Endocardial LV lead for resynchronization therapy - a viable alternative.

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Abstract

Objectives: Describe an alternative to conventional LV lead placement. Background: Conventional left ventricular (LV) lead placement is not always possible due to anatomic and technical limitations. In selected patients LV endocardial lead placement is a viable alternative. Methods: Five patients on warfarin with unsuccessful coronary sinus lead placements and contraindications to epicardial lead placement elected to undergo addition of an LV endocardial lead. The left ventricle was accessed through the interatrial septum via a combined superior and inferior approach resulting in an active fix lead placed on the LV endocardial surface. Results: All patients underwent successful LV endocardial lead placement. There were no acute procedural complications. Two patients died 2 years following the procedure from unrelated causes. The other patients were alive and well at a mean follow up of 2.8 years, with significant symptomatic improvement and no evidence of cardioembolic complications. Conclusions: The placement of LV endocardial leads is a viable alternative in highly selected patients with limited options.

Endocardial LV lead for resynchronization therapy - a viable alternative.

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Describe an alternative to conventional LV lead placement.

Background:

Conventional left ventricular (LV) lead placement is not always possible due to anatomic and technical limitations. In selected patients LV endocardial lead placement is a viable alternative.

Methods:

Five patients on warfarin with unsuccessful coronary sinus lead placements and contraindications to epicardial lead placement elected to undergo addition of an LV endocardial lead. The left ventricle was accessed through the interatrial septum via a combined superior and inferior approach resulting in an active fix lead placed on the LV endocardial surface.

Results:

All patients underwent successful LV endocardial lead placement. There were no acute procedural complications. Two patients died 2 years following the procedure from unrelated causes. The other patients were alive and well at a mean follow up of 2.8 years, with significant symptomatic improvement and no evidence of cardioembolic complications.

Conclusions:

The placement of LV endocardial leads is a viable alternative in highly selected patients with limited options.

Key Words:

Left Ventricular Endocardial lead, alternative left ventricular pacing, cardiac resynchronization therapy

Condensed Abstract:

Objectives:

Describe an alternative to CS lead placement.

Background:

In selected patients LV endocardial lead placement is an alternative to conventional LV lead placement.

Methods:

Five patients underwent LV endocardial lead placement. The lead was placed via a superior/inferior approach resulting in an active fix lead placed on the endocardial surface.

Results:

All underwent LV placement without complications. Two patients died 2 years following the procedure from unrelated causes. Three had symptomatic improvement and no complications at a mean follow up of 2.8 years.

Conclusions:

LV endocardial lead placement is a viable alternative in selected patients with limited options.

Abbreviation List:

CRT – Cardiac Resynchronization Therapy

LV – Left Ventricle

CS – Coronary Sinus

CMV – Common Femoral Vein

RA – Right Atrium

EF – Ejection Fraction

ICD – Implantable Cardiac Defibrillator

LBB – Left Bundle Branch

ECG – Electrocardiogram

Background:

Cardiac resynchronization therapy (CRT) decreases mortality, reduces heart failure hospitalizations, and improves quality of life.[1-7] Conventionally the left ventricular (LV) lead is placed via the coronary sinus (CS). However, frequently encountered problems during CS lead placement include anatomic and technical difficulties, such as inability to cannulate the CS, limited lateral or posterolateral branches, venous occlusion, extracardiac stimulation, or high pacing thresholds.[8] Additionally, there are a significant number of patients that do not clinically benefit from CRT, as high as 20-40% in some series.[7]

Given these issues, alternative pacing sites have been described including the His bundle, left bundle branch, surgical epicardial, as well as LV endocardial locations. Conduction system pacing is not possible in every patient, epicardial leads are higher risk given the requirement for surgical placement while LV endocardial leads carry an increased risk of ischemic stroke.[9-15]

Despite the risks, LV endocardial pacing does offer several advantages including access to the entire LV for lead placement and impulse propagation starting in the endocardium allowing for more physiologic depolarization.[16-19]

The current practice of CS or His bundle lead placement are preferable due to their minimal risk of implantation, negligible stroke risk, and reduced bleeding risk given that long-term anticoagulation is not required. This case series, however, highlights the continued need for alternative approaches and describes a viable option for scenarios in which the current standard practice is not feasible.

