

Research Correspondence

Superior Vena Cava Defibrillator Coils Make Transvenous Lead Extraction More Challenging and Riskier

To the Editor: Studies have demonstrated equivalent defibrillation efficacy and all-cause mortality in patients with single and dual coil implantable cardioverter-defibrillator (ICD) leads (1,2). Despite this equivalency, the vast majority of implanted ICD leads are dual coil (3). The widespread use of dual coil ICD leads is relevant to lead management because of the challenges and risks of transvenous lead extraction (TLE). Defibrillator coils enable fibrous tissue in-growth and the superior vena cava (SVC) coil is often positioned in a high-risk region and may be associated with increased difficulty and risk of TLE. The purpose of this analysis was to determine the relationship between the presence of an SVC coil and the risk of major complications and the difficulty of TLE.

A retrospective analysis of patient and lead characteristics, procedural outcomes, and complications of consecutive patients undergoing ICD lead extraction at 9 high-volume centers was performed. The TLE technique has been described previously (4). Extraction time was defined as the active time for successful removal of all targeted leads from the first attempt to remove the lead to final lead removal. Difficulty of TLE was defined as the combined endpoint of the need for specialized extraction tools, namely, powered sheaths, and/or extraction time >75th percentile.

Outcomes were based on the Heart Rhythm Society lead management consensus (5). Patients were followed up in-hospital, and intraprocedural outcomes are reported. Continuous variables were expressed as mean ± SD or median and interquartile range. Fisher exact tests were used to compare categorical variables with the exception of the complications data. Given the occurrence of zero cell data with major complications in single coil ICD leads,

the likelihood ratio test was used. Logistic regression analysis was utilized to identify clinical variables associated with the combined endpoint. All tests of significance were 2-sided, with p value < 0.05 considered significant. Statistical data analysis was performed using SAS Version 9.2 (SAS Institute, Cary, North Carolina).

Between January 2000 and February 2011, a total of 2,201 patients underwent TLE of 2,274 ICD leads. Lead model information was not available in 25 cases, and these patients were excluded from further analysis. Baseline and procedural characteristics and outcomes are presented in Table 1. The majority of ICD leads removed had an SVC coil (82.4%) and an active fixation mechanism (73.0%). Extraction sheath assistance was implemented in 73% cases, with powered sheath use necessary in 55% of cases. Complete procedural success was achieved in 98.8% of cases. There was no difference in procedural time, extraction sheath use, or procedural success between single and dual coil leads. Powered sheath use was more common with dual coil leads (p < 0.0001).

Eighteen major complications were observed, all in cases involving dual coil ICD leads (p = 0.031). No single lead model predominated in the cases with complications. These included 10 cases of pericardial tamponade and 1 case each of respiratory failure and hemodynamic instability requiring vasopressors/intra-aortic balloon pump placement. Four cases of pericardial tamponade required urgent/emergent thoracotomy/sternotomy for treatment. In these, the sites of tears/avulsions were identified as an SVC tear, an avulsion in the right atrium, and 2 cases of tears at the RA/SVC junction. The sites of tear/avulsion in the cases of pericardial tamponade managed with percutaneous drainage were presumed

Table 1. Baseline and Procedural Characteristics

Characteristics	Single Coil (n = 385)	Dual Coil (n = 1,791)	p Value
Baseline characteristics			
Age, yrs	59 ± 17	62 ± 15	
Male	70.9 (273)	63.0 (1,373)	
TLE indication			
Systemic infection	24.1 (92)	34.6 (618)	
Local infection	33.3 (127)	41.6 (744)	
Lead malfunction	23.8 (91)	11.3 (201)	
Device upgrade	15.7 (60)	5.3 (95)	
Other	12 (3.1)	128 (7.2)	
Implant duration, months	48.3 (24.1–72.1)	38.2 (19.5–60.6)	
No. of leads explanted	1.5 (1–2)	1 (1–2)	
Active fixation mechanism	81.9 (266)	71.1 (1,066)	
ePTFE/MABF leads	62.5 (198)	47.9 (728)	
Procedural characteristics			
Procedure time, min	4.5 (2–22)	7 (3–43.8)	0.002
ES assistance	67.4%	74.6%	0.005
Powered sheath use	43.3%	57.3%	<0.0001
Complete procedural success	99.0%	98.7%	NS
Major complications	0%	1.0%	0.031

Values are mean ± SD, % (n), or median (interquartile range). ePTFE = expanded polytetrafluoroethylene; ES = extraction sheath; ICD = implantable cardioverter-defibrillator; IQR = interquartile range; MABF = medical adhesive back-filled; NS = not significant; TLE = transvenous lead extraction.

to be the right atrium in 3 cases. There was no speculation as to the location of the tear/avulsion in the remaining 3 percutaneous pericardial drainage cases. One patient subsequently died after emergent sternotomy, and 6 additional deaths were observed (0.31%, related to device-related systemic infection in all cases). The deaths occurred between post-operative day 1 and post-operative day 19. All patients had a pre-operative diagnosis of *Staphylococcal* bacteremia/endocarditis.

Difficulty of TLE was significantly associated with the presence of an SVC coil on both unadjusted analysis (1.73 [1.38 to 2.15], $p < 0.0001$) and after adjusting for age, sex, implant duration, TLE indication, fixation mechanism, number of leads removed, and presence of expanded polytetrafluoroethylene-coated/medical adhesive back-filled ICD coils (2.57 [1.95 to 3.38], $p < 0.0001$).

This is the first study to report the risk of complications and difficulty associated specifically with the extraction of dual coil ICD leads. Our group of high-volume, experienced operators found TLE of ICD leads with an SVC coil to be associated with a 1.0% major complication rate as compared with no major complications during removal of single coil ICD leads despite longer lead implant durations among the single coil leads ($p = 0.008$). In addition, dual coil ICD leads were 2.6 times more difficult to remove after adjusting for age, sex, implant duration, TLE indication, presence of expanded polytetrafluoroethylene-coated/medical adhesive back-filled ICD coils, fixation mechanism, and number of leads removed ($p < 0.0001$).

Dual coil ICD leads appear to have become the de facto choice for device implantation. The preferred use of dual coil ICD leads seems to be a vestige of the abdominal device era when the presence of a second high voltage shocking coil was necessary. Despite the advent of pectoral, active cans and biphasic defibrillation waveforms, dual coil ICD leads remain the considered standard on the basis of habit and early small studies demonstrating superior defibrillation efficacy. Recent and more contemporary studies contradict these findings (1,2).

The challenges and risks of TLE are directly related to the robust fibrosis that develops in areas of direct contact between the lead and the vasculature and endocardium. The ICD defibrillator coils enable vigorous fibrous tissue in-growth resulting in dense vascular and myocardial adhesions, adding to the challenge of extraction. An SVC coil, in an area at high risk, exacerbates this problem.

Although fibrotic tissue ingrowth into the SVC coil is the postulated mechanism for the observed findings in this study, lead design and diameter and the location of the SVC coil may also play a role. Many experts consider the presence of an SVC coil to increase the challenge and risk of extraction, but this is the first study to directly compare extraction of single and dual coil ICD leads.

Given the defibrillation equivalency of single and dual coil leads, these findings suggest that a paradigm shift is warranted. In the current era, lead management should predominate and implanters should "think before they choose" and opt for single coil defibrillator leads as the new standard of care.

This study is a retrospective analysis, and thus is subject to bias and the other well-known limitations of nonexperimental designs. The cohort was limited to 9, high-volume centers. This selection of highly experienced sites may have led to an under-estimation of the "real world" complication rate.

In conclusion, the presence of an SVC coil is associated with significantly higher complication rates and TLE of dual coil ICD leads is 2.6 times more difficult as compared with single coil ICD

leads. Given the lack of benefit of dual coil ICD leads in the vast majority of patients and the above noted risks, routine implantation of dual coil ICD leads should be discouraged.

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<http://dx.doi.org/10.1016/j.jacc.2012.12.014>

