

Implantation of left atrial-ventricular epicardial pacemaker system and subcutaneous implantable cardioverter-defibrillator in a single setting: The "extravascular" cardiac resynchronization therapy

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Introduction

In several clinical trials, cardiac resynchronization therapy with implantable cardioverter-defibrillator (CRT-D) has provided long-term survival benefit and improved clinical outcomes for patients with heart failure with reduced ejection fraction.^{1–4}

However, for patients with contraindications to transvenous leads (such as recurrent endocarditis) and/or limited venous access, the implantation of a cardiac resynchronization therapy (CRT) device could be challenging. For such patients, the implantation of a left atrial-ventricular (AV) epicardial pacemaker system with a subcutaneous implantable cardioverter-defibrillator (S-ICD) serves as an alternate technique for providing CRT. This device system can be implanted via a completely extravascular approach, thereby eliminating the need for transvenous leads. Since it is an extravascular device system that provides CRT, we have termed it the "extravascular CRT-D."

The feasibility of simultaneous implantation of S-ICD and epicardial pacemaker has been described in some previous studies.^{5–7} However, in most of these studies the S-ICD was implanted following a previously implanted epicardial pacemaker system and there was no indication for CRT. We report a case series of patients requiring CRT, with contraindications for transvenous leads, who underwent simultaneous implantation of a left AV epicardial pacemaker system and an S-ICD in the same setting.

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Case report

Altogether, 5 patients underwent simultaneous implantation of a left AV epicardial pacemaker system and an S-ICD. Patient characteristics are further described in Table 1.

Case 1

Case 1 involves a 60-year-old male patient with familial nonischemic cardiomyopathy, chronic atrial fibrillation, and complete heart block with pacemaker dependence. He experienced severe weight loss from cardiac cachexia, resulting in lead erosion through the implantable cardioverterdefibrillator pocket. After reimplantation of a new CRT-D on the right side, he presented with pocket infection and methicillin-resistant *Staphylococcus aureus* endocarditis, mandating explant of the leads from the right side as well. Ultimately, to avoid recurrent pocket infections and endocarditis, we considered implanting the extravascular CRT-D.

Case 2

Case 2 involves a 71-year-old male patient with diabetes mellitus, hypertension, and end-stage renal disease on hemodialysis via left-sided AV fistula. He had ischemic cardiomyopathy and underwent right-sided CRT-D implantation. He later developed infective endocarditis with blood cultures positive for coagulase-negative *Staphylococcus aureus*. Consequently, the entire CRT system was extracted from the right side and to avoid infection, the extravascular CRT-D was implanted.

Case 3

Case 3 involves a 49-year-old male patient with end-stage renal disease on hemodialysis via left-sided AV fistula, and coronary artery disease with 4-vessel coronary artery bypass graft. He had long-standing history of ischemic cardiomyopathy. Ultimately, he developed left bundle branch block, meeting criteria for CRT-D upgrade. Unfortunately, the right-sided venous system was occluded and the venogram showed extensive collaterals at the time of attempted

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KEYWORDS Cardiac resynchronization therapy; Device interactions; Epicardial pacemaker; Implantable cardioverter-defibrillator; S-ICD; Subcutaneous implantable cardioverter-defibrillator

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KEY TEACHING POINTS

- In patients with contraindications to transvenous leads and an indication for cardiac resynchronization therapy (CRT), the implantation of a subcutaneous implantable cardioverter defibrillator with a left atrial-ventricular epicardial pacemaker system serves as an alternative approach for providing CRT.
- Eliminating the need for transvenous leads, this device system can be implanted in a completely extravascular manner, and we term it the "extravascular CRT-D."
- The entire system can be implanted on the left side in the same setting. This avoids the need for 2 different surgeries and reduces the number of incisions required for these patients.

upgrade. Owing to the AV fistula on the left side, and inability to maintain viable right-sided access despite the lead extraction, we decided to implant the extravascular CRT-D.

