

## Percutaneous left ventricular endocardial leads: adverse outcomes and a percutaneous extraction case series

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Background	Conventional cardiac resynchronization therapy (CRT) involves the placement of an epicardial left ventricular (LV) lead through the coronary venous tree. However, alternative approaches of delivering CRT have been sought for patients who fail to respond to conventional methods or for those where coronary venous anatomy is unfavour-able. Biventricular pacing through an endocardial LV lead has potential advantages; however, the long-term clinical and safety data are not known.
Case summary	This article details a case series of four patients with endocardial LV leads; three of these for previously failed con- ventional CRT and a fourth for an inadvertently placed defibrillator lead.
Discussion	We describe the clinical course and adverse events associated with left-sided leads and subsequently describe the safe and feasible method of percutaneous extraction.
Keywords	LV endocardial • Pacing lead • Transvenous extraction • Case series

#### Learning points

- Endocardial left ventricular pacing is becoming increasingly common for delivery of cardiac resynchronization therapy (CRT), especially in patients who fail to respond to conventional CRT.
- Persistence of a pacing lead in the arterial circulation and across the mitral valve apparatus is not without potential risks and these must be borne in mind.
- Percutaneous extraction of endocardial leads is feasible and safe from this limited case series. Prior discussion through a multidisciplinary meeting is strongly advised.

## Introduction

Cardiac resynchronization therapy (CRT) is a highly effective electrical treatment for patients with drug-refractory heart failure, poor left ventricular (LV) systolic function, and a broadened QRS complex.<sup>1,2</sup> Although there is no consensus on the definition of response to CRT, there is good evidence to suggest a sizeable proportion fails to derive benefit.<sup>3</sup> Several animal and small clinical studies have suggested that stimulation of the LV endocardium produces a superior haemodynamic and electrical effect compared with conventional LV epicardial stimulation.<sup>4–6</sup> Implantation of an LV endocardial lead for

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CRT therefore represents an alternative option for those who fail a conventional approach and an increasing number of patients are being treated with this technique. However, the longer-term sequelae of pacing leads within the systemic blood pool are less well known, and this is reflected in limited published clinical outcome data. Particular concerns include the risk of thromboembolism, device-related infection, and injury to the mitral valve apparatus. In this case series, we describe the clinical course and outcomes of four patients with LV endocardial leads that required removal. was impaired, a biventricular pacemaker was implanted with a coronary venous LV lead. Initially, LV thresholds were stable and he obtained a good haemodynamic response to LV pacing. However, insurmountable positional phrenic nerve stimulation required LV lead deactivation—subsequently heart failure recurred. As the coronary venous anatomy was considered to be unfavourable, an LV endocardial lead was placed transatrially via a patent foramen ovale. Despite initial clinical improvement, he presented with worsening breathlessness after 9 months. Transoesophageal echocardiography (TOE) demonstrated severe mitral regurgitation with tethering of the posterior mitral valve

## Timeline

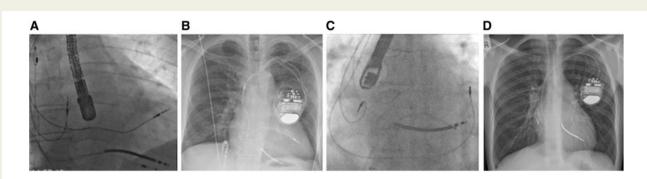
Case number	1	2	3	4
Age (years)	65	53	77	23
Sex	Male	Male	Male	Male
Aetiology	Refractory atrial fibrillation and impaired LV function (LVEF 32%)	Non-ischaemic cardiomyop- athy (LVEF 25 %)	lschaemic cardiomyopathy (LVEF 28%)	Hypertrophic cardiomyop- athy (LVEF 30%)
ECG prior to original	Atrial fibrillation	Sinus rhythm	Sinus rhythm	Sinus rhythm
implant	QRSd 110 ms	LBBB, QRSd 160 ms	LBBB, QRSd 156 ms	QRSd 100 ms
Heart failure medications	Ramipril 10 mg	Ramipril 10 mg	Ramipril 7.5 mg	Ramipril 10 mg
	Bisoprolol 7.5 mg	Bisoprolol 10 mg	Bisoprolol 5 mg	Bisoprolol 10 mg
	Spironolactone 25 mg	Spironolactone 25 mg		
Device indication	Pace and ablate CRTP	Primary prevention CRTD	Primary prevention CRTD	Primary prevention ICD
LV endocardial lead	Medtronic 5076	Medtronic 5076	Medtronic 3830 SelectSecure	Medtronic 6935M
	CapsureFix, 85 cm	CapsureFix, 85 cm	IS-1	Quattro Secure DF4
			Fixed helix	Active fixation
Time from implant to extrac- tion (months)	10	30	36	20
Extraction procedure time (min)	40	60	120	30
Extraction tools	Firm stylet	LLD stylet	LLD stylet	Firm stylet
	LV length	Spectranetics	Spectranetics	RV length
	Medtronic			Medtronic
Successful extraction	Yes	Yes	Yes	Yes
Total number of device pro- cedures prior to extraction	3	5	8	2
Follow-up post-extraction (months)	20	18	14	10
Clinical status	Residual mitral regurgitation, surgical valve replacement	Worsening congestive cardiac failure. Died 6 months later	WiSE CRT implant. Improved NYHA status	No further thromboembolic events