Methods:

Five patients with an indication for CRT, on life-long warfarin for other indications, with relative contraindications to epicardial lead placement elected to undergo addition of an LV endocardial lead (Table 1). All patients were offered this procedure as an alternative to surgical LV epicardial lead placement, and most of these patients underwent the procedure prior to the widespread use of physiologic pacing. All the procedures were done in either the cardiac operating room or the electrophysiology lab under general anesthesia or monitored anesthesia care.

All patients underwent the following general procedure with some minor variations detailed below. All patients had a device prior to the index procedure.

First, the prior pocket was opened and a new axillary venous access was obtained. A femoral venous access site was also obtained in the right common femoral vein (CFV). A 10 or 11 Fr peel away sheath was advanced over the left subclavian wire. An Amplatz Gooseneck snare system was then introduced via the axillary sheath and advanced into the right atrium (RA) through a long Medtronic (Dublin, Ireland) peel away sheath (c304, the deflectable His bundle delivery tool). An SL-0 or SL-1 sheath and dilator were advanced over a wire from the femoral vein into the SVC. The gooseneck snare was placed over the SL sheath. Then, a Brockenbrough transseptal needle was advanced through the femoral SL sheath (Figure 1A) and a transseptal puncture was performed with guidance from either transesophageal echocardiography or

intracardiac echocardiography along with fluoroscopy. Once the transseptal needle was in the left atrium, the snare was tightened at the dilator/sheath interface and the dilator, femoral sheath, and snare were advanced into the LA (Figure 1B). This carried the axillary peel-away sheath into the LA. Once in the LA, the snare was freed from the femoral sheath (Figure 1C) and removed leaving the axillary sheath in the LA (Figure 1D). Next, an active fixation pacing lead (Medtronic 5076 or the equivalent) was advanced through the deflectable sheath (Figure 1E), across the mitral valve and fixed on the LV endocardial surface (Figure 1F). Lead placement and capture were confirmed, sheaths were peeled away and the pocket was closed in the standard fashion. Follow-up chest X-ray to confirm lead placement prior to discharge (Figure 2).[20,21] Pre and post Electrocardiograms (ECGs) were obtained with expected shortening of QRS complex (Figure 3).

Case 1

A 71 year-old female patient with a past medical history of hypertension, dyslipidemia, breast cancer in remission after left radical mastectomy, chemotherapy and radiation therapy in the late 1990's, paroxysmal atrial fibrillation on warfarin therapy, symptomatic complete heart block with a dual chamber pacemaker 7 years prior to the procedure, non-ischemic cardiomyopathy and previously preserved ejection fraction (EF) was referred for upgrade to a Bi-V ICD after a decline in her EF to 20% and progression of HF symptoms. Unfortunately, attempts at CS lead placement were unsuccessful and the pacemaker was only upgraded to a dual chamber ICD. She continued to have heart failure symptoms and an attempt was made to upgrade her to a Bi-V ICD. During the procedure she was noted to have an occluded axillary vein and underwent extraction of a previously abandoned RV lead. Following extraction, another attempt to place a CS lead was unsuccessful due to a lack of target branches. An LV endocardial lead was placed using the procedure described above. The procedure was well tolerated, and warfarin was resumed with a heparin bridge, targeting an INR of 2.5-3.5. Her EF did not improve after 3 years of follow-up. On follow-up of 6 years there has been no evidence of TIA or stroke, but she had developed severe mitral regurgitation from lead impingement on the mitral valve. She developed worsened heart failure symptoms, prompting plan for LV lead extraction with plan for attempt at physiologic pacing.

Case 2

A 79 year-old male with past medical history of ischemic cardiomyopathy and systolic heart failure (EF <30%) with a dual chamber ICD initially placed 8 years prior, previous AV nodal ablation and upgrade to a Bi-V ICD one year prior and subsequent device infection requiring extraction and reimplantation who was referred for LV endocardial lead placement after an unsuccessful attempt to re-implant a CS lead from the right. During placement there were no significant variations from the described procedure above. There were no complications including stroke or TIA. He did well until 2 years post procedure when he developed renal failure and ultimately opted for hospice care. There was no follow-up evaluation of EF and functional status was NYHA class III.