Case 4

Case 4 involves a 64-year-old male patient with advanced ischemic cardiomyopathy and left bundle branch block, who underwent CRT-D implantation. Three years after the implant, he presented with methicillin-resistant *Staphylococcus aureus* endocarditis. He had multiple comorbidities, including severe peripheral vascular disease, uncontrolled diabetes mellitus, and chronic kidney disease. Cardiothoracic surgery was consulted and a decision was made to extract the

 Table 1
 Patient characteristics

CRT system and treat the endocarditis medically. Owing to the high risk for recurrent infection with an intravascular device, the extravascular CRT-D was implanted.

Case 5

Case 5 involves a 61-year-old male patient with permanent atrial fibrillation and nonischemic dilated cardiomyopathy. The patient was morbidly obese with a body mass index of 50 kg/m². He underwent CRT-D implantation and an AV node ablation procedure, done in separate settings. Four weeks following the AV node ablation, the patient presented with a dislodged right ventricular lead. The dislodged lead was repositioned, but soon the lead dislodged again. Unfortunately, the patient had a total of 4 episodes of recurrent lead dislodgement. The cause of recurrent lead dislodgement was not known. Finally a temporary pacemaker system was placed and we decided to implant the extravascular CRT-D.

Procedure

The epicardial lead implantation procedure via left lateral thoracotomy was performed in the operating room under general anesthesia. The patient was placed in a right lateral decubitus position with an outstretched arm, and the left chest was prepped and draped in a standard surgical manner.

Implantation of left AV epicardial pacemaker system

A vertical left lateral thoracotomy incision of about 15 cm was made in the midaxillary line extending from the third to fifth intercostal space (Figure 1A). The lung was retracted posterolaterally, exposing the pericardium. The pericardium was then divided above the phrenic nerve and retracted. The left atrial appendage and the posterolateral surface of the left ventricle (LV) was identified.

First, 2 sutureless bipolar nonsteroidal-eluting Myopore epicardial leads (Model 511212; Enpath Medical Inc, St.

	Case				
	1	2	3	4	5
Sex	Male	Male	Male	Male	Male
Age at implant (years)	60	71	49	64	61
ICD indication	Primary prevention	Primary prevention	Secondary prevention	Primary prevention	Primary prevention
Pacemaker indication	Complete heart block	LBBB	LBBB	LBBB	Complete heart block
Endovascular contraindication	Bacterial endocarditis	Bacterial endocarditis	AV fistula on the left side with limited right-sided venous access Bacterial endocarditis	Bacterial endocarditis	Recurrent lead dislodgement
Left ventricular EF (%)	20%-25%	20%-25%	30%	20%	20%-25%
NYHA class	III	III	III	III	III
Complicating history	Chronic atrial fibrillation	ESRD, diabetes mellitus, hypertension	ESRD	PVD, diabetes mellitus, chronic kidney disease	Morbid obesity

AV = atrial-ventricular; EF = ejection fraction; ESRD = end-stage renal disease; ICD = implantable cardioverter-defibrillator; LBBB = left bundle branch block; NYHA = New York Heart Association; PVD = peripheral vascular disease.



Figure 1 Epicardial leads and the subcutaneous implantable cardioverter-defibrillator (S-ICD) pocket. Image showing the operative field of a patient in right lateral decubitus position with left arm extended. A: Left lateral thoracotomy incision. B: The outline of the S-ICD pocket created using the same incision. C: The epicardial pacemaker leads that are tunneled to the subrectus sheath.

Paul, MN; now Greatbatch Medical, Alden, NY) were implanted on the lateral or posterolateral portion of the LV. A FINELINE II Sterox EZ Pacing Lead (Model 4470; Boston Scientific, Marlborough, MA) was placed over the left atrium and 0 silk sutures were used to secure the cathode and anode for good tissue contact. A pacemaker pocket was created on the left side underneath the rectus sheath. All 3 leads were tunneled to the subrectus pocket (Figure 1B). The leads were connected to the Valitude CRT-P (Model U125; Boston Scientific) pacemaker, which was then placed in this pocket.

Implantation of S-ICD

The S-ICD was implanted using the 2-incision technique. The original left lateral thoracotomy incision used for epicardial lead placement was used to create a deep left chest pocket for the pulse generator. This pocket was extended to the midaxillary line between the fifth and sixth intercostal spaces, as seen in the outline in Figure 1C. In order to place the S-ICD lead, a small horizontal incision was made 1 cm to the left of the xiphoid midline (xiphoid incision). An S-ICD lead was tunneled from the S-ICD pocket to the xiphoid incision and sutured in the xiphoid incision using 0 silk. Using the 12-French Peel-Away Introducer Sheath (Cook Medical, Bloomington, IN), the lead was subsequently tunneled approximately 14 cm above the xiphoid incision, to a superior site lateral to the sternal midline. The sheath was peeled away, leaving the S-ICD lead in place. The lead was then connected to the Boston Scientific S-ICD pulse generator.



Figure 2 The extravascular cardiac resynchronization therapy (CRT-D) device system. **A:** Chest radiograph after implantation of subcutaneous implantable cardioverter-defibrillator (S-ICD) and left atrial-ventricular epicardial pacemaker system. The epicardial leads are fixed to the free wall of the left atrium (*black arrowhead*) and left ventricle (*black arrow*). The S-ICD lead is placed in a left parasternal position (*white arrow*). The generator of the S-ICD is positioned in a subcutaneous pocket at the lower left-lateral thorax. **B:** Chest radiograph after implantation of the extravascular CRT-D. The figure demonstrates the optimal position of the S-ICD lead placed in the left parasternal position (*white arrow*). The epicardial leads are fixed to the free wall of the left ventricle (*black arrows*). The generator of the S-ICD is positioned in a subcutaneous pocket at the lower left-lateral position (*white arrow*). The epicardial leads are fixed to the free wall of the left ventricle (*black arrows*). The generator of the S-ICD is positioned in a subcutaneous pocket at the lower left-lateral position (*white arrow*). The epicardial leads are fixed to the free wall of the left ventricle (*black arrows*). The generator of the S-ICD is positioned in a subcutaneous pocket at the lower left-lateral thorax.

The S-ICD pulse generator was sutured to the underlying fascia with 0 silk and secured in the original left lateral thoracotomy pocket (Figure 2).

Defibrillation threshold testing was performed. Ventricular fibrillation (VF) was induced via a 50-Hz burst of energy. The S-ICD appropriately detected VF and converted all patients to sinus rhythm.

The S-ICD pocket, the xiphoid incision, and the left lateral thoracotomy incision were all closed in 3 layers with 2-0 Vicryl for deep and subcutaneous layers and staples were used for the skin.

Device settings and testing of defibrillation threshold

Screening for epicardial pacing was not possible for our patients because both the S-ICD and epicardial pacemaker systems were implanted in the same setting in a sterile field. All 5 patients underwent S-ICD implantation regardless, and all vectors were evaluated after the procedure. At least 1 vector in each patient demonstrated good sensing parameters. The best vector for sensing and with the lowest probability for double counting was selected.

An important concern of simultaneous implantation of an S-ICD with epicardial pacemakers is the complex interaction between the 2 devices. The potential for QRS or T-wave oversensing, with double counting and inappropriate shocks, has been well documented in previous experiences, especially in paced rhythms.^{6,8} To avoid double counting of atrial and ventricular pacing through the S-ICD, we programmed the upper tracking rate of the pacemaker to 100 beats per minute and VF detection rate through the S-ICD to 220 beats per minute, which is more than twice the upper pacing rate. We evaluated each vector for all patients after the procedure in both supine and upright position, and none of the patients presented double counting or inappropriate shock delivery.

VF was induced via a 50-Hz burst of energy. In all cases, the epicardial pacemaker correctly sensed the induced VF and inhibited pacing. As a result, the S-ICD appropriately detected VF with no delay in detection and effective defibrillation at 65 joules of energy.

Discussion

Over the past 10 years, the S-ICD has been used concurrently with other devices, including transvenous and epicardial pacemakers, and favorable outcomes have been reported.^{7,9,10} However, the simultaneous implantation of a left AV epicardial pacemaker system and an S-ICD has not been described previously.

We implanted the epicardial pacemaker using the left atrium and LV via a left lateral thoracotomy. The left lateral thoracotomy incision was used for the implantation of the epicardial pacing leads as well as the S-ICD pulse generator.

