

Lead Extraction in Pediatric and Congenital Heart Disease Patients

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Background—Transvenous pacemaker and defibrillator implantation is an expanding practice in pediatric and congenital heart disease patients, and given the finite longevity of current lead designs, lead extraction is an eventuality for a significant subset of these patients. Data on the safety and efficacy of different lead extraction techniques in this specific patient population are limited.

Methods and Results—We report our experience from a single-center cohort study with a retrospective review of prospectively collected data on all lead extractions performed between January 2002 and December 2008. Lead extraction procedures involved a total of 144 patients and 203 leads. Of these, 61 patients (42%) were female and 86 (60%) had structural heart disease. Successful simple extraction, requiring the use of only a nonlocking stylet, was achieved in 59 (29%) leads. Of the remaining leads, 35 were abandoned and 109 underwent complex extraction techniques, including a radiofrequency-powered sheath used in 78 of 109 leads. Successful extraction was achieved in 80% (162/203) of all leads and 94% (103/109) of leads undergoing a complex extraction. On multivariable analysis, older lead age (odds ratio [OR], 0.63; 95% confidence interval [CI], 0.48 to 0.82; $P<0.0001$), ventricular lead position (OR, 0.40; 95% CI, 0.20 to 0.79; $P=0.015$), and polyurethane insulation (OR, 0.34; 95% CI, 0.14 to 0.80; $P=0.017$) were found to be associated with a decreased likelihood of simple extraction. There were 4 major and 4 minor procedural complications involving 8 patients and no procedure-related deaths. On univariate analysis, lead age (OR, 1.28; 95% CI, 1.09 to 1.50; $P=0.002$) was the only factor associated with procedural complications.

Conclusions—The majority of leads implanted in pediatric and congenital heart disease patients can be extracted successfully; however, the procedure carries a risk of serious complications. Older lead age, ventricular leads, and polyurethane insulation were independent predictors of the decreased likelihood of an extraction by simple traction. (*Circ Arrhythm Electrophysiol.* 2010;3:437-444.)

Key Words: pediatric ■ children ■ young adult ■ congenital heart disease ■ pacemaker ■ defibrillator
■ lead ■ extraction

Transvenous pacemaker and implantable cardioverter-defibrillator (ICD) implantation in the pediatric and congenital heart disease (CHD) patient population has markedly increased in the past decade. Consequently, a subset of these patients faces the eventual need for lead extraction. Several large series have investigated the different lead extraction techniques and their safety and efficacy in adult patients without CHD.¹⁻¹⁴ However, data on lead extraction in pediatric and CHD patients remain limited.¹⁵⁻¹⁸

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This patient population is unique because it offers several challenges, including the optimal age for transvenous device implantation, somatic growth after implantation, complex

vascular and cardiac anatomy, a high rate of lead failure, and an anticipated patient life span that exceeds that of conventional leads and devices.¹⁹⁻²² An understanding of the outcomes of lead extraction is essential in the evaluation of these interrelated challenges and in the care of these patients. To better understand these issues, we report our single-center experience on lead extraction in a large cohort of pediatric and congenital patients.

Methods

In this cohort study, data were collected prospectively on all patients having undergone pacemaker or ICD implantation and a lead extraction performed >30 days after lead implant. All procedures were performed at Children's Hospital Boston and spanned the period from January 2002 to December 2008, inclusively. The

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Table 1. Patient Characteristics Compared Between Methods of Lead Extraction

Variable	All Patients (n=144)	Simple Extraction Group (n=37)	Complex Extraction Group (n=107)	P Value*
Age at first lead implant, y†	14.9 (12.8)	16.6 (13.2)	14.2 (12.9)	0.013
Age at lead extraction, y†	21.5 (14.4)	20.8 (13.7)	21.6 (14.5)	0.691
Weight, kg	64.4 (21.6)	66.0 (22.7)	63.9 (21.3)	0.618
Height, cm†	167.0 (13.8)	168.0 (13.0)	167.0 (14.0)	0.969
BSA, m ²	1.69 (0.32)	1.71 (0.32)	1.68 (0.32)	0.699
Sex, male	83 (58%)	21 (57%)	62 (58%)	0.999
Presence of SHD	87 (60%)	24 (65%)	63 (59%)	0.999
HCM	5 (3%)	2 (5%)	3 (3%)	
DCM	1 (<1%)	1 (3%)	0	
ASD/VSD/AVSD	14 (10%)	4 (11%)	10 (10%)	
AS	11 (8%)	3 (8%)	8 (7%)	
TOF	16 (11%)	3 (8%)	13 (12%)	
d-TGA	24 (17%)	5 (14%)	19 (18%)	
ccTGA	9 (6%)	2 (5%)	7 (6%)	
SV/Fontan	5 (3%)	3 (8%)	2 (2%)	
Other	2 (1%)	1 (3%)	1 (1%)	
EP diagnosis				
SND	36 (25%)	12 (32%)	24 (22%)	0.183
CAVB	63 (44%)	13 (35%)	50 (47%)	
LBBB	1 (<1%)	1 (3%)	0	
VT	44 (30.5%)	11 (30%)	33 (31%)	
Procedure indication				
Lead failure	94 (65%)	28 (75%)	66 (62%)	0.308
Generator at ERT	18 (12.5%)	1 (3%)	17 (16%)	
System upgrade	18 (12.5%)	5 (14%)	13 (12%)	
Infection	11 (8%)	2 (5%)	9 (8%)	
Other	3 (2%)	1 (3%)	2 (2%)	
Device sidedness, left	135 (94%)	34 (92%)	101 (94%)	0.695
Device type				
ICD	50 (35%)	13 (35%)	37 (35%)	0.100
PM	91 (63%)	22 (60%)	69 (64%)	
BiVi ICD	1 (<1%)	0	1 (1%)	
BiVi PM	2 (1.4%)	2 (5%)	0	
No. of leads per patient				
1	94 (65%)	30 (81%)	64 (60%)	0.103
2	44 (31%)	7 (19%)	37 (34%)	
3	3 (2%)	0	3 (3%)	
4	3 (2%)	0	3 (3%)	

Values are mean (SD) or median (interquartile range), n (%).