CRT, cardiac resynchronization therapy; CRTP, cardiac resynchronization therapy pacemaker; ECG, electrocardiogram; ICD, internal cardioverterdefibrillator; LBBB, left bundle branch abnormality; LLD, lead locking device; LV, left ventricular; LVEF, left ventricular ejection fraction; NYHA, New York Heart Association; RV, right ventricular.

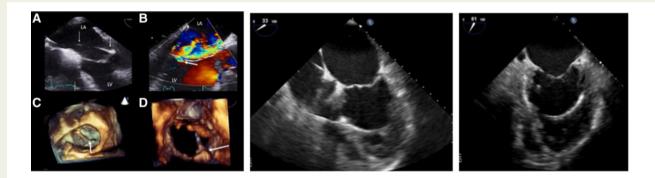
## **Case presentation**

#### Case 1

A 65-year-old man underwent a pace-and-ablate strategy for drugrefractory, symptomatic atrial arrhythmias. Since LV systolic function leaflet to the LV lead (*Figure 2*, left-hand panel). A decision was made by the multi disciplinary team (MDT) to undertake percutaneous removal with surgical standby, and the LV lead was extracted using a firm, LV length non-locking stylet and simple traction. The lead detached from the LV endocardium without any acute consequences and was successfully removed (Supplementary video – endo lead removal



**Figure I** (*A*–*D*) Cases 1–4: AP radiographs of left ventricular endocardial leads prior to removal. Cases 1 (*Panel A*) and 2 (*Panel B*) have left ventricular endocardial leads delivered through the transatrial septal route. Case 3 (*Panel C*) demonstrates the left ventricular lead implanted through the transventricular septal route. Case 4 (*Panel D*) shows a DF4 internal cardioverter-defibrillator lead inadvertently implanted through a superior vena cava–right upper pulmonary vein connection into the left ventricular endocardium.



**Figure 2** Case 1 (left-hand panel): reproduced with permission.<sup>7</sup> Transoesophageal echocardiogram. The left ventricular lead is crossing the left atrium towards the posterior mitral valve leaflet at 0 degree (A). There is significant valvular regurgitation depicted by the white arrow at 120 degrees (B). Three-dimensional reconstruction shows an en-face view of the mitral valve with the white arrow demonstrating the endocardial left ventricular lead preventing complete apposition of mitral valve leaflets at the P2/A2 scallops (C). The lead penetrates the mitral valve orifice at P2 (D). Case 3: transoesophageal echocardiography demonstrating the left ventricular lead crossing the mid-ventricular septum at 33 degrees (middle panel) and 61 degrees (right-hand panel).

case 1). An LV lead was reimplanted via the coronary sinus and deployed without phrenic nerve capture. The patient had a good clinical response at 6 months follow-up. $^7$ 

#### Case 2

A 53-year-old male with non-ischaemic cardiomyopathy, heart block, and bronchiectasis in the context of an auto-inflammatory syndrome, underwent implantation of a primary prevention biventricular defibrillator. Despite long-term antibiotic therapy, recurrent device infections occurred, requiring repeated extractions and re-implantations. A lack of viable coronary venous options indicated the implantation of a transatrial septal LV endocardial lead in a second procedure. Thirty months following this, a device infection developed and a full system extraction was undertaken.

The right atrial (RA) and right ventricular (RV) leads were extracted in their entirety with lead locking device stylets (LLD, Spectranetics) and 11 and 13 Fr mechanical sheaths (Tightrail, Spectranetics). The LV endocardial lead (Medtronic 5076

CapsureFix, 85 cm) was successfully removed using gentle traction and an LLD stylet. Following recovery from active infection, a surgical epicardial system was implanted.

#### Case 3

A 77-year-old male with ischaemic cardiomyopathy underwent dualchamber pacing for high-degree atrioventricular (AV) block. He had repeated device infections with subsequent extractions and reimplantations. He was referred for upgrade to a biventricular defibrillator on the basis of impaired LV function, drug-refractory symptoms of heart failure, and high-degree AV block.<sup>8</sup> Conventional LV lead placement failed due to unfavourable coronary venous anatomy and a transatrial LV endocardial lead was implanted as part of the Alternate Site Cardiac Resynchronization (ALSYNC) study.<sup>9</sup> During this implant procedure, he suffered a thromboembolic stroke which left him with permanent loss of vision in his left eye—he responded favourably to CRT therapy. However, an early device infection developed necessitating system extraction. Given his excellent response to CRT, a transventricular LV endocardial lead<sup>10</sup> with a new cardiac resynchronization therapy defibrillator (CRTD) system was implanted successfully. After 3 years he presented once again with device-related infection necessitating complete system extraction. Transoesophageal echocardiography images of the LV lead traversing the ventricular septum can be seen in Figure 2 (middle- and righthand panels)(Supplementary video - transventricular lead on 4ch echo case 3). Lead locking device stylets were deployed to all three leads (LLD, Spectranetics). The RA lead was removed with gentle traction alone. The RV lead required the addition of a 13 Fr mechanical sheath (Tightrail, Spectranetics). The endocardial LV lead was easily removed with simple traction. A small residual ventricular septal defect (VSD) was evident on intraoperative TOE. However, there was no clear shunt evident at repeat transthoracic echocardiography 48 h later. The patient underwent a dual-chamber internal cardioverter-defibrillator (ICD) implant on the contralateral side and was subsequently implanted with a wireless LV endocardial electrode (WiSE CRT, EBR systems, USA). After 6 months of follow-up he remains well, free from infection with improved exercise tolerance.

#### Case 4

A 23-year-old male with hypertrophic cardiomyopathy underwent primary prevention dual-chamber ICD implantation in 2009. The original implant procedure was complicated by a blood-stained pericardial and pleural effusion requiring readmission and drainage, the aetiology of which was unclear. In 2016, the original RV lead developed noise and was removed and replaced uneventfully. In 2018, he presented with a grandmal seizure, on a background of non-specific neurological (predominantly visual) symptoms over the preceding 2 years. Subsequent echocardiography and cardiac computed tomography demonstrated the ventricular lead had inadvertently traversed a (previously unknown) superior vena cava (SVC) to right pulmonary vein connection and was in fact implanted in the LV endocardium. Embolism of material attached to the ventricular lead was thought to be the cause of his neurological symptoms. Following review in the multi disciplinary team (MDT) meeting, a full system extraction was scheduled in a hybrid theatre and cardiac catheter laboratory with cardiothoracic surgical standby. Both leads required simple traction alone for successful removal using stiff non-locking lead stylets and this was performed without complication (Supplementary video - lv icd lead removal). The patient was subsequently implanted with a subcutaneous ICD. He also underwent angiography confirming congenital anomalous connection between the right upper pulmonary vein and the SVC.

### Discussion

Our case series demonstrates that extraction of LV leads percutaneously can be undertaken safely by using relatively simple techniques. It also illustrates the hazards of cardiac rhythm management device insertion. Left ventricular endocardial pacing is primarily employed only after failure of other approaches and soberingly, in the patients presented, further complications arose.