Although there have been a few studies that describe coimplantation of an epicardial pacemaker and S-ICD,^{6,8} our approach differs in several ways:

- The entire system can be implanted on the left side in the same setting. This avoids the need for 2 different surgeries in these patients.
- Both devices can be implanted simultaneously using the same incision. This reduces the number of incisions required for these patients, thus decreasing the risk for pocket infection.
- A left AV epicardial pacemaker system was implanted. It has been shown in prior studies that LV-only pacing is as safe and effective as biventricular pacing.¹¹ As a result, this serves as a feasible approach for patients with heart failure with reduced ejection fraction, with an indication for CRT.

As mentioned previously, this approach exhibits several challenges owing to potential interaction between the 2 devices. The S-ICD and epicardial pacemaker system have to be programmed accurately to avoid QRS or T-wave oversensing and double counting. Another concern is the potential inability of the epicardial pacemaker to detect VF, resulting in continued pacing through the VF event. This could lead to VF undersensing by the S-ICD and withholding of appropriate therapy. However, in all cases, the epicardial pacemaker correctly sensed VF and inhibited pacing. Consequently, the S-ICD appropriately detected VF and delivered therapy without delay. All patients showed adequate device function and reasonable device threshold on the epicardial leads. There was no evidence of double counting, tachycardia, or any therapies delivered postoperatively.

The major limitation of our report is limited follow-up. As a result, the long-term safety and efficacy of this procedure could not be determined.

Conclusion

Our report demonstrates that simultaneous implantation of a permanent left AV epicardial pacemaker system and an S-ICD in the same setting, using the same incision, is feasible. For patients requiring a totally extravascular device system with the needs of CRT and defibrillation, this can be an effective and feasible alternative, eliminating the need for repeated interventions in these patients.

References

- Ziaeian B, Zhang Y, Albert NM, et al. Clinical effectiveness of CRT and ICD therapy in heart failure patients by racial/ethnic classification: insights from the IMPROVE HF registry. J Am Coll Cardiol 2014;64:797–807.
- Tang AS, Wells GA, Talajic M, et al. Cardiac-resynchronization therapy for mildto-moderate heart failure. N Engl J Med 2010;363:2385–2395.
- Kozlowski B. [Commentary to the article: Moss AJ, Hall WJ, Cannom DS, et al. Cardiac-resynchronization therapy for the prevention of heart-failure events. N Engl J Med 2009;361:1329-1338]. Kardiol Pol 2009;67:1417–1418.
- Moss AJ, Hall WJ, Cannom DS, et al. Cardiac-resynchronization therapy for the prevention of heart-failure events. N Engl J Med 2009;361:1329–1338.
- Huang J, Patton KK, Prutkin JM. Concomitant use of the subcutaneous implantable cardioverter defibrillator and a permanent pacemaker. Pacing Clin Electrophysiol 2016;39:1240–1245.
- Kossidas K, Kalman R, Follis WP, Cooper JM. Managing cross talk between a subcutaneous implantable cardioverter-defibrillator and a dual-chamber unipolar pacemaker system. HeartRhythm Case Rep 2017;3:579–583.
- Kuschyk J, Stach K, Tulumen E, et al. Subcutaneous implantable cardioverterdefibrillator: First single-center experience with other cardiac implantable electronic devices. Heart Rhythm 2015;12:2230–2238.

- Steinberg C, Chakrabarti S, Krahn AD, Bashir J. Nothing inside the heart -Combining epicardial pacing with the S-ICD. HeartRhythm Case Rep 2015; 1:419–423.
- **9.** Porterfield C, DiMarco JP, Mason PK. Effectiveness of implantation of a subcutaneous implantable cardioverter-defibrillator in a patient with complete heart block and a pacemaker. Am J Cardiol 2015;115:276–278.
- Lambiase PD, Barr C, Theuns DA, et al. Worldwide experience with a totally subcutaneous implantable defibrillator: early results from the EFFORTLESS S-ICD Registry. Eur Heart J 2014;35:1657–1665.
- Leclercq C, Ansalone G, Gadler F, et al. Biventricular vs. left univentricular pacing in heart failure: rationale, design, and endpoints of the B-LEFT HF study. Europace 2006;8:76–80.