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Please note: Dr. Epstein has received research grants from and is a consultant for Boston Scientific, Medtronic, Spectranetics, and St. Jude Medical, and has equity in and served as a board member for Carrot Medical. Dr. Love has received research grants from Biotronik, Boston Scientific, Medtronic, and St. Jude Medical, and is a consultant for Biotronik, Boston Scientific, Cook Vascular, Medtronic, Sorin/ELA, St. Jude Medical, Spectranetics, and TyRx. Dr. Wilkoff has received research grants from Biotronik, Boston Scientific, LifeWatch, Medtronic, Spectranetics, and St. Jude Medical, and is a consultant for Boston Scientific, LifeWatch, Medtronic, Spectranetics, and St. Jude Medical. Dr. Chung participates in industry-sponsored research with Biotronik, Boston Scientific, Medtronic, and St. Jude Medical, and serves on a steering committee for Biotronik. Dr. Fischer is currently a paid employee of St. Jude Medical. Dr. Carrillo is a consultant for Medtronic, Sorin/ELA, Spectranetics, and St. Jude Medical. Dr. Kennergren has consulted with, presented on behalf of, or performed studies with Biotronik, Boston Scientific, Medtronic/Vitatron, Mentice, Sorin/ELA, Spectranetics, and St. Jude Medical. Roger Viklund is currently a paid employee of Boston Scientific. Dr. Mittal has received fellowship and research support from and is a consultant for Bard, Biosense Webster, Biotronik, Boehringer, Boston Scientific, Medtronic, Spectranetics, and St. Jude Medical. Dr. Ellenbogen has received research grants from and is a consultant for Boston Scientific and Medtronic, and has received honorarium from Biotronik, Boston Scientific, Medtronic, and St. Jude Medical. Dr. John participates in industry-sponsored research with Biosense Webster, Medtronic, and ThermoMedical Inc., and is a consultant for St. Jude Medical. All other authors have reported they have no relationships relevant to the contents of this paper to disclose.

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Letters to the Editor

Is Prolong Use of Statins Associated With Increase in the Risk of Diabetes?

The study by Wang et al. (1) assessed the risk of diabetes associated with statin use in the general population. The authors concluded that statin therapy is associated with an elevated risk for diabetes. However, the study does not indicate the classes or proportion of the different antihypertensive drugs (AHDs) administered in the statin-treated and control populations. This information is imperative because thiazide diuretics and specific beta-blockers exhibit undesirable glycemic effects.

Assessment of the ALLHAT study (Antihypertensive and Lipid-Lowering Treatment to Prevent Heart Attack Trial) revealed that the 4-year incidence of new-onset diabetes mellitus was significantly elevated in the chlorthalidone group compared with either the amlodipine or lisinopril group (11.6% vs. 9.8% and 8.1%, respectively; $p < 0.05$) (2). Comparable outcomes were also obtained from the INSIGHT (International Nifedipine GITS Study of Intervention as a Goal in Hypertension Treatment) and ASCOT-BPLA (Anglo-Scandinavian Cardiac Outcomes Trial–Blood Pressure Lowering Arm) trials (3,4). These effects of diuretic AHDs on glucose metabolism are plausibly due to hypokalemia induced by these drugs.

Hyperglycemia induced by beta-blockers is due to the reduction in peripheral blood flow, followed by the channeling of blood away from locales of glucose uptake, thereby reducing glucose clearance. A systematic review by Elliott and Meyer (5), with 48 randomized groups of 22 clinical trials involving 143,153 participants, revealed that association of AHDs with incident diabetes is the highest for beta-blockers and diuretics (in rank order).

Therefore, the question that remains unrequited in the current study – “Is the adverse glycemic effect of statins observed in the present study getting augmented, as a greater number of subjects in the statin-group are being treated for hypertension with diuretics or beta-blockers?”

Furthermore, a prospective population-based cohort study by Dunder et al. (6) examined the impact of blood glucose elevation

on the risk of developing myocardial infarction in individuals between 50 and 60 years of age who were receiving AHDs. They found that the elevated blood glucose and proinsulin levels produced by use of diuretics and beta-blockers were linked to the increased risk of myocardial infarction in these subjects. Therefore, in the current study, if the statin-treated group has a higher number of subjects receiving diuretics and beta-blockers, then the favorable outcome of statins may be further augmented.

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<http://dx.doi.org/10.1016/j.jacc.2012.10.044>

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Reply

We thank Dr. Banerjee for his comments regarding our publication on statin therapy and the risk of incident diabetes (1). He highlighted for us the importance of diabetogenic effects of concomitant medications, particularly diuretics and beta-blockers, which have been independently associated with a higher risk of diabetes (2,3).

The effects of diuretics and beta-blockers were essential in our analysis because 73.9% of subjects in our population had hypertension and 8.6% had heart failure. Our approach of matching measurable comorbid risks to establish the study cohort resulted in a similar distribution of demographic characteristics and cardiovascular comorbidities. There was no significant difference in the proportions of diuretic and beta-blocker use among the control group and the statin group (13.1% vs. 13.0%, $p = 0.795$ [diuretics]; 34.5% vs. 34.3%, $p = 0.693$ [beta-blockers]). Statins, diuretics, and beta-blockers were associated with an increase in risk of incident diabetes; hazard ratios (95% confidence intervals) were