Published in final edited form as:

Heart Rhythm. 2010 July ; 7(7): 890–897. doi:10.1016/j.hrthm.2010.04.020.

Effectiveness of Implantable Cardioverter Defibrillator Lead Coil Treatments in Facilitating Ease of Extraction

Joseph W Hackler, DO⁺, Zhiyuan Sun, MS[#], Bruce D Lindsay, MD^{*}, Bruce L Wilkoff, MD^{*,^}, Mark J Niebauer, MD, PhD^{*}, Patrick J. Tchou, MD^{*}, and Mina K Chung, MD^{*,^}

^{*} Department of Cardiovascular Medicine, Heart and Vascular Institute, Cleveland Clinic, Cleveland, OH

⁺ Department of Internal Medicine, Medicine Institute, Cleveland Clinic, Cleveland, OH

[#] Quantitative Health Sciences, Lerner Research Institute, Cleveland Clinic, Cleveland, OH

[^] Cleveland Clinic Lerner College of Medicine of Case Western Reserve University School of Medicine, Cleveland, OH

Abstract

Background—Expanded polytetrafluoroethylene (ePTFE) coated and medical adhesive backfilled (MABF) implantable cardioverter defibrillator (ICD) coils have been promoted to reduce the fibrous ingrowth into coils that can complicate lead extraction.

Objective—The aim of this study was to test the hypothesis that ePTFE or MABF coatings are associated with greater ease of extraction.

Methods—Consecutive isolated ICD lead extraction cases were identified from a prospectively collected clinical database. Primary endpoints included total procedure and fluoroscopy times, radiation dose and fibrosis sites. Data were analyzed using univariate and multivariate analyses in total and propensity matched groups, adjusting for lead age and other factors.

Results—Among 329 patients (80% male; age 63.7±5.4 years), 284 (86.3%) had standard coil ICD and 45 (13.7%) had treated coil ICD leads extracted, of which 17 (5.2%) were ePTFE-coated and 28 (8.5%) were MABF ICD leads. ePTFE and MABF leads were associated with lower procedure and fluoroscopy times, radiation dose and fibrosis sites, including after adjustment for lead age, which was significantly shorter in the treated-coil leads. To further adjust for the difference in lead age, a propensity matched group was analyzed. Procedure time, fluoroscopy time, radiation dose, and brachiocephalic fibrosis remained significantly lower in the treated coil lead group.

Address correspondence to: Mina K. Chung, MD, Department of Cardiovascular Medicine, Heart & Vascular Institute, Cleveland Clinic, 9500 Euclid Avenue, Desk J2-2, Cleveland, OH 44195, Phone: 216-444-2290, FAX: 216-636-6951, chungm@ccf.org.

Conflicts of Interest:

Bruce D. Lindsay, MD: participates in industry sponsored research with Medtronic, Boston Scientific, St. Jude Medical, Biotronik.
 Bruce L. Wilkoff, MD: participates in industry sponsored research with Medtronic, Boston Scientific, St. Jude Medical, Biotronik, Spectranetics. Consulting modest: Medtronic, St. Jude Medical, Boston Scientific, Spectranetics. Consulting significant: LifeWatch.
 Mark J. Niebauer, MD, PhD: participates in industry sponsored research with Medtronic, Boston Scientific, St. Jude Medical, Biotronik, and Zoll. Received honoraria from Zoll.
 Patrick J. Tchou, MD: participates in industry sponsored research with Medtronic, Boston Scientific, St. Jude Medical, Biotronik.
 Mina K Chung, MD: participates in industry sponsored research with Medtronic, Boston Scientific, St. Jude Medical, Biotronik.

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Conclusions—ePTFE and MABF treated coils appear to provide some incremental benefit in ease of extraction over conventional, non-treated coil ICD leads. Although many current ICD leads do not have fibrosis in-growth limiting strategies, our study may rationalize consideration of adding such technologies to future leads.

Keywords

Lead extraction; Implantable cardioverter defibrillators; Coated defibrillator leads; Outcomes; Complications

INTRODUCTION

With expansion of indications for implantable cardioverter defibrillator (ICD) implantation, the number of ICDs placed on a yearly basis has increased over the last two decades. Since 1984, ICD implantation rates have doubled from 6 cases/100,000 persons per year in 1984 to 12.7 cases/100,000 persons per year in 2000 (1). In 2004, there were greater than 100,000 ICDs implanted in the United States (2). In addition, the National ICD Registry has collected data on 270,373 implants from April 2006 to June 2008 (3). Inherent to the increasing number of ICD implants is the potential requirement for additional ICD lead extractions due to complications, including infection, conductor or insulation failure, or stenosis or occlusion of the large veins draining into the heart (4).

To combat the formation of fibrous connections, which contributes to the difficulty and risk of lead extraction, manufacturers have produced ICD coils coated with expanded polytetrafluoroethylene (ePTFE) or back-filled with medical adhesive (MABF). Both have been shown in the ovine model to be easier than their standard counterpart to extract due to a decreased incidence of fibrosis on and around the filars of the coils (4). However, demonstration of improved outcomes in human patients is lacking.

This study aimed to test the hypothesis that ePTFE-coated or MABF leads are associated with greater ease of extraction. Outcomes included total procedure and fluoroscopy times, radiation exposure, and sites of fibrosis.

METHODS

Patient Population

Eligible patients were retrospectively identified from a prospectively collected database maintained in the Cleveland Clinic Cardiac Electrophysiology Laboratory. Demographic, clinical history, extracted leads, extraction indications, procedure times, radiation exposure, sites of fibrosis, and extraction tools were recorded. To minimize confounding variables, including multiple lead extractions and time required for lead reimplantation, only single ICD lead extraction procedures without implantation of a new lead were included. The study was approved by the Cleveland Clinic Institutional Review Board for retrospective medical records review and performed in accordance with institutional guidelines.

ICD Lead Categorization

Primary analyses were based on the presence or absence of ICD lead coil treatments. Group 1 (“standard coil”) consisted of patients who had a standard ICD lead extracted. Group 2 (“treated coil”) consisted of patients who underwent extraction of ICD leads with ePTFE-coated or MABF coils. ICD leads studied included standard coil leads from Medtronic, Inc., Boston Scientific Corp./Guidant Corp./Cardiac Pacemakers, Inc. (CPI), St. Jude Medical, Inc./Ventritex, Inc./Pacesetter, Inc., Biotronik, and ELA Medical. Treated coil leads included

ePTFE-coated leads from Boston Scientific Corp./Guidant Corp. and MABF leads from St. Jude Medical. Subgroup analyses were performed within Group 2 patients, comparing extraction of ePTFE coated ICD leads and MABF ICD leads.

Extraction Outcome Endpoints

To assess ease of extraction, primary extraction procedure outcomes studied included total procedure time, fluoroscopy time, and radiation dose. In addition, sites of fibrosis, as recorded in the database by the extracting clinician, were analyzed. Fibrosis is a generic term used to describe the scar tissue and thrombotic tissue on the leads. Sites of fibrosis generally indicated areas at which resistance was encountered during extraction and included fibrosis at the right ventricle endocardium, right atrium endocardium, superior vena cava, left pre-pectoral region, and brachiocephalic vein.

Statistical Analysis

Unless otherwise stated, continuous variables are presented as mean $\pm$ standard deviation. Group comparisons between standard coils and treated coils for categorical variables were made using Chi-square or Fisher's exact tests. Continuous variables were compared between groups using independent t tests. Statistical significance was set at a P value less than 0.05. Subgroup analyses, comparing ePTFE to standard coils, MABF to standard coils, and ePTFE to MABF coils, were also performed.

To adjust for potential confounding factors, multivariable regression was performed using a stepwise selection procedure to identify factors associated with extraction outcome endpoints. Variables with $p < 0.05$ and treated vs. standard coil lead group were retained in the final models. Lead group factor was forced into the final models. Variables that were considered in the modeling processes included the following: age, sex, race, New York Heart Association (NYHA) functional class, coronary artery disease, non-ischemic cardiomyopathy, hypertrophic cardiomyopathy, valvular heart disease, amiodarone usage, beta-adrenergic blocker usage, calcium channel blocker usage, left ventricular ejection fraction, number of ICD coils (dual vs. single coil leads), lead insulation (silicone vs. polyurethane vs. unknown), lead diameter (French size, Fr), and lead implant age (see Figure 2).