Case 3

An 89-year-old male with a prior history of atrial fibrillation with tachy-brady syndrome s/p single chamber Medtronic pacemaker 9 months prior, status post left carotid endarterectomy, hypertension, hyperlipidemia, hypothyroidism, diabetes, COPD, GERD and BPH requiring home bladder catheterizations was referred for biventricular pacemaker upgrade for heart failure. After a challenging initial upgrade, the CS lead dislodged prompting referral for an endocardial LV lead placement. CS lead placement was again attempted however there were no favorable lateral branches. LV lead placement was then performed with the following variations:

Despite going through a PFO, at first pass the peel away sheath from above could not be fully advanced into the left atrium, as became clear when trying to advance the lead through the sheath. After several attempts to direct the lead to the LV, the apparatus was pulled back to the right side. The transseptal was repeated, and this time, after the SL0 sheath was in the LA, the transseptal needle and dilator were exchanged for a deflectable quadripolar EP catheter. This allowed for greater maneuverability, and ultimately allowed the superior sheath to be directed to the LV. Additionally, there was a small, not hemodynamically

significant pericardial effusion noted on TEE that remained stable throughout the procedure. On follow-up, the LV EF improved from 25-30% to 35-40% with further improvement to 40-45% 1 year post procedure with improvement to NYHA class II. On most recent follow-up 3 years post procedure there had been no complication from the LV endocardial lead including stroke or TIA, however, the patient expired from unrelated causes 4 years after the procedure.

Case 4

A 78-year-old male with permanent atrial fibrillation on warfarin and longstanding dilated cardiomyopathy with depressed ejection fraction despite optimal medical therapy was referred for Biventricular upgrade. However, a previous attempt to place a coronary sinus lead was unsuccessful 2 months prior. After discussion, the decision was made to attempt LV endocardial lead placement. The procedure was well tolerated without complications. Follow-up has been limited since the procedure with no repeat EF testing or assessment of functional status documented.

Case 5

A 78-year-old female with a past medical history of paroxysmal non-valvular atrial fibrillation, non-ischemic cardiomyopathy status post primary prevention CRT-D 3 years prior was noted to have elevated RV and LV thresholds with early battery depletion. She underwent placement of a His bundle pacing lead. Unfortunately, the threshold following the procedure was elevated. As she had responded quite well to CRT previously, the recently placed His lead was removed and another unsuccessful attempt at CS lead placement was made and aborted due to high thresholds. At this point, procedure was transitioned to placement of an LV endocardial lead. LV endocardial lead placement was performed without significant variation from the previously described procedure. On follow-up 2 years after the procedure she was doing well without any complications, NYHA class II, but no repeat evaluation of EF.

Discussion:

Placement of a traditional LV lead in the CS has a number of anatomic and technical limitations including inadequate lateral or posterolateral branches, venous occlusion, phrenic nerve stimulation, or high pacing thresholds. [8] Additionally, 20-40% of patients do not respond to biventricular pacing .[7] Given these issues, alternative sites for LV lead placement have been proposed. Epicardial placement has a higher periprocedural morbidity and some concerns regarding long term durability.[8,16]

Physiologic pacing techniques, such as His bundle pacing and Left bundle branch (LBB) pacing are also a viable alternative in select patients. His bundle is the most commonly used physiologic approach, and there have been many studies evaluating the feasibility and clinical efficacy of the technique. However, there are some drawbacks to His bundle pacing including difficulty finding the His signal, damage to the His bundle during implantation of the lead, high or unstable pacing thresholds, low R wave amplitudes or large atrial signals which can complicate pacing, and block distal to the pacing site in the conduction system. However, there is some evidence to suggest that His bundle pacing may be an alternative in CRT non-responders.[20-30]

LBB pacing is another physiologic approach to pacing but is less common and newer than His bundle pacing. There is some evidence to support the feasibility of this approach as an alternative to traditional CRT.[31,32] However, there are some complications that include LV perforation, injury to the right bundle, septal coronary artery injury, and tricuspid valve entrapment.[32]

Other novel techniques include “wireless” LV lead stimulation as described in the WiSE-CRT trial and SELECT-LV study where a patient undergoes a wireless LV electrode triggered by subcutaneous ultrasound that is coordinated with an RV lead. However, this requires a pre-screening process, a complex procedure, and had non-negligible complication rates of stroke, electrode embolization, pericardial effusion, and infection.[33]

LV endocardial lead placement via the interatrial septa was initially described in 1998 and techniques have advanced since then.[34] An alternative technique to the one used in this series is known as the Jurdham procedure and involves placement of the LV endocardial lead from the femoral vein and extracting the

proximal end into the subclavian pocket.[35] LV endocardial pacing has hemodynamic advantages to epicardial pacing as the entirety of the endocardial LV is available for optimal lead placement, whereas with epicardial pacing there are limitations due to venous anatomy, coronary anatomy, and phrenic nerve location.[36,37] However, there are some issues to consider with this approach, including exacerbation of mitral regurgitation, the need for lifelong anticoagulation, and technical challenges including the need to repeat the transseptal process if the apparatus comes out of the LA. There are also potentially challenging scenarios that may arise that currently lack a clear resolution such as what to do if the LV lead needs to be extracted or if a LV assist device is needed. One patient in this series developed severe mitral regurgitation from lead impingement on the leaflets and has been planned for extraction with the goal of attempting physiologic pacing. There is limited data on the outcomes of LV endocardial lead extraction, but there are some limited case reports and case series highlighting some approaches to extraction.[38, 39]

One of the biggest concerns with LV endocardial leads is the risk of stroke. This was not observed in our small series, however, we only consider LV endocardial lead placement in patients who already have a lifelong indication for warfarin, and have been on warfarin for at least one year without complications.

This series describes an underutilized approach that mitigates some of the anatomical challenges of LV endocardial lead placement using combined superior and inferior access to snare and carry a wire from the subclavian vein transseptally. Overall the procedure was well tolerated and effective. Of note, all patients had previously been on lifelong anticoagulation with warfarin and had contraindications to both CS and epicardial lead placement. While there are currently several alternatives to traditional coronary sinus leads, a complete toolbox for placement of a CRT system should include endocardial LV lead placement.

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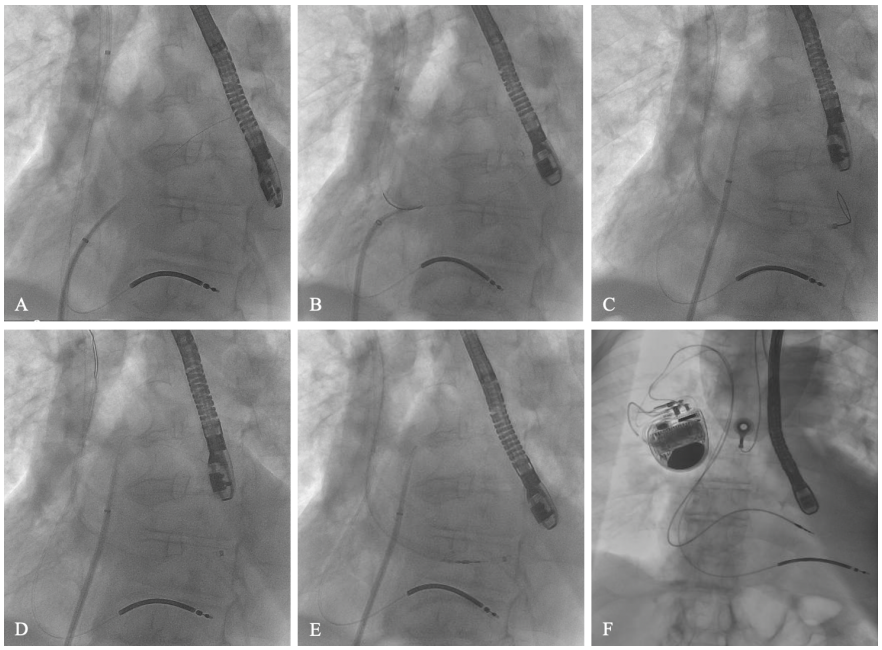
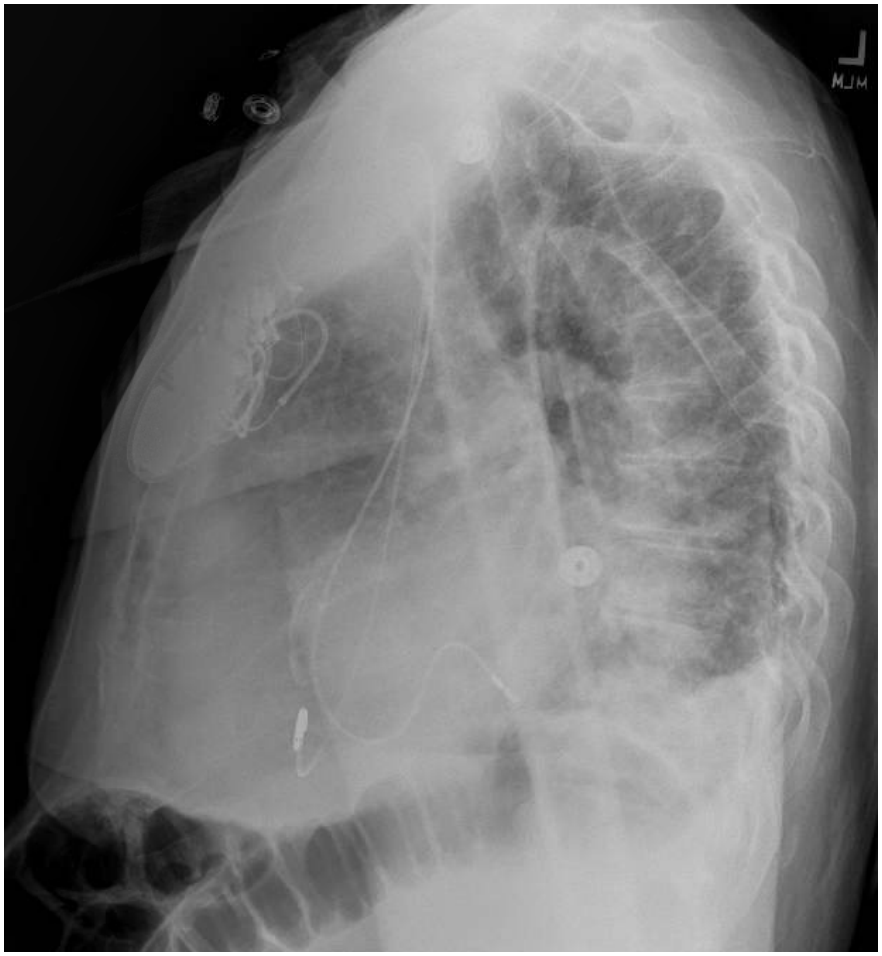