With increasing numbers of device implantations and the inevitable proportion of individuals who fail to derive benefit from conventional CRT, it is unsurprising that new tools and techniques have been developed to address the unmet need in this group of patients. The constraints of the coronary venous system are an important and insurmountable limitation of current CRT. A growing body of data in both animal models and small clinical and modelling studies has suggested that delivery of biventricular pacing using LV endocardial stimulation may confer superior haemodynamics in addition to a more physiological activation of the ventricles.<sup>4,5,11,12</sup>

Most of the clinical outcome data from LV endocardial pacing relate to small clinical studies. The largest body of evidence is from the ALSYNC study which was a prospective feasibility and safety initiative of 138 patients.<sup>9</sup> The implant was successful in 89% of cases and at 6 months, 59% and 55% of patients considered non-responders to conventional CRT were clinical and echocardiographic responders. Despite this efficacy, there were a number of stroke events in this study. Furthermore, a recent meta-analysis of all clinical endocardial LV implants (n362) calculated the overall incidence of stroke as 2.6 per 100 patient-years (1.56-4.07 95% confidence interval) with an overall stroke rate of 4.7% during the follow-up period.<sup>13</sup> Of note, however, these stroke rates were calculated over a mean of 22 months: extrapolating these data over a longer period may have led to a conceivable higher stroke rate. In addition, the infection rates in patients receiving an endocardial LV lead were higher compared with conventional CRT (3.6% vs 1.0%); this may reflect a more complicated patient group with multiple previous device procedures. Indeed, as our case series demonstrates, patients undergoing LV endocardial pacing appear to be at risk of embolic cerebral events, mitral valve injury, and increased infection and these risks should be borne in mind when considering this approach.

With respect to the technical aspects of the extraction, the removal of the three pacing leads and one ICD lead were all straightforward and utilized stiff or locking stylets and simple traction alone without the need for more advanced tools (*Timeline*). The larger and inelastic mass of the LV provides an intrinsic countertraction, which facilitates easier detachment of the pacing lead helix. We believe the stiff mass of the LV makes eversion far less likely given conventional forward pressure and locking stylet countertraction was required to a far lesser extent here, as compared with extraction of leads from the right side.

As the case series demonstrates, these cases often involve patients with multiple comorbidities and their management may be best guided with a dedicated multidisciplinary team as was the case here. High-risk cases may ideally be undertaken within a hybrid surgical and catheter lab setting to facilitate any emergency surgical approach if required. Furthermore, for patients with neurological symptoms and evidence of thrombus adherent to an LV endocardial pacing lead, the pre-procedural placement of carotid artery filters could be considered. In addition, real-time TOE may assist in assessing any residual injury to nearby structures, e.g. mitral valve, atrial septal defect (ASD)/VSD.

Our case series illustrates that percutaneous extraction is feasible and appears relatively safe. The wireless LV endocardial CRT system (WiSE CRT, EBR systems) may ameliorate some of the disadvantages of systemic pacing leads whilst providing LV endocardial pacing. Published evidence to date suggests this technology may be effective for patients unable to be treated using conventional CRT,<sup>14</sup> and a larger randomized study is underway to evaluate its efficacy (SOLVE CRT, NCT 02922036).

## Conclusion

Left ventricular endocardial pacing leads may be safely extracted percutaneously; simple traction appears sufficient for lead removal.

## Lead author biography



Jonathan M. Behar is a Consultant Cardiologist and Electrophysiologist at the Royal Brompton and Harefield NHS Foundation Trust. He underwent fellowship training in electrophysiology and device implantation at the Barts Heart Centre. He obtained a PhD from Kings College London at St Thomas' Hospital for the development and clinical testing of a software platform which merges cardiac MRI and X-Ray images together in real time for tailoring cardiac procedures (GUIDE CRT).

## Supplementary material

Supplementary material is available at *European Heart Journal - Case* Reports online.

**Slide sets:** A fully edited slide set detailing this case and suitable for local presentation is available online as Supplementary data.

**Consent:** The author/s confirm that written consent for submission and publication of this case report including image(s) and associated text has been obtained from the patient in line with COPE guidance.

#### Conflict of interest: none declared.

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