment of the captured QRS morphology can determine LV or epicardial pacing with the presence of a dominant R-wave in V1 or pseudo-delta wave not typical for endocardial RV pacing. This can be useful for interventricular septal perforations and leads capturing from the pericardial space. In the absence of myocardial capture, stimulating at high outputs can lead to diaphragmatic, intercostal, or right phrenic nerve stimulation in the event of lead perforation.

Threshold discrepancies

Bipolar and unipolar threshold tests should both be performed where possible. With perforated lead tips no longer in contact with the myocardium, bipolar thresholds are often raised consistent with anodal capture from the ring electrode only. In contrast, unipolar thresholds will be significantly higher or show no capture at all. This threshold discrepancy between bipolar and unipolar is highly indicative of lead tip perforation. No capture in either pacing configuration combined with small or no intracardiac signals is highly suggestive that both tip and ring electrodes are no longer in contact with myocardium due to greater extent of perforation.

Unipolar electrograms

In high-voltage devices where it is not possible to pace in a unipolar configuration, assessing the morphology of the sensed unipolar electrogram can be valuable. Septal RV leads can have more of an initial R-wave due to the wavefront directionality of the interventricular septum; however, leads placed in the atrium or RV apex, where perforations are more common, dominant initial R-waves in unipolar sensing should raise suspicion of perforation. Normal wavefront depolarization travelling away from the endocardium results in a QS morphology; however, dominant R-waves represent wavefront movement towards the tip electrode when located near the epicardial surface. An example of the unipolar electrogram in a patient with atrial lead tip perforation is shown in *Figure 5*.

It is noteworthy that the 6Fr (2.0 mm) single filar Ingevity 7742 MRI active fixation, steroid eluting, pace-sense lead was the most numerous identified perforating lead (42%). Without accurate denominators for inter-lead perforation rate comparison, this study is not able to attribute a higher risk of perforation to the Ingevity lead, and the finding regarding the Ingevity lead should be interpreted with caution.

In addition, this study highlights the limitations of fluoroscopy when assessing lead position during implantation. Eighteen percent of perforations involved the RV free wall and were likely felt to be in a 'septal' position at implantation but had been placed in an adjacent location e.g. anterior wall or anteroseptal groove. As well as routine orthogonal fluoroscopic assessment, the surface ECG may provide clues to identify true septal pacing during implantation with early transition seen in the QRS morphology of precordial leads during true septal pacing.[21]

Limitations

This study's retrospective design limits the completeness of these data. Cases of perforation may have been omitted and the prevalence of perforation may be underestimated. We also cannot account for referral patterns and practice at other centres. The prevalence calculated in these data represents a real-world estimate of clinically significant perforation; however, patients managed conservatively at other centres, and asymptomatic perforations without significant lead parameter changes or in redundant leads may be missed. We have also been unable to estimate individual lead model perforation rates due to incomplete datasets precluding accurate denominator estimation.

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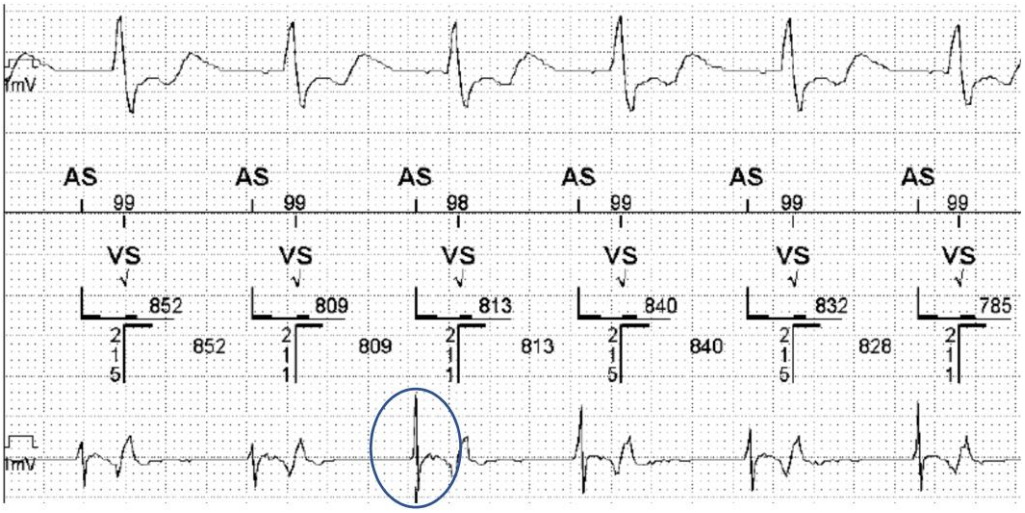

Figure 5 Channels: Top, discrimination. Middle, Markers. Bottom, Atrial unipolar tip. Circled: Dominant initial positive deflection with varying amplitude due to respiration. Examples from a patient with recurrent pericardial effusions before RA lead revision.

Owing to the demonstrated potential for late presentation of cardiac perforation, the denominator for the whole cohort may require extended follow-up for several years to provide a fully accurate estimate of peroration rate for this cohort. However, only two cases of perforation in this cohort presented later than 1 year; therefore, it is unlikely that our quoted rate of 0.5% would significantly change. In addition, complete follow-up data are also missing for a small proportion (6%) of patients.

Even with the use of large CIED databases across three UK tertiary cardiac centres, these results are based upon a relatively small number of cases. Despite this, the study adds real-world insight into the management and outcomes of cardiac perforation in general and specifically for practice in the UK. A larger multicentre prospective study with longitudinal follow-up is necessary to accurately define risk factors and compare management strategies e.g. whether RV mid-septal pacing in elderly patients reduces rates of perforation and improves outcomes.

Conclusions

Cardiac perforation due to PM or ICD leads is a rare but important complication. The presence of pericardial effusion with tamponade was associated with significantly increased risk of 30-day all-cause mortality and major complications. Cardiac CT was highly sensitive for confirming a suspected perforation. A percutaneous strategy is feasible, effective, and associated with an overall low complication rate, including worsening pericardial effusion. Despite the rare requirement for cardiac surgical intervention, case complexity is highly variable requiring both skilled operators and multi-disciplinary management to achieve good outcomes.

Funding

This research did not receive any specific support in the form of equipment, drugs, or grants from funding agencies in the public, commercial, or not-for-profit sectors.

Conflict of interest: None declared.

Data availability

The data underlying this article will be shared on reasonable request to the corresponding author.

References

1. Hsu JC, Varosy PD, Bao H, Dewland TA, Curtis JP, Marcus GM. Cardiac perforation from implantable cardioverter-defibrillator lead placement: insights from the national cardiovascular data registry. *Circ Cardiovasc Qual Outcomes* 2013;**6**:582–90.
2. Birnie DH, Healey JS, Wells GA, Ayala-Paredes F, Coutu B, Sumner GL, *et al.* Continued vs. interrupted direct oral anticoagulants at the time of device surgery, in patients with moderate to high risk of arterial thrombo-embolic events (BRUISE CONTROL-2). *Eur Heart J* 2018;**39**:3973–9.
3. Kirkfeldt RE, Johansen JB, Nohr EA, Jørgensen OD, Nielsen JC. Complications after cardiac implantable electronic device implantations: an analysis of a complete, nationwide cohort in Denmark. *Eur Heart J* 2014;**35**:1186–94.
4. Ghani A, Delnoy PP, Ramdat Misier AR, Smit JJ, Adiyaman A, Ottervanger JP, *et al.* Incidence of lead dislodgement, malfunction and perforation during the first year following device implantation. *Neth Heart J* 2014;**22**:286–91.
5. Vamos M, Erath JW, Benz AP, Bari Z, Duray GZ, Hohnloser SH. Incidence of cardiac perforation with conventional and with leadless pacemaker systems: a systematic review and meta-analysis. *J Cardiovasc Electrophysiol* 2017;**28**:336–46.
6. Hirschl DA, Jain VR, Spindola-Franco H, Gross JN, Haramati LB. Prevalence and characterization of asymptomatic pacemaker and ICD lead perforation on CT. *Pacing Clin Electrophysiol* 2007;**30**:28–32.
7. Lim YM, Uhm JS, Kim M, Kim IS, Jin MN, Yu HT, *et al.* Subclinical cardiac perforation by cardiac implantable electronic device leads detected by cardiac computed tomography. *BMC Cardiovasc Disord* 2021;**21**:346.
8. Acha M R, Rafael A, Keaney JJ, Elitzur Y, Danon A, Shauer A, *et al.* The management of cardiac implantable electronic device lead perforations: a multicentre study. *Europace* 2019;**21**:937–43.
9. Rajkumar CA, Claridge S, Jackson T, Behar J, Johnson J, Sohal M, *et al.* Diagnosis and management of iatrogenic cardiac perforation caused by pacemaker and defibrillator leads. *Europace* 2017;**19**:1031–7.
10. Migliore F, Zorzi A, Bertaglia E, Leoni L, Siciliano M, De Lazzari M, *et al.* Incidence, management, and prevention of right ventricular perforation by pacemaker and implantable cardioverter defibrillator leads. *Pacing Clin Electrophysiol* 2014;**37**:1602–9.
11. Burri H, Sunthorn H, Dorsaz PA, Viera I, Shah D. Thresholds and complications with right ventricular septal pacing compared to apical pacing. *Pacing Clin Electrophysiol* 2007;**30**:S75–8.
12. Laske TG, Vieau SA, Skadsberg ND, Iaizzo PA. High pacing impedances: are you overtorquing your leads? *Pacing Clin Electrophysiol* 2005;**28**:883–91.
13. Refaat MM, Hashash JG, Shalaby AA. Late perforation by cardiac implantable electronic device leads: clinical presentation, diagnostic clues, and management. *Clin Cardiol* 2010;**33**:466–75.

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14. Mahapatra S, Bybee KA, Bunch TJ, Espinosa RE, Sinak LJ, McGoon MD, *et al.* Incidence and predictors of cardiac perforation after permanent pacemaker placement. *Heart Rhythm* 2005;**2**:907–11.
15. Ohlow MA, Lauer B, Brunelli M, Geller JC. Incidence and predictors of pericardial effusion after permanent heart rhythm device implantation: prospective evaluation of 968 consecutive patients. *Circ J* 2013;**77**:975–81.
16. Poole JE, Gleva MJ, Mela T, Chung MK, Uslan DZ, Borge R, *et al.* Complication rates associated with pacemaker or implantable cardioverter-defibrillator generator replacements and upgrade procedures: results from the REPLACE registry. *Circulation* 2010;**122**:1553–61.
17. Glikson M, Nielsen JC, Kronborg MB, Michowitz Y, Auricchio A, Barbash IM, *et al.* 2021 ESC Guidelines on cardiac pacing and cardiac resynchronization therapy. *Europace* 2022;**24**:71–164.
18. Laborderie J, Barandon L, Ploux S, Deplagne A, Mokrani B, Reuter S, *et al.* Management of subacute and delayed right ventricular perforation with a pacing or an implantable cardioverter-defibrillator lead. *Am J Cardiol* 2008;**102**:1352–5.
19. Kusumoto FM, Schoenfeld MH, Wilkoff BL, Berul CI, Birgersdotter-Green UM, Carrillo R, *et al.* 2017 HRS expert consensus statement on cardiovascular implantable electronic device lead management and extraction. *Heart Rhythm* 2017;**14**: e503–51.
20. Huang XM, Fu HX, Zhong L, Osborn MJ, Asirvatham SJ, Sinak LJ, *et al.* Outcomes of lead revision for myocardial perforation after cardiac implantable electronic device placement. *J Cardiovasc Electrophysiol* 2014;**25**:1119–24.
21. Döring M, Müssigbrodt A, Ebert M, Bode K, Lucas J, Dagres N, *et al.* Transvenous revision of leads with cardiac perforation following device implantation-Safety, outcome, and complications. *Pacing Clin Electrophysiol* 2020;**43**:1325–32.