Figure 1: Left ventricular endocardial lead placement procedure: Brockenbrough needle and sheath in the RA **(A)** . Snare is tightened over transseptal sheath/needle **(B)** . Snare and sheath in the left ventricle with transseptal apparatus removed **(C)** . Sheath still in place in the left ventricle **(D)** . LV lead is advanced through sheath from the axillary vein into the LV **(E)** . Final procedural image with LV lead in the endocardium **(F)** .



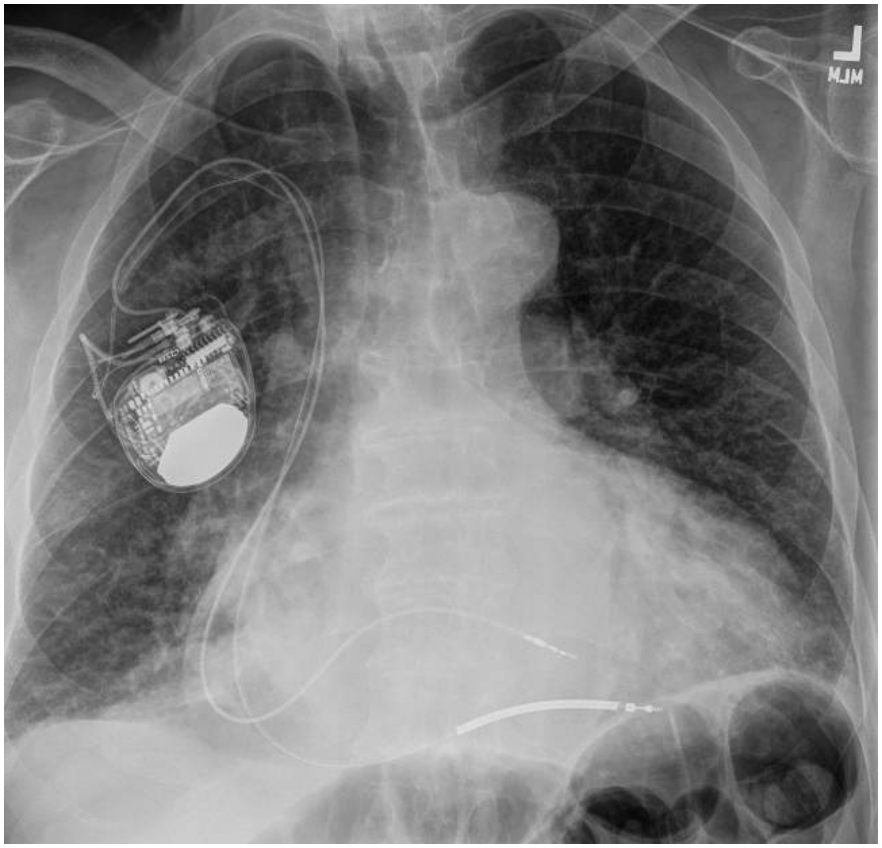


Figure 2: Final Pre-Discharge - 2 View Chest X-Ray

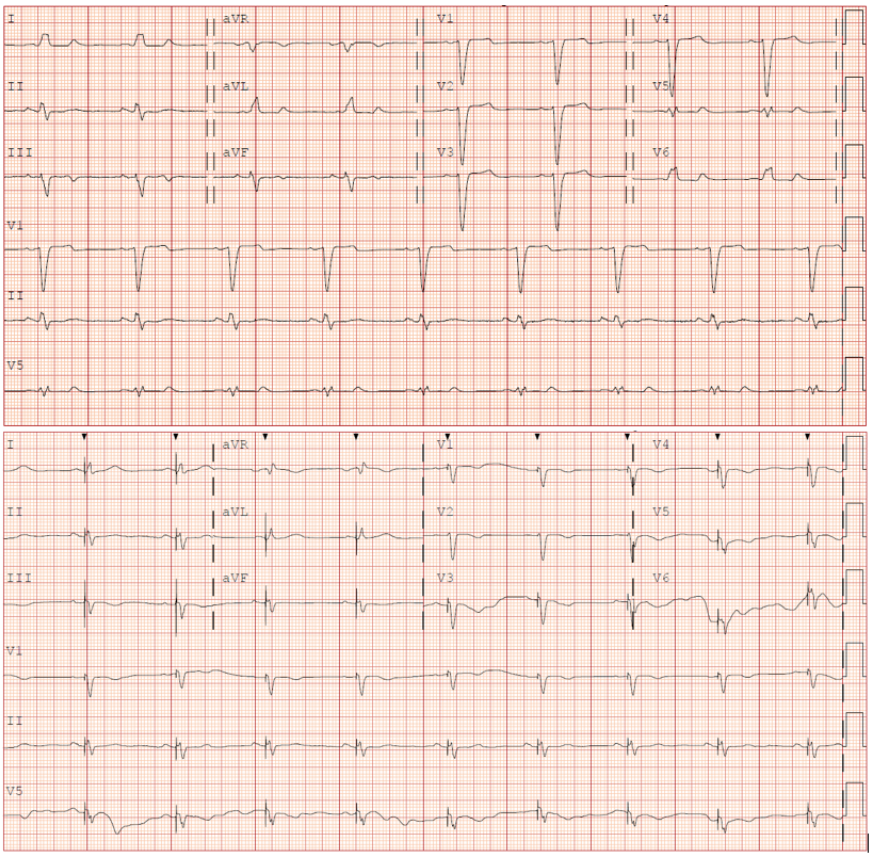


Figure 3: Representative ECG Pre and Post Procedure: Pre-procedure (A). Post procedure (B).

Tables

	Type of Cardiomyopathy	**Prior Device Related Procedures**	**Indication for warfarin**	**Outcome**
Case 1	Non-ischemic, likely chemotherapy-related	- Dual chamber device - Unsuccessful coronary sinus lead placement	Atrial Fibrillation	- No complication - No change in EF - Functional improvement to NYHA class II
Case 2	Ischemic	- Biventricular device - Extraction of Biventricular device due to infection - Attempt at Biventricular device with failed coronary sinus lead placement	Atrial Fibrillation	- No complication - No follow-up EF - Functional status unchanged - Passed from renal failure

	Type of Cardiomyopathy	**Prior Device Related Procedures**	**Indication for warfarin**	**Outcome**
Case 3	Non-ischemic	- Single chamber device - Biventricular device placement complicated by CS lead dislodgement	Atrial Fibrillation	- No complications - EF improved from 25-30% to 40-45% - Functional improvement to NYHA class II
Case 4	Non-ischemic	- Dual chamber device - Unsuccessful coronary sinus lead placement	Atrial Fibrillation	- No complications - No follow-up since procedure
Case 5	Non-ischemic	- Biventricular device with elevated thresholds - His lead placed but developed elevated thresholds - Unsuccessful repeat CS lead placement	Atrial Fibrillation	- No complications - No follow-up EF - Functional improvement to NYHA class II

Table 1: Case information.