BSA indicates body surface area; HCM, hypertrophic cardiomyopathy; DCM, dilated cardiomyopathy; ASD, atrial septal defect; VSD, ventricular septal defect; AVSD, atrioventricular septal defect; AS, aortic stenosis; TOF, tetralogy of Fallot; TGA, transposition of the great vessels; ccTGA, congenitally corrected TGA; SV, single ventricle; EP, electrophysiology; SND, sinus node dysfunction; CAVB, complete atrioventricular block; LBBB, left bundle-branch block; VT, ventricular tachycardia; BiVi, biventricular; ERT, elective replacement time; PM, pacemaker; and n/a, not applicable.

*Comparing simple with complex extraction groups.

†Data are reported as median value and interquartile range for nonnormally distributed data.

institutional review board approved the study. All authors had access and agreed to the data as presented. Data collection included demographic, clinical, and pacemaker/defibrillator system characteristics as well as details of the procedural techniques, outcomes, and complications. The data were divided into patient-specific and lead-specific characteristics (Tables 1 and 2). Patients undergoing

more than 1 extraction procedure and procedures involving more than 1 lead extraction were identified.

The primary outcome of interest was “simple” extraction. The secondary outcomes were failure of “complex” extraction and procedural complications. A lead extraction was defined as simple when it required only manual traction with the use of a nonlocking stylet.

Table 2. Lead Characteristics Compared Between Methods of Lead Extraction

Variable	All Leads (n=203)	Simple Extraction Group (n=59)	Complex Extraction Group (n=144)	P Value*
Lead age, y	6.2 (4.4)	3.0 (2.9)	7.6 (4.3)	<0.0001
Body diameter, mm	2.3 (0.4)	2.2 (0.3)	2.4 (0.4)	0.009
Circumferential area, mm ² †	4.5 (1.9)	3.8 (1.7)	4.5 (1.9)	0.151
Lead type				
Pacing	164 (81%)	48 (81%)	116 (81%)	0.999
Defibrillation	39 (19%)	11 (19%)	28 (19%)	
Lead location				
Atrium	82 (40%)	30 (51%)	52 (36%)	0.009
Ventricle	119 (59%)	27 (46%)	92 (64%)	
Coronary sinus	2 (1%)	2 (4%)	0	
Lead polarity, bipolar	195 (96%)	57 (97%)	138 (96%)	0.999
Active fixation	174 (86%)	55 (93%)	119 (83%)	0.075
Steroid-eluting tip	158 (78%)	55 (93%)	103 (72%)	0.001
Insulation type				
Silicone	128 (63%)	46 (78%)	82 (57%)	0.006
Polyurethane	75 (37%)	13 (22%)	62 (43%)	

Values are mean (SD), n (%).

*Comparing simple with complex extraction groups.

†Data are reported as median value and interquartile range for nonnormally distributed data.

Otherwise, an extraction was defined as complex when simple extraction was unsuccessful and either the procedure required the use of additional tools such as a locking stylet or sheaths or when the lead was abandoned after a failed simple extraction. Extraction outcomes were defined per patient and per lead, whereas procedural complications were defined per patient only. Patients with only simple extractions were included in the simple group; otherwise, if they had at least 1 complex lead extraction, they were included in the complex group.

Procedural success and complications were classified as per the Heart Rhythm Society published definitions and guidelines.²³ Complete success was the removal of all lead material from the vascular space. Success was deemed “partial” if a small portion of the lead remained in situ, consisting of the electrode tip and/or ≤ 4 cm of the conductor coil/insulation. Otherwise, the extraction was considered a failure if >4 cm of lead length remained in situ. Procedural complications were considered major if they resulted in death or serious harm to bodily function or structure or if intervention or transfusion was required to prevent death. Otherwise, complications were considered minor if medical or minor procedural intervention was required to remedy, or prolonged hospital stay, or limited the patient’s function.

Extraction Techniques

Lead extraction procedures performed at our institution followed a specific sequence of consecutive techniques during each procedure. Initially, a venogram was obtained by injecting contrast (Optiray 350, Mallinckrodt Inc, Hazelwood, Mo) via a peripheral intravenous line in the arm ipsilateral to the lead insertion site. The pacemaker or defibrillator pocket was then opened and the leads were all visually inspected and tested for sensing, impedance, and capture threshold values. We then proceeded with the lead extraction, which was performed under fluoroscopic monitoring. The generator was removed from the pocket, dissection was performed down to the anchor sleeve, and the sutures were released. Next, a nonlocking stylet was inserted into the lead lumen, the helical screw was retracted when possible for active fixation leads, and constant

traction was then applied. If this simple extraction approach was unsuccessful, the lead was either abandