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

Arnoldas Giedrimas, MD, FHRS, * Brian Sisson, MS, † David Casavant, MS †

From the *Southcoast Health and Warren Alpert School of Medicine at Brown University, Providence, Rhode Island, and †Boston Scientific Inc, Marlborough, Massachusetts.

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 ACUTY 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 Debrillator 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
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.

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.
References

1. Kini V, Soufi MK, Deo R, Epstein AE, Bala R, Riley M, Groeneveld PW, Shalaby A, Dixit S. Appropriateness of primary prevention implantable cardioverter-defibrillators at the time of generator replacement: are indications still met? J Am Coll Cardiol 2014;63:2388–2394.

2. Manfredi JA, Al-Khatib SM, Shaw LK, Thomas L, Fogel RI, Padanilam B, Rardon D, Vatthyam R, Gemma LW, Golden K, Prystowsky EN. Association between left ventricular ejection fraction post-cardiac resynchronization treatment and subsequent implantable cardioverter defibrillator therapy for sustained ventricular tachyarrhythmias. Circ Arrhythm Electrophysiol 2013;6:257–264.

3. Schliamser JE, Kadish AH, Subacius H, Shalaby A, Schaechter A, Levine J, Goldberger JJ; DEFINITE Investigators. Significance of follow-up left ventricular ejection fraction measurements in the Defibrillators in Non-Ischemic Cardiomyopathy Treatment Evaluation trial (DEFINITE). Heart Rhythm 2013;10:838–846.

4. Narducci ML, Biffi M, Ammendola E, et al. Appropriate implantable cardioverter-defibrillator interventions in cardiac resynchronization therapy-defibrillator (CRT-D) patients undergoing device replacement: time to downgrade from CRT-D to CRT-pacemaker? Insights from real-world clinical practice in the DECODE CRT-D analysis. Europace 2018;20:1475–1483.

5. Madhavan M, Waks JW, Friedman PA, et al. Outcomes after implantable cardioverter-defibrillator generator replacement for primary prevention of sudden cardiac death. Circ Arrhythm Electrophysiol 2016;9:e003283.

6. Wilber DJ, Zareba W, Hall WJ, Brown MW, Lin AC, Andrews ML, Burke M, Moss AJ. Time dependence of mortality risk and defibrillator benefit after myocardial infarction. Circulation 2004;109:1082–1084.

7. Zhang Y, Guallar E, Blasco-Colmenares E, Butcher B, Norgard S, Nauffal V, Marine JE, Eldadah Z, Dickfeld T, Ellenbogen KA, Tomasselli GF, Cheng A. Changes in follow-up left ventricular ejection fraction associated with outcomes in primary prevention implantable cardioverter-defibrillator and cardiac resynchronization therapy device recipients. J Am Coll Cardiol 2015;66:524–531.

8. Manne M, Rickard I, Varma N, Chung MK, Tchou P. Normalization of left ventricular ejection fraction after cardiac resynchronization therapy also normalizes survival. Pacing Clin Electrophysiol 2013;36:970–977.

9. Heidemreich PA, Tsai V, Bao H, Curtis J, Goldstein M, Curtis L, Hernandez A, Peterson P, Turakhia MP, Masoudi FA. Does age influence cardiac resynchronization therapy use and outcome? JACC Heart Fail 2015;3:497–504.

10. Kelli HM, Merchant FM, Mengistu A, Casey M, Hocksins M, El-Chami MF. Intermediate-term mortality and incidence of ICD therapy in octogenarians after cardiac resynchronization therapy. J Geriatr Cardiol 2014;11:180–184.