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https://doi.org/10.1093/europace/euac060
Online publish-ahead-of-print 4 August 2022

First use of a rotating mechanical dilator sheath to extract an epicardial defibrillator lead from the pericardial space

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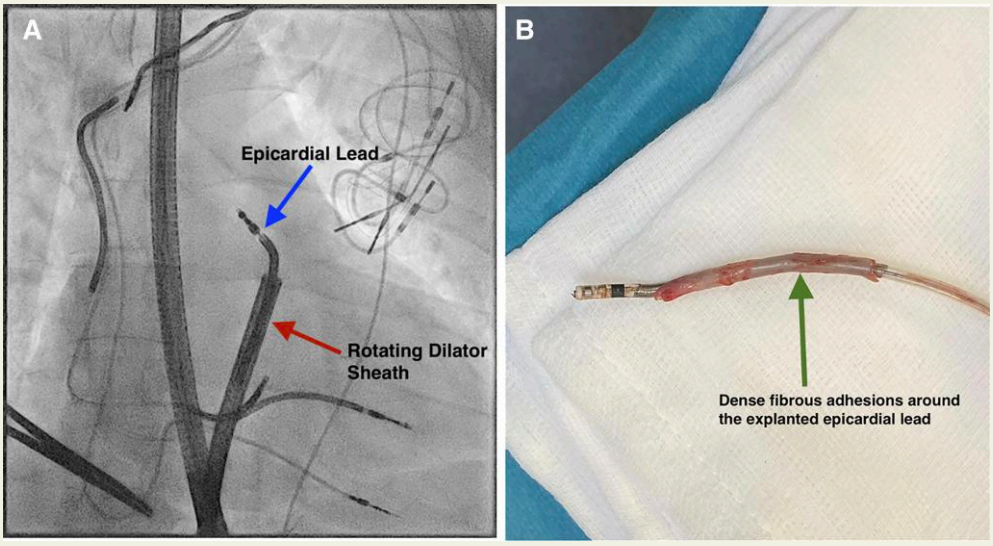
A 39-year-old male with an implantable cardioverter defibrillator was referred for device extraction. Multiple system failures resulted in the implant of an epicardial system with a single coil (Sprint Quatro, Medtronic, MN, USA) placed in the posterior pericardium, a single coil (Transvene, Medtronic, MN, USA) placed subcutaneously, and a Capsurefix 5076 (Medtronic, MN, USA) pace-sense lead all tunnelled to a subrectus generator.



Two years later, positron emission tomography–computed tomography confirmed system infection. Explant of the infected material occurred in a hybrid theatre. A subxiphoid incision was performed for direct visualization of the pericardial space. The proximal portion of the pericardial lead was visualized using a Convergent introducer sheath (Atricure, West Chester, OH, USA) and thoracoscope; however, the tip was not visualized. The lead was prepared with retraction of the screw mechanism and a lead locking device (LLD EZ™, Philips Healthcare, USA) stylet was deployed. Gentle manual traction was applied, but the lead was adhered within the pericardial space. A rotating dilator sheath (13F 545-513 Tightrail, Spectranetics, CO, USA) under direct visualization was used to successfully extract the pericardial lead (*Panel A*). The outer sheath was not used as venous access did not need to be maintained and allowed greater flexibility of the tool. Mechanical extraction was undertaken to free the lead from the fibrous binding sites (*Panel B*).

We describe the first epicardial shock lead extracted with a rotating mechanical cutting tool aided by direct visualization, thereby avoiding sternotomy.

The full-length version of this report can be viewed at: https://www.escardio.org/Education/E-Learning/Clinical-cases/Electrophysiology.

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