A novel method to enable biventricular defibrillator to biventricular pacemaker downgrade involving DF4 defibrillator lead

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Introduction

The decision to replace or downgrade a cardiac resynchronization therapy–defibrillator (CRT-D) system upon reaching battery depletion status carries important considerations, especially in patients who have benefited from cardiac resynchronization therapy (CRT) but have not experienced ventricular tachyarrhythmias. We review some of the ethical, practical, and technical considerations that are encountered when deciding to downgrade a CRT-D system to a cardiac resynchronization therapy–pacemaker (CRT-P) system. We present the case report of a carefully vetted, off-label means to downgrade a CRT-D to CRT-P by fitting the existing DF4 implantable cardioverter–defibrillator (ICD) lead into the IS4 connector of a CRT-P device.

Case report

An 86-year-old woman with a history of hypertension, paroxysmal atrial fibrillation, and coronary artery disease presented for replacement of her biventricular ICD in early 2018 due to battery depletion. The initial indication in 2012 included left bundle branch block, nonischemic cardiomyopathy, and systolic heart failure with left ventricular ejection fraction (LVEF) 25% and New York Heart Association functional class III HF symptoms. Her CRT-D system consisted of a bipolar IS1 DEXTRUS model 4135 right atrial (RA) lead, a dual-coil DF4 ENDOTAK RELIANCE 4-Site model 0295 right ventricular (RV) lead, a bipolar IS1 ACUITY steerable model 4554 left ventricular (LV) lead, and an INCEPTA model N160 CRT-D (all Boston Scientific, Marlborough, MA) device having IS1, DF4, and IS1 ports for the RA, RV, and LV leads, respectively.

The patient had responded to CRT with complete normalization of LV function and improvement in heart failure symptoms. She had also undergone mitral valve repair for severe mitral regurgitation in 2016. She had no history of any ventricular tachyarrhythmia. Based on these considerations and the patient's age and preference, the decision was made to downgrade to a biventricular pacemaker. Her underlying rhythm exhibited normal sinus function with intact atrioventricular conduction.

Ultimately, the decision was made to perform a CRT-D to CRT-P downgrade using a VALITUDE X4 model U128 CRT-P (Boston Scientific) and inserting the CRT-D's DF4 RV lead connector into the IS4 LV port. The IS1 RA lead was inserted into the RA port, and the bipolar IS1 LV lead was inserted into the RV port (Figure 1).

Discussion

The management of ICDs at end of life represents a clinical challenge with limited empirical data. Retrospective studies have shown that a significant portion of patients (25%–28%) receiving an ICD for primary prevention have improvement in LV function.[1] Some studies have shown a lower risk of ICD therapies in patients with normalized LVEF.[2] However, there is also evidence of residual increased risk of sudden death, with rates of appropriate ICD therapies up to 5% per year in this population.[3,4] Observations from the Multicenter Automatic Defibrillator Implantation Trial (MADIT) II and other trials also showed increasing survival benefit over time, up to 15 years from remote myocardial infarction.[5,6]

The role of CRT in biventricular ICDs further challenges their management after generator depletion. Studies have shown a higher percentage of patients with improvement in LV function, but the prognostic significance of this is not fully known.[7] In retrospective studies, "super-responders" (LVEF improvement to ≥50%) had survival similar to the general population and similar to those having a CRT-D or CRT-P device.[8]

In another retrospective study, in the patient group that demonstrated LVEF improvement to ≥45% and no ICD therapy after 1 year, 8.2% had subsequent appropriate ICD therapy, whereas "super-responders" with LVEF improvement to

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KEY TEACHING POINTS

- The decision to replace or downgrade a cardiac resynchronization therapy–defibrillator (CRT-D) system upon reaching battery depletion status carries important considerations, especially in patients who have benefited from cardiac resynchronization therapy but have not experienced ventricular tachyarrhythmias.
- There is currently no commercially available DF4 to DF1 adapter, which limits the ability to downgrade a CRT-D to a cardiac resynchronization therapy–pacemaker (CRT-P) system, which uses a DF4 implantable cardioverter–defibrillator (ICD) lead.
- We present a case report of connecting a DF4 ICD lead to the quadripolar left ventricular (LV) port of a CRT-P and the bipolar LV lead to the right ventricular pacing port in a Boston Scientific system.
- This approach is limited to bipolar and unipolar LV leads and does not apply to quadripolar leads.

≥50% had 2-year risk for ventricular tachycardia/ventricular fibrillation of 1.5%.[2]

The appropriateness of CRT in octogenarians has also been considered.[9] A retrospective analysis compared the outcomes of patients 80+ years old who received either CRT-P or CRT-D therapy to those of randomly selected CRT patients <80 years. At 3 years, there was no significant difference in all-cause mortality between octogenarians (11%) and controls (8%). The rate of appropriate ICD shocks in octogenarians was lower than in controls (14% vs 27%; $P = .02$), whereas inappropriate ICD shock incidence was similar (3% vs 6%; P = NS).[10]

After the clinical decision was made to downgrade from CRT-D to CRT-P, the approach was carefully vetted by the electrophysiology team and industry professionals. Detailed inspection and comparison of IS4 and DF4 connector specifications revealed that the interconnector spacing corresponding to the distal-most electrodes on the IS4 lead was aligned to the tip and ring connectors on the DF4 lead (Figure 2). Moreover, the DF4 and IS4 leads pin and connector diameters matched perfectly.

Programming of the replacement CRT-P device had to be carefully considered. Because the ventricular leads were reversed, DDD mode timing was effectively LV based. All ventricular-based algorithms including V-V pacing offset, LV protection period, biventricular trigger, and autothreshold testing had to be considered. Because the connector rings corresponding to the RV and superior vena cava shocking conductors of the CRT-D lead mapped to the distal electrodes of the CRT-P device (ie, E3 and E4), programming of the CRT-P device to LV pacing vectors using a cathode other than E1 or E2 would have been ineffective. Thus, available options were limited to E1-E2, E1-Can, and E2-Can. There was no reason to consider E3 (RV coil) or E4 (superior vena cava coil) as potential anodes. Importantly, instructions alerting the user to programming considerations were added to the CRT-P device's comment field. This approach allowed for a downgrade to a CRT-P device while avoiding the risks of adding new leads or extraction.

Conclusion

The decisions related to CRT device replacement at the end of battery life, including possible downgrade from a CRT-D to a CRT-P carry ethical, clinical, and financial implications, particularly in octogenarians. Once the decision is made, the adaptability of a replacement device to the chronically implanted lead system must be considered. There is currently no commercially available DF4 to DF1 adapter, leading to concerns about downgrade of CRT-D to a CRT-P system that uses a DF4 ICD lead. This report describes an important option that may be considered in a subgroup of patients having a DF4 RV lead and an IS1 LV lead. Importantly, this innovation is feasible only in individuals with a bipolar or unipolar LV lead having an IS1 connector. Because LV pacing leads are increasingly quadripolar, the solution described in this case is not applicable to all leads.

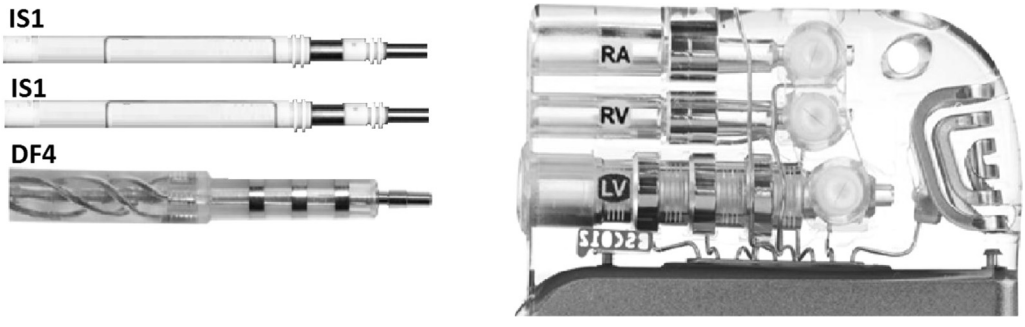

Figure 1 Schematic showing IS1 right ventricular (RV) lead, IS1 left ventricular (LV) lead, and DF4 RV lead aligned before insertion into the model U128 CRT-P (Boston Scientific, Marlborough, MA). Note that the RV and LV leads are reversed. RA = right atrium.

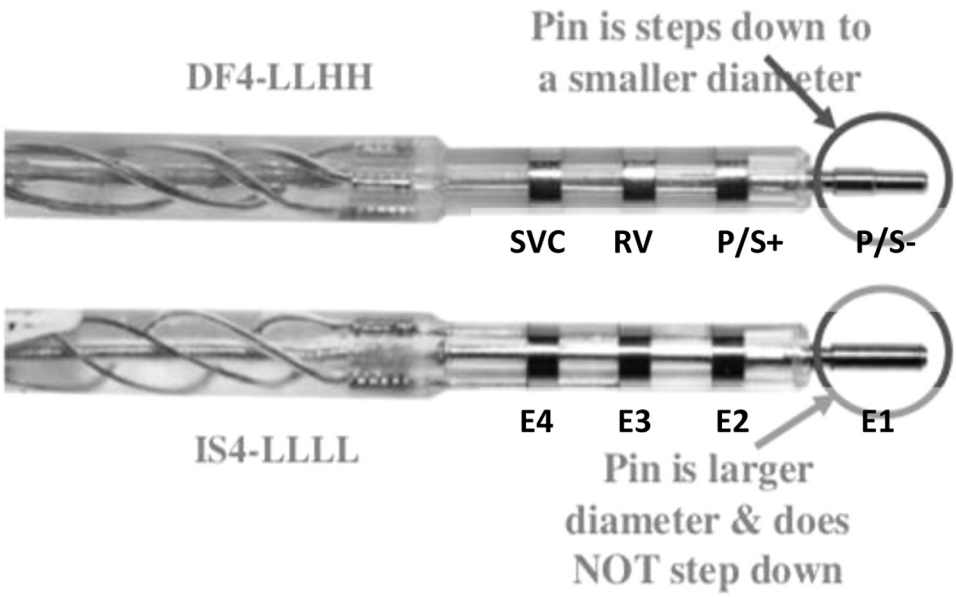

Figure 2 Pictorial showing subtle difference in DF4 and IS4 connectors. DF4 pin stepdown is designed to prevent insertion of IS4 into the DF4 connector because it presents the dangerous possibility of shock delivery through pace/sense (P/S) electrodes. However, insertion of a DF4 lead into an IS4 connector port is not restricted, and there is no risk of delivering a high-voltage shock through low-voltage pacing electrodes. Note that superior vena cava (SVC) and right ventricular (RV) correspond to DF4 coil connections; and P/S+ and P/S– of the DF4 lead map to E1 and E2 of the IS4 lead.

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