Single-coil and dual-coil defibrillator leads and association with clinical outcomes in a complete Danish nationwide ICD cohort

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BACKGROUND The best choice of defibrillator lead in patients with routine implantable cardioverter-defibrillator (ICD) is not settled. Traditionally, most physicians prefer dual-coil leads but the use of single-coil leads is increasing.

OBJECTIVE The purpose of this study was to compare clinical outcomes in patients with single- and dual-coil leads.

METHODS All 4769 Danish patients 18 years or older with first-time ICD implants from 2007 to 2011 were included from the Danish Pacemaker and ICD Register. Defibrillator leads were 38.9% single-coil leads and 61.1% dual-coil leads. The primary end point was all-cause mortality. Secondary end points were lowest successful energy at implant defibrillation testing, first shock failure in spontaneous arrhythmias, structural lead failure, and lead extraction outcomes.

RESULTS Single-coil leads were associated with lower all-cause mortality with an adjusted hazard ratio of 0.85 (95% confidence interval 0.73–0.99; $P = .04$). This finding was robust in a supplementary propensity score–matched analysis. However, dual-coil leads were used in patients with slightly higher preimplant morbidity, making residual confounding by indication the most likely explanation for the observed association between lead type and mortality. The lowest successful defibrillation energy was higher using single-coil leads (23.2 ± 4.3 J vs 22.1 ± 3.9 J; $P < .001$). No significant differences were observed for other secondary end points showing high shock efficacies and low rates of lead failures and extraction complications.

CONCLUSION Shock efficacy is high for modern ICD systems. The choice between single-coil and dual-coil defibrillator leads is unlikely to have a clinically significant impact on patient outcomes in routine ICD implants.

KEYWORDS Implantable cardioverter-defibrillator; ICD; Leads; Coil; Mortality; Defibrillation; Lead failure; Lead extraction

ABBREVIATIONS **aHR** = adjusted hazard ratio; **CCI** = Charlson Comorbidity Index; **CI** = confidence interval; **DFT** = defibrillation threshold; **DPIR** = Danish Pacemaker and ICD Register; **HR** = hazard ratio; **ICD** = implantable cardioverter-defibrillator; **OR** = odds ratio; **SVC** = superior vena cava

(Heart Rhythm 2015;0:1–7)

Introduction

Prevention of sudden cardiac death using implantable cardioverter-defibrillators (ICDs) is recommended in selected high-risk patients.[1,2] The ICD can treat life-threatening arrhythmias using antitachycardia pacing or high-voltage shocks. The shock is delivered through the myocardium between the active generator surface and 1 or 2 shock coils on the defibrillator lead. There is no consensus on the choice of best lead in routine ICD implants, with an approximately 1:1 preference for single coil and dual coil.[3,4]

Several small randomized studies[5–12] have demonstrated either no differences or marginally lower implant defibrillation threshold (DFT) using dual-coil vectors. However, DFT is not associated with shock efficacy in spontaneous arrhythmias and all-cause mortality, probably because of high-energy output with abundant safety margins in modern ICD systems.[13] This is in accordance with no observed benefit of implant defibrillation testing in routine ICD

This study was supported by the Danish Heart Foundation, grant 13-04-R94-A4630-22789, the Danish Pacemaker and ICD Register, and the Department of Cardiology at Aalborg University Hospital. Dr Larsen has received research grant from the Danish Heart Foundation. Dr Nielsen has received speaker's fees from Biotronik and Biosense Webster and consulting fees from Boston Scientific. Dr Johansen has received consulting fees from Medtronic and Boston Scientific. **Address reprint requests and correspondence:** Dr Jacob M. Larsen, Department of Cardiology, Aalborg University Hospital, Hobrovej 18-22, PO Box 365, 9000 Aalborg, Denmark. E-mail address: jaml@rn.dk.

implants.[14] Traditionally, dual-coil leads are more difficult and riskier to extract because of fibrotic adherence of the proximal coil to the superior vena cava (SVC).[15,16] However, fibrotic adhesions are reduced by silicone backfilling or GORE coating (Boston Scientific, Marlborough, MA) coating of the coils in the latest lead generations.[17]

Three nonrandomized studies[18–20] with low numbers of single-coil leads have not demonstrated differences in a wide range of clinical outcomes. Similarly, a large nonrandomized remote monitoring database study[4] with limited patient data has not demonstrated difference in shock efficacy, but single-coil leads were associated with a higher rate of all-cause lead discontinuation and lower all-cause mortality.