Propensity score methodology was also used for a sensitivity analysis for comparing lead groups. A propensity score was created to match the groups to reduce inherent patient difference and make less-biased group comparisons (5). Multivariate logistic regression was performed to develop a parsimonious model identifying factors that were associated with the treated coil group. All variables in Figure 2 were considered in the analysis. The parsimonious model was then augmented with the rest of the patient factors in Figure 2 to form a propensity model and calculate propensity scores. The propensity score for each patient was the probability for the patient to use an ePTFE-coated or MABF ICD lead. Patients were then matched based on the propensity score to form a matched subgroup for analysis. Each ePTFE or MABF patient was matched to one patient with a standard ICD lead. The greedy matching method was used to match a treated coil patient with a standard coil patient with the nearest propensity score (6). The largest distance to be considered as a valid match was 0.1. Distance was calculated as the absolute case-control difference in propensity score.

RESULTS

Patient Characteristics

Of 575 patients who underwent consecutive ICD lead extractions between 2004 and 2009, 329 patients met inclusion criteria and were included in this study. Of these, 284 (86.3%) had standard coil ICD leads extracted and 45 (13.7%) had treated coil ICD leads extracted, of which

17 (5.2%) were ePTFE-coated and 28 (8.5%) were MABF ICD leads. Of the various indications for ICD lead extraction within each group, infection was the most common, with 301 of the 329 extractions performed for this indication.

Patient characteristics are summarized in Table 1. The mean age of patients in the study was 63.7 ± 15.4 years, 280 (85%) were white, and 264 (80%) were male. There were no significant differences between baseline characteristics, except for a higher proportion of females ($p=0.04$), a trend toward higher NYHA functional class ($p=0.055$), a lower proportion of leads insulated with silicone ($p=0.006$), a smaller average lead diameter ($p<0.001$), and a significantly shorter lead implant age (409 ± 454 vs. 1287 ± 1091 days, $p<0.001$) in the treated coil group.

Extraction outcomes

Compared to standard coil ICD leads, treated coil ICD leads were associated with significantly shorter total procedure time (90.4 ± 37.8 vs. 130 ± 62.9 minutes, $p<0.001$) and fluoroscopy time (3.32 ± 4.0 vs. 8.33 ± 11.6 minutes, $p<0.001$), as well as lower radiation dose (0.19 ± 0.23 vs. 0.49 ± 0.7 gray [Gy], $p<0.001$) (Table 2). Fibrosis was also noted significantly less frequently in the treated coil lead group at all recorded sites, including the right ventricle (27% vs. 44%, $p=0.028$), right atrium (4% vs. 21%, $p=0.007$), superior vena cava (13% vs. 41%, $p<0.001$), left pre-pectoral region (8.9% vs. 28%, $p=0.006$), and brachiocephalic vein (6.7% vs. 39%, $p<0.001$).

Subgroup analyses were performed on the following groups: standard coil vs. ePTFE, standard coil vs. MABF, and ePTFE vs. MABF (Table 3). Compared to standard coil ICD leads, ePTFE ICD leads were associated with significantly shorter total procedure time (87 ± 35.7 vs. 130 ± 62.9 minutes, $p<0.001$), fluoroscopy time (2.6 ± 3.4 vs. 8.3 ± 11.6 minutes, $p<0.001$), and radiation dose (0.12 ± 0.18 vs. 0.49 ± 0.70 Gy, $p<0.001$). Similarly, compared to standard coil ICD leads, MABF ICD leads were associated with significantly shorter total procedure time (92.5 ± 39.6 vs. 130 ± 62.9 minutes, $p<0.001$), fluoroscopy time (3.8 ± 4.4 vs. 8.3 ± 11.6 minutes, $p<0.001$), and radiation dose (0.23 ± 0.24 vs. 0.49 ± 0.70 Gy, $p<0.001$). No statistically significant differences were found between ePTFE and MABF ICD leads as measured by total procedure time, fluoroscopy time, and radiation exposure.

