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Implantable Cardioverter-Defibrillator Lead Failure in Children and Young Adults

A Matter of Lead Diameter or Lead Design?

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Objectives This study aimed to investigate the impact of lead diameter and design on implantable cardioverter-defibrillator (ICD) lead survival in children and young adults.

Background Recent reports have called attention to high rates of lead failure in adults with small-diameter ICD leads, but data in the pediatric population is limited.

Methods We reviewed lead performance in consecutive subjects ≤30 years with transvenous right ventricular ICD leads implanted at our center between January 1995 and October 2011. Lead failure was defined as fracture, perforation, or sensing failure necessitating revision.

Results A total of 120 ICD leads were implanted in 101 patients at a mean age of 15.5 ± 4.9 years. There were 47 small-diameter (≤8-F) and 73 standard-diameter (>8-F) leads. During a median follow-up of 28.7 months (interquartile range: 14.4 to 59.2 months), there were 25 lead failures (21% prevalence), with an incidence of 5.6%/year (95% confidence interval: 3.4 to 7.8). Sprint Fidelis (SF) (Medtronic, Inc., Minneapolis, Minnesota) leads had lower 3-year (69% vs. 92%, $p < 0.01$) and 5-year (44% vs. 86%, $p < 0.01$) survival probabilities than standard-diameter leads. In multivariate Cox regression, SF design conferred the greatest hazard ratio for lead failure (hazard ratio: 4.42, 95% confidence interval: 1.73 to 11.29, $p < 0.01$). Age and linear growth were not significantly associated with lead failure.

Conclusions In this single-center pediatric study that evaluated lead diameter, lead design, and patient factors, the SF design conferred the highest risk of lead failure, suggesting that design rather than diameter is the critical issue in ICD lead performance. (J Am Coll Cardiol 2014;63:133–40) © 2014 by the American College of Cardiology Foundation

The population of children and young adults with implantable cardioverter-defibrillators (ICDs) has grown over the last decade, in part due to advances in technology that have enabled smaller leads and devices (1). Although the ICD can be a life-saving device, it carries a significant risk of morbidity, including lead-related complications (2–4).

Small-diameter ICD leads gained popularity because of their relative ease of insertion and because they are less likely to cause venous obstruction and tricuspid valve distortion (5). Reduced lead diameter is a particularly useful feature for children, whose small size might preclude transvenous placement of standard-diameter leads. However, recent reports have demonstrated an increased rate of complications in adults with small-diameter leads (6–8).

The Sprint Fidelis (SF) high-voltage, small-diameter lead (Medtronic, Inc., Minneapolis, Minnesota) was recalled in 2007 due to its high incidence of premature conductor fracture, with a failure rate of 2.6% to 4.8%/year (9–12). More recently, in November 2011, the St. Jude Riata and Riata ST leads (St. Jude Medical, Sylmar, California) were recalled due to premature insulation failure, resulting in externalization of conductor cables (13,14). Riata lead failure rates have been reported to range from 0.7 to 2.8%/year (12,13,15,16). The active fixation Riata models have also been associated with a significantly increased incidence of cardiac perforations and lead revisions (7,17,18).

The failure of 2 small-diameter leads from different manufacturers has raised the question of whether small-diameter leads are robust enough to endure over time (12). However, the real issue might be the recent alterations in engineering and design rather than absolute lead diameter.

There is a significant cohort of pediatric patients with small-diameter leads in place, and few data exist on their

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Abbreviations and Acronyms

CHD = congenital heart disease
CI = confidence interval
HR = hazard ratio
ICD = implantable cardioverter-defibrillator
IQR = interquartile range
RV = right ventricle/ventricular
SF = Sprint Fidelis

performance in this population (19). Children have previously been shown to have substantially higher rates of transvenous lead-related complications than adults (19,20). Prevalence of lead failure in the pediatric population has ranged from 14% to 21% (2,3). This observation has been attributed to higher activity levels and growth-related lead stress (3,20,21).

This study sought to examine the impact of lead diameter, lead design, and patient factors on ICD lead survival in children and young adults.

Methods

Data were collected in accordance with hospital institutional review board guidelines. This was a retrospective chart review of subjects who underwent transvenous right ventricular (RV) ICD lead implantation at the Children's Hospital of Philadelphia between January 1, 1995, and October 1, 2011. All consecutive subjects who were 30 years of age or younger at the time of lead implantation and who had a minimum of 1 month of follow-up were evaluated. All implantation procedures were performed by experienced electrophysiologists. Lead implantation was performed via the subclavian vein in all cases, which is the standard practice in our institution. Baseline patient, lead, and device characteristics were recorded.

Small-diameter ICD leads were defined as having lead diameter ≤8-F, and standard-diameter ICD leads were of diameter >8-F (7).

Lead status was reviewed from the time of implant to the most recent patient encounter. Lead functionality was assessed by device interrogation, including analysis of lead impedance and sensed electrograms. The primary outcome was lead failure. This included lead fracture, defined as a sudden increase in long-term pacing and high-voltage impedance (≥50% as compared with chronic values) and/or electrical noise artifact from sensed nonphysiologic, make-break potentials (12). In addition, we included in the analysis instances of lead perforation as well as sensing failure necessitating lead revision (3). Oversensing of noncardiac potentials, such as electromagnetic interference, was not considered lead failure for the purpose of this analysis. Patients without follow-up for more than 1 year were considered lost to follow-up, and lead status was documented as of the last encounter. Similarly, in the instance of death or transplant, lead status was censored at the time of the last evaluation before the event. For subjects with multiple leads implanted during the study period, each lead was analyzed separately.

The presence or absence of inappropriate shocks secondary to lead failure as well as any associated pro-arrhythmic events were documented. Strategies to address failed leads were analyzed, including use of extraction tools, outcomes, and complications.

Statistical analysis. Descriptive statistics were expressed as mean ± SD for normally distributed continuous variables and as medians with interquartile ranges (IQRs) for skewed distributions. Categorical variables were reported as frequency counts and percentages. Student *t* tests were used to compare continuous variables, and chi-square tests were used to compare categorical variables. Rates of lead failure/100 person-years and 95% confidence intervals (CIs) were calculated. Kaplan-Meier survival analysis was used to estimate survival probability for small and standard-diameter leads, censoring cases at the time of death or transplant and when lost to follow-up. Simple Cox regression was used to identify patient and lead-related variables associated with lead survival. A multivariate Cox regression model was then created to compare the survival between small and standard-diameter leads, controlling for variables that were significant at a p value ≤0.2 from the simple Cox regression.

Results

Patient population. During the study period, 120 RV ICD leads were inserted in 101 patients. The patient population included 60% male and 40% female subjects. There was a primary prevention indication in 66% and a secondary prevention indication in 34% of patients. Underlying disease substrate included primary electrical disease in 46%, cardiomyopathy in 34%, and congenital heart disease (CHD) in 20%. Mean age at time of lead implantation was 15.5 ± 4.9 years.

Lead characteristics. Of the 120 leads, 94% (n = 113) were implanted in the left subclavian vein (6% right subclavian vein), 58% (n = 70) had a single-coil (42% dual-coil), and 72% (n = 86) were implanted in the context of single-chamber devices (28% dual-chamber). Characteristics of lead models represented in this cohort are outlined in Table 1. Small-diameter leads represented 39% of the cohort (n = 47). Medtronic SF accounted for 53% (n = 25) of small-diameter leads. St. Jude models, including Riata (n = 6), Riata ST (n = 7), and Durata (n = 8), accounted for 45% of small-diameter leads. There was 1 Biotronik (Biotronik SE and Company, Berlin, Germany) small-diameter model. Medtronic Sprint Quattro and Sprint series were the most commonly used standard-diameter leads, accounting for 53% (n = 39) and 33% (n = 24) of standard-diameter leads, respectively. The remaining 14% (n = 10) of standard-diameter leads comprised Endotak leads from Boston Scientific (Boston Scientific, Inc., Natick, Massachusetts). All implanted leads had an active fixation mechanism, regardless of diameter. All leads demonstrated acceptable performance at initial implant.

In comparing patients who received standard and small-diameter leads, there were no significant differences in