The aim of the present study was to compare clinical outcomes in a large unselected nationwide cohort of patients with ICD with single- and dual-coil defibrillator leads.

Methods

Design

The study is a retrospective, nonrandomized, complete nationwide cohort study.

Population

The study included all Danish patients 18 years or older with first-time ICD implants without previous pacing systems from January 1, 2007, to December 31, 2011. The implants were performed at 5 university hospitals covering the entire Danish population. Thirty-one patients were excluded: 1 abdominal implant, 7 with unknown implant diagnosis, and 23 with implant of a supplementary defibrillation lead.

Data sources

Data were extracted from 3 national registries with prospectively collected data and supplementary retrospective review of medical records.

1. *The Danish Pacemaker and ICD Register (DPIR)* holds data from the implant and follow-up of all cardiac implantable electronic devices in Denmark.[21] Missing values were collected from medical records, if available.
2. *The Danish Civil Registration System* holds data on all persons alive and living in Denmark, including vital status.[22]
3. *The Danish National Patient Register* holds data on diagnoses and interventions from all inpatient and outpatient visits at Danish hospitals. The Charlson Comorbidity Index (CCI) was calculated as a measure of preimplant comorbidity on the basis of 19 diagnoses registered in 5 years before ICD implantation.[23] The CCI predicts all-cause mortality and is a commonly used measure used to adjust for confounding. Comorbidity was classified as low (CCI 0), medium (CCI 1–2), and high (CCI $\geq$3).

End points

The primary end point was *all-cause mortality*. Secondary end points were as follows: (1) *lowest successful shock energy* at implant defibrillation testing registered in the DPIR. There was no standardized defibrillation test protocol; (2) *shock failure* at the first episode eliciting appropriate shock therapy after implant registered in the DPIR and validated by review of medical records and available stored electrograms; (3) *structural lead failure* with conductor break, insulation failure, noise oversensing, high impedance, and extracardiac stimulation as registered in the DPIR and validated by review of medical records (failures $\leq$30 days after implant were excluded); (4) *failure of complete lead extraction* by simple traction (leads implanted $<$1 year were excluded) or by using specialized tools with noncomplete lead removal, disabling complication, or procedure-related death; (5) *any procedure-related complication* requiring medical or surgical intervention or leading to death (surgical removals were excluded). Definitions of lead failure and extraction outcomes are in accordance with recommendations by the Heart Rhythm Society.[24–26]

Statistical analysis

The analysis was performed using Stata 13.1 (StataCorp, College Station, TX). P values $<$.05 were considered statistically significant. All-cause mortality was illustrated with a Kaplan-Meier failure plot with log-rank test. Hazard ratios (HRs) and adjusted hazard ratios (aHRs) were estimated using Cox regression for time-to-event data. Odds ratios (ORs) and adjusted ORs were estimated using logistic regression for dichotomous outcomes. Crude and adjusted differences in continuous outcomes were estimated using linear regression. Covariates in multivariable regression models were based on predefined lists of potential confounders and risk factors with a maximal model complexity of about 1 parameter for each 10 events (dichotomous outcome) or 20 patients (continuous outcome). Included covariates are listed in the tables of the Result section.

All-cause mortality

Patients were censored at lead discontinuation or administratively on February 20, 2013. Predefined subanalyses were performed for left-sided and right-sided implants. Additional predefined subanalyses for left-sided implants were performed only for implant diagnosis and left ventricular ejection fraction, whereas an exploratory analysis for septal and apical lead positions was not predefined but stimulated by later discussion with fellow researchers. A supplementary propensity score analysis was performed on the basis of similar covariates as the main analysis with a 1:1 matching.

Structural lead failure

Patients were censored at the time of death, lead discontinuation from nonstructural reasons, or administratively on February 20, 2013.

Power calculation

The study size was limited by the number of patients in the Danish ICD population. A power calculation with an