Within the group as a whole, major acute procedural complications were rare. Of the 329 patients included in the study, only 2 developed major complications. Both of these patients had standard ICD leads extracted. One patient developed hypotension due to a pericardial effusion, which did not require operative intervention. The other patient developed hypotension secondary to a pericardial effusion, which required operative intervention to repair a tear noted in the superior vena cava.

Multivariable Analysis

To account for the differences in lead age and other factors between standard coil and treated coil leads, multivariable analyses were performed on total procedure time, fluoroscopy time, and radiation dose, adjusted for lead age and other significant factors identified by a stepwise selection procedure (Table 4). Older lead age was associated with an increase in total procedure time of 2.92 minutes per year of lead age (95% CI 0.01, 5.84, $p=0.049$), fluoroscopy time of 0.95 minutes per year of lead age (95% CI 0.54, 1.36, $p<0.001$), and radiation dose of 0.047 Gy per year of lead age (95% CI 0.022, 0.072, $p<0.001$). After adjusting for lead age and other significant factors, compared to standard coil leads, treated coil leads remained associated with significantly shorter total procedure time by 24 minutes (95% CI -43.1 , -5.0 , $p=0.013$), and trends toward lower radiation dose and decreased fluoroscopy time.

Propensity Score Matched Group Analyses

To further minimize the effects of lead age and other patient differences, analyses were performed on propensity score matched groups. Propensity matching was performed based on the following variables: age, sex, race, lead implant age, coronary artery disease, non-ischemic cardiomyopathy, hypertrophic cardiomyopathy, valvular heart disease, amiodarone usage, beta-adrenergic blocker usage, calcium channel blocker usage, NYHA functional class, number of ICD coils (dual vs. single coil leads), insulation material, lead diameter, and lead implant age. The parsimonious propensity score model included three variables, lead age ($p<0.001$), insulation material ($p=0.003$), and lead diameter ($p=0.034$). These three variables, identified by multiple logistic regression with a stepwise selection procedure, were the only significant factors associated with coil group membership. The C-statistic of this parsimonious model was 0.774. Using propensity score matching, matches were found for 38 of the 45 patients in the treated coil lead group. Mirrored histograms of propensity scores before (Figure 1A) and after (Figure 1B) matching show more similar distribution of propensity scores after matching. A covariate balance plot (Figure 2), showing the standardized differences in patient characteristics, also demonstrates closer matching of variables, including lead age, insulation material, and lead diameter. Distributions of lead age before and after matching are shown in Supplementary Materials Figure 1. Patient characteristics of the propensity matched groups showed no significant differences between the standard coil and treated coil groups after matching. Using 0.25 as the threshold of the standardized difference indicating covariates that are not matched well, only nonischemic cardiomyopathy ($|d| = 0.27$ after matching) showed a significant imbalance after matching. This variable was then added to the regression models of the matched groups. The C statistic for the propensity score model was 0.84.

When comparing standard coil ICD leads to treated coil ICD leads in the propensity matched groups, treated coil ICD leads were associated with shorter total procedure time (87.6 ± 37.2 vs. 115.0 ± 47.2 minutes, $p=0.006$), shorter fluoroscopy time (3.56 ± 4.11 minutes vs. 6.97 ± 6.68 minutes, $p=0.009$), and decreased radiation dose (0.22 ± 0.24 Gy vs. 0.40 ± 0.40 Gy, $p=0.019$) (Table 5). Treated coil leads were also associated with less brachiocephalic vein fibrosis (7.9% vs. 32%, $p=0.010$).

In multivariable models for the statistically significant outcomes (total procedure time, fluoroscopy time, radiation dose, and brachiocephalic vein fibrosis), lead group was an independent predictor of procedure time, fluoroscopy time, and radiation dose. Independent predictors of brachiocephalic vein fibrosis included lead group and lead age (Table 6). The treated coil lead group was associated with a shorter procedure time by 28.2 minutes ($p=0.006$), shorter fluoroscopy time by 3.4 minutes ($p=0.009$), and decreased radiation dose of 0.18 Gy ($p=0.017$) after adjusting for lead age, insulation material, lead diameter, and nonischemic cardiomyopathy. In addition, the treated coil lead group was associated with a decreased risk of developing brachiocephalic vein fibrosis (odds ratio [OR] =0.18, $p=0.026$) after adjusting for lead age, insulation material, lead diameter, and nonischemic cardiomyopathy. Older lead age (per year) was associated with an increased risk of developing brachiocephalic vein fibrosis (OR=1.95, $p=0.010$) after adjusting for lead group, insulation material, lead diameter, and nonischemic cardiomyopathy.

