Should Single-Coil Implantable Cardioverter Defibrillator Leads Be Used in all Patients?

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KEYWORDS

• Single-coil • Dual-coil • Defibrillation threshold • Lead extraction • Mortality

KEY POINTS

- Dual coil implantable cardioverter defibrillator leads were originally designed to compensate for elevated defibrillation thresholds encountered with old device technology.
- The high safety margins generated by contemporary devices have rendered the modest difference in defibrillation threshold between single- and dual-coil leads clinically insignificant.
- Dual-coil leads are associated with a higher all-cause mortality, and a greater risk of major complication and/or death with transvenous lead extraction.
- Single-coil leads in conjunction with active left-pectoral generators are clinically effective, and a reasonable first choice in de novo implants and/or younger patients with longer life expectancies.

INTRODUCTION

Implantable cardioverter defibrillator (ICD) remains the mainstay therapy for patients at risk of malignant arrhythmias and sudden cardiac death (SCD).[1,2] This is achieved by the delivery of high voltage energy to the myocardium. The initial ICD platforms consisted of a large abdominal pulse generators and epicardial lead patches.[3,4] Unfortunately, implantation of these epicardial systems required a thoracotomy, which carried a reasonable risk of perioperative mortality, and a high rate of lead malfunction.[5–7] Over the past 2 decades, considerable advances in generator and lead technology have led to substantial improvements in the delivery and reliability of ICD therapy. The development of active pectoral pulse generators, biphasic waveforms, and transvenous leads simplified the implant procedure, and dramatically improved defibrillation efficacy and safety margins. To accommodate the transition from the abdomen to an active left pectoral implant site, there came a necessary reduction in pulse generator size.[8] To compensate for the smaller generator, additional shocking coils were evaluated in an attempt to increase the defibrillation surface area. These coils were tested in multiple locations within the superior vena cava,[9,10] inferior vena cava,[11] right atrium, and coronary sinus.[12] Independent of these unipolar lead configurations, a more complex single-pass lead design was developed containing 2 separate defibrillator coils, one in the right ventricle (RV) and one in the superior vena cava (SVC).[9]

For years, dual-coil leads were preferred over ICD leads with a single coil in the RV. Used in

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conjunction with an active pulse generator, this 3-electrode (triad) configuration became common practice. In a large US cohort of 129,520 ICD patients, 85.2% of patients received a dual-coil lead between 2004 and 2014.[13] This practice was driven by a presumption of superior shock efficacy mainly based on early data suggesting that SVC coils may lower DFTs compared with a single coil in the RV alone.[8,10] However, the veracity of the evidence and its clinical value in light of the large safety margins achieved with contemporary high output pectoral generators are uncertain. A signal toward higher mortality rate and higher risk of lead extraction with dual-coil leads has also brought the utility of an SVC coil into question.[13,14] This article summarizes the current literature and re-evaluates the incremental benefits of a dual-coil over single-coil ICD leads.

EFFICACY

Differences in Defibrillation Threshold

The differences in defibrillation threshold between single- and dual-coil leads have been studied in several randomized and nonrandomized studies[8–10,14–24] (**Table 1**). Many early studies reported a statistically significant reduction in DFT with dual-coil systems.[8,10,11,18,19,23,25] However, subsequent studies showed conflicting results, with differences observed in some cohorts,[17,21–23,25] but not in others.[13,16] Two meta-analyses published earlier this year summarized the cumulative data comparing outcomes between the 2 ICD lead designs.[14,24] In a pooled analysis of 15 cohort studies and 2975 patients, a meta-analysis by Sunderland and colleagues showed that DFTs were lower in dual-coil leads compared single-coil leads. However, the absolute difference was small, with a mean difference of only 0.83 J (95% confidence interval [CI]: −1.39–0.27; P = .004). When the 2 randomized controlled trials were included in the analysis, no difference in DFT or first shock efficacy was observed between the 2 groups. Similar results were reported by Kumar and colleagues, where data pooled from 14 studies showed a mean DFT difference of 0.81 J (95% CI: 0.31–1.30 J; P = .0014) in favor of dual-coil leads with no difference in first-shock efficacy. Therefore, there appears to a real but fairly modest difference in DFT between the 2 lead models, with no difference in first-shock efficacy. With the high safety margin of contemporary biphasic, high-voltage, active pectoral pulse generators, this small difference may have limited clinical importance. Most ICDs can usually achieve a DFT that is 10 to 20J less than its maximum output with a 90% chance that the first shock will successfully terminate the clinical arrhythmia.[26,27] Routine DFT testing has also gradually fallen out of favor. With reliable ICD technology rendering routine DFTs unnecessary,[28] and data suggesting that they are potentially harmful[29] and not predictive of shock failure[30] or death,[31] peri-implant DFT testing has become antiquated.[13]

Right-Sided Pulse Generators

Among the most instrumental innovations that led to a reduction in defibrillation thresholds was the development of an active pulse generator, where the titanium outer shell functions as a cathode. In this configuration, the anatomic location of the pulse generator becomes an important determinant of DFT and shock efficacy. Although a unipolar defibrillation system with a single coil in the RV and an active left-sided pectoral generator has proven to be a clinically reliable platform,[32,33] data on right-sided pulse generators are lacking. The few data that exist suggest that DFTs may be higher when the generator is on the right chest.[31,33–37] This observation may be due to a less favorable shock vector in this configuration. When an active pectoral generator is on the right, shock current is directed away from the left ventricle and toward the right shoulder. Because a coil in the SVC would shunt the current in a similar rightward direction, there should be no significant advantage of a dual-coil lead when partnered with a right-sided generator. This was confirmed in 2 cohort studies where, despite a lower shock impedance with dual-coil leads, no difference in DFT was observed between the 2 lead designs.[34,38] One study found that when shocking between 2 coils without an active pulse generator, the optimal position for the second coil was in the left subclavian, which directs current more toward the left ventricle compared with placing the coil in the SVC.[39] However, there was no incremental benefit to the second coil's position when an active left pectoral can was part of the shocking circuit.[18] This suggests that an SVC coil may be redundant if an active left pectoral generator is part of the circuit.

RISK

Transvenous Lead Extraction Outcomes

Much of the movement away from dual-coil leads has been fueled by data suggesting that extraction of dual-coil ICD leads are more complex and higher risk compared with single-coil leads.[40–42] Technical challenges, longer procedural times, and greater risk of serious vascular complications