DISCUSSION

Since the 1980s, advances in lead technology that have impacted the ease of lead extraction included the use of active fixation leads, instead of passive fixation leads, which may have increased fibrous tissue growth around lead tip tines (1). Other technological advances include the excimer laser sheath in 1994 and the electrosurgical dissection sheath in 2001 (1). Nevertheless, extraction of ICD leads may be more difficult than extraction of standard pacing leads due to their larger diameter and exposed defibrillation coils that may facilitate the

ingrowth of fibrous tissue. Although success rates of ICD lead extraction are reported to range from 90–98%, major risks accompanying lead extraction include cardiac perforation (1%–4%), emergency cardiac surgery (1%–2%), and death (0.28%–0.8%)(7,8,9,10,11). Less frequently, complications can include tricuspid valve injury or the formation of an arteriovenous fistula. Many of the major risks seem to be mediated by fibrous tissue growth into exposed portions of the ICD lead and the forces applied to separate the lead from these fibrous connections (12,13,14,15). More recent innovations have focused on technology to decrease the amount of fibrous tissue in-growth into the ICD lead coil.

While much data exists on the extraction of ICD leads, there is a relative paucity of data on extraction of treated coil ICD leads. A MEDLINE search for ePTFE ICD leads yielded only three studies, of which only one study was on lead extraction. In this article, Wilkoff, et al., showed in the ovine model that MABF and ePTFE ICD leads led to increased ease of extraction due to decreased fibrotic tissue adherent to the filars on the lead coil (3). The only human data reported on ePTFE ICD coils, from the REFLEx study investigators, showed that “ePTFE-covered leads are not inferior to comparative leads with respect to electrical performance and implant cardioversion testing” (16).

The current study showed that treated coil ICD leads appear superior to standard coil ICD leads in terms of ease of extraction, as estimated by statistically significant decreases in total procedure and fluoroscopy time, radiation dose, and sites of fibrosis. This study also showed that the two strongest predictors of extraction endpoints were lead implant age and treated vs. standard coil ICD leads. After matching for propensity score, effectively matching for lead implant age, total procedure time and brachiocephalic vein fibrosis remained statistically significant in a propensity-matched analysis. There were no significant differences between ePTFE and MABF ICD leads in extraction endpoints. The significance of brachiocephalic vein fibrosis differences between the two groups may reflect differences in fibrosis in or around proximal ICD coils extending from the brachiocephalic to the superior vena cava. The brachiocephalic to superior vena cava junction is a potentially difficult and risk-associated area for extraction, as fibrosis is not uncommonly encountered here where the lead/coils are in contact with the lateral wall of the bend at the junction of the two vessels, often requiring a relatively acute turn of the extraction sheath to track down the ICD lead to the right atrium.

To test the hypothesis that treated ICD leads were superior to standard ICD leads and to remove the potential confounders of multiple lead extraction and reimplantation times, the population was limited to patients undergoing isolated extraction of single ICD leads without reimplantation. This limited population facilitated estimation of the ease of lead extraction by fluoroscopy time and radiation dose, as fluoroscopy would mainly be used during extraction attempts. Standard extraction practice simultaneously visualizes the lead with fluoroscopy during traction or laser application.

The significant difference in lead implant age between treated coil vs. standard coil leads reflects the more recent technology of the treated coil leads. Fibrosis is likely highly related to the age of the lead implant. This limitation was addressed in this study by two methods: adjusting for lead age in multivariate analyses and performing an analysis in propensity matched cohorts with closer matching of lead age. Coil treatment remained a significant predictor of total procedure time and radiation dose after adjusting for lead age in multivariate analysis. In the matched cohorts, coil treatment predicted total procedure time. Of interest, the presence of dual coil compared to single coil leads, which might be expected to predict length of extraction times, was not a significant predictor of extraction outcomes both in the entire cohort and in the propensity-score matched groups.

LIMITATIONS

Because the study included only single ICD lead extractions without reimplantation, the main indication for lead extraction in this study was infection. Generalization to other lead extraction indications may require additional studies. For propensity matched analyses, there is a limitation in that results can be generalized only to the population that actually receives treatment with the coated leads. In addition, other factors which may have affected lead extractability may not have been accounted for in this study.

CONCLUSIONS

When compared to standard coil ICD leads, extraction of ePTFE and MABF ICD leads was associated with decreased total procedure time, fluoroscopy time, radiation dose, and fibrosis, although these outcomes were highly associated with the age of the leads. After performing a multivariate analysis adjusting for the age of the leads, extraction of ePTFE and MABF ICD leads remained associated with a decreased total procedure time and trends toward decreased fluoroscopy time and radiation dose. In propensity matched groups with closer matching of lead implant age, lead diameter, and type of insulation, extraction of ePTFE and MABF ICD leads remained significantly associated with decreased total procedure time, fluoroscopy time, radiation dose, and brachiocephalic vein fibrosis. Treated coils appear to provide some incremental benefit in ease of extraction over conventional, non-treated coil ICD leads. Although many current ICD leads do not have fibrosis in-growth limiting strategies, our study may rationalize consideration of adding such technologies to future leads.

Supplementary Material

Refer to Web version on PubMed Central for supplementary material.

Acknowledgments

Financial Support: MKC: Supported by NIH/NHLBI grant R01 HL090620. The content is solely the responsibility of the authors and does not reflect the views of the funding agencies.

Abbreviations

ePTFE	expanded polytetrafluoroethylene
MABF	medical adhesive back-filled
ICD	implantable cardioverter defibrillator
NYHA	New York Heart Association
Fr	French
OR	odds ratio
Gy	gray

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Figure 1. Mirrored histograms of propensity scores before (A) and after (B) matching

A. Mirrored histogram of propensity scores before matching. The distribution of propensity scores before matching for the standard coil lead group is shown on the top and for the treated coil lead group on the bottom. B. Mirrored histogram of propensity scores after matching. The distribution of propensity scores after matching for the standard coil lead group is shown on the top and for the treated coil lead group on the bottom.

Covariate Balance

Figure 2. Covariate balance plot before and after propensity score matching

The covariate balance plot in the total patient population (blue triangles) shows significant imbalance between standard vs. treated coil leads in lead implant age and gender with a trend toward differences in NYHA functional class (see Table 1). Multivariable logistic regression was performed to develop a model identifying factors that were associated with being in the treated coil group. To more accurately compare groups, this model was then augmented with the rest of the patient factors to form a propensity model and calculate propensity scores. Variables that were included in these analyses are shown along the Y axis. The propensity score for each patient was the probability for the patient to use an ePTFE-coated or MABF ICD lead. Patients were then matched based on the propensity score to form a matched subgroup for analysis. The covariate balance plot in this matched subgroup (red squares) shows much less imbalance between standard vs. treated coil leads. Standardized differences were calculated as follows:

$$\text{For continuous variables, } d = \frac{100(\bar{x}_{\text{standard}} - \bar{x}_{\text{treated}})}{\sqrt{\frac{s^2_{\text{standard}} + s^2_{\text{treated}}}{2}}}$$

$$\text{For binary variables, } d = \frac{100(p_{\text{standard}} - p_{\text{treated}})}{\sqrt{\frac{p_{\text{standard}}(1-p_{\text{standard}}) + p_{\text{treated}}(1-p_{\text{treated}})}{2}}}$$

LVEF = left ventricular ejection fraction, Amio = amiodarone usage, White = white race, HCM = hypertrophic cardiomyopathy, NICM = nonischemic cardiomyopathy, VHD = valvular heart disease, Ca⁺ channel = calcium channel blocker usage, Beta = beta blocker usage, CAD = coronary artery disease, NYHA = New York Heart Association Functional Class.

Table 1

Patient characteristics.

	Total Population (n=329)	Standard coil (n=284)	Treated coil (n=45)	P value*
Patient age, years	63.7 ± 15.4	64.2 ± 15.3	61.1 ± 16	0.24
Gender, male (%)	264 (80%)	233 (82%)	31 (69%)	0.04
Race, Black (%)	42 (13%)	34 (12%)	8 (18%)	0.55
White (%)	280 (85%)	244 (86%)	36 (80%)	0.3
Other (%)	7 (2.1)	6 (2%)	1 (2%)	
Coronary artery disease	188 (57%)	158 (56%)	30 (67%)	0.16
Non-ischemic cardiomyopathy	54 (16%)	47 (17%)	7 (16%)	0.87
Hypertrophic cardiomyopathy	9 (2.7%)	8 (3%)	1 (2%)	>0.9
Valvular heart disease	51 (16%)	44 (15%)	7 (16%)	>0.9
Amiodarone usage	57 (17%)	52 (18%)	5 (11%)	0.24
Beta-adrenergic blocker usage	199 (60%)	168 (59%)	31 (69%)	0.21
Calcium channel blocker usage	17 (5.2%)	14 (4.9%)	3 (6.7%)	0.71
Left ventricular ejection fraction, (%)	33.0 ± 15.4	33.5 ± 15.6	30.1 ± 13.5	0.14
NYHA Functional Class 1	103 (31%)	92 (32%)	11 (24%)	0.055
2	116 (35%)	103 (36%)	13 (29%)	
3	104 (32%)	86 (30%)	18 (40%)	
4	6 (1.8%)	3 (1%)	3 (7%)	
Dual coil leads	277 (85%)	237 (84%)	40 (89%)	0.4
Insulation material				0.006
Silicone	309 (94%)	271 (95%)	38 (84%)	
Polyurethane	4 (1%)	4 (1.4%)	0 (0%)	
Unknown	16 (5%)	9 (3.2%)	7 (16%)	
Lead diameter, French	8.31 ± 1.26	8.44 ± 1.26	7.5 ± 0.79	<0.001
Lead implant age, days	1167 ± 1071	1287 ± 1091	409 ± 454	<0.001
Indication for extraction				0.56
Infection/Erosion	301 (91.5%)	261 (91.9%)	40 (88.9%)	
Incessant pain	1 (0.3%)	1 (0.4%)	0 (0%)	
Lead Fracture	2 (0.6%)	2 (0.7%)	0 (0%)	
Device recall	1 (0.3%)	1 (0.4%)	0 (0%)	
No longer needed/Patient request	11 (3.3%)	10 (3.5%)	1 (2.2%)	
Proarrhythmia	1 (0.3%)	0 (0%)	1 (2.2%)	
Unknown	11 (3.3%)	9 (3.2%)	2 (4.4%)	

*
p value comparison between standard and treated coil groups

Table 2

Extraction outcomes

	Total Population (n=329)	Standard coil (n=284)	Treated coil (n=45)	P value
Procedure time, minutes	125 ± 61.6	130 ± 62.9	90.4 ± 37.8	<0.001
Fluoroscopy time, minutes	7.64 ± 11.0	8.33 ± 11.6	3.32 ± 4.0	<0.001
Radiation dose, Gy	0.45 ± 0.66	0.49 ± 0.7	0.19 ± 0.23	<0.001
Right ventricle endocardium fibrosis	137 (42%)	125 (44%)	12 (27%)	0.028
Right atrium endocardium fibrosis	63 (19%)	61 (21%)	2 (4%)	0.007
Superior vena cava fibrosis	123 (37%)	117 (41%)	6 (13%)	<0.001
Left pre-pectoral region fibrosis	84 (26%)	80 (28%)	4 (8.9%)	0.006
Brachiocephalic vein fibrosis	113 (34%)	110 (39%)	3 (6.7%)	<0.001

*
p value comparison between standard and treated coil groups

Table 3

Primary extraction outcomes by ICD lead subgroup types

	Standard coil (n=284)	ePTFE coil (n=17)	P value [*]	MABF coil (n=28)	P value [†]	P value [‡]
Procedure time, minutes	130 ± 62.9	87 ± 35.7	<0.0001	92.5 ± 39.6	<0.0001	0.64
Fluoroscopy time, minutes	8.3 ± 11.6	2.6 ± 3.4	<0.0001	3.8 ± 4.4	<0.0001	0.33
Radiation dose, Gy	0.49 ± 0.7	0.12 ± 0.18	0.0001	0.23 ± 0.24	0.0001	0.087

^{*} p value comparison between standard and ePTFE coil groups[†] p value comparison between standard and MABF coil groups[‡] p value comparison between ePTFE and MABF coil groups

Table 4

Multiple regression analysis

Variable	Parameter Estimates	95% Confidence Interval	P value
Procedure time			
Treated vs. standard coil lead group	-24.0	-43.1, -5.0	0.013
Lead age (per year)	2.92	0.01, 5.84	0.049
Patient age (per year)	0.57	0.15, 0.98	0.006
Lead diameter (French)	7.63	0.82, 14.63	0.028
Fluoroscopy time			
Treated vs. standard coil lead group	-2.71	-6.17, 0.76	0.13
Lead age, (per year)	0.95	0.54, 1.36	<0.001
Radiation dose			
Treated vs. standard coil lead group	-0.19	-0.40, 0.02	0.077
Lead age (per year)	0.047	0.022, 0.072	<0.001
Calcium channel blocker	0.38	0.07, 0.70	0.018

Table 5

Extraction outcomes in propensity score matched groups

	Total matched population (n=76)	Standard coil (n=38)	Treated coil (n=38)	P value *
Procedure time, minutes	101.3 ± 44.4	115.0 ± 47.2	87.6 ± 37.2	0.006
Fluoroscopy time, minutes	5.26 ± 5.77	6.97 ± 6.68	3.56 ± 4.11	0.009
Radiation dose, Gy	0.31 ± 0.34	0.4 ± 0.4	0.22 ± 0.24	0.019
Right ventricle endocardium fibrosis	24 (32%)	12 (32%)	12 (32%)	0.99
Right atrium endocardium fibrosis	7 (9%)	5 (13%)	2 (5.3%)	0.43
Superior vena cava fibrosis	17 (22%)	11 (29%)	6 (16%)	0.17
Left pre-pectoral region fibrosis	11 (14%)	8 (21%)	3 (7.9%)	0.10
Brachiocephalic vein fibrosis	15 (20%)	12 (32%)	3 (7.9%)	0.010

* p value comparison between propensity matched standard and treated coil groups

Table 6

Multivariable models of procedure time, fluoroscopy time, radiation dose, and brachiocephalic vein fibrosis in propensity matched cohorts.

	Parameter Estimates or Odds Ratio	95% Confidence Interval	P value
Procedure time	Parameter estimates		
Treated vs. standard coil lead group	-28.2	-48.0, -8.3	0.006
Lead age, per year	2.5	-5.4, 10.4	0.53
Insulation material (silicone)	11.0	-51.3, 73.2	0.73
Lead diameter, per French unit	5.5	-6.2, 17.2	0.35
Nonischemic cardiomyopathy	-12.0	-37.9, 14.0	0.36
Fluoroscopy time	Parameter estimates		
Treated vs. standard coil lead group	-3.4	-6.0, -0.9	0.009
Lead age, per year	0.7	-0.3, 1.7	0.18
Insulation material (silicone)	-6.1	-14.1, 1.9	0.13
Lead diameter, per French unit	0.45	-1.05, 1.96	0.55
Nonischemic cardiomyopathy	-0.97	-4.32, 2.36	0.56
Radiation dose	Parameter estimates		
Treated vs. standard coil lead group	-0.18	-0.33, -0.03	0.017
Lead age, per year	0.046	-0.013, 0.106	0.13
Insulation material (silicone)	-0.37	-0.83, 0.10	0.12
Lead diameter, per French unit	0.04	-0.05, 0.13	0.35
Nonischemic cardiomyopathy	-0.09	-0.28, 0.11	0.37
Brachiocephalic vein fibrosis	Odds Ratio		
Treated vs. standard coil lead group	0.18	0.04, 0.81	0.026
Lead age, per year	1.95	1.18, 3.27	0.010
Insulation material (silicone)	0.16	0.003, 8.10	0.36
Lead diameter, per French unit	2.09	0.90, 4.88	0.087
Nonischemic cardiomyopathy	2.55	0.54, 11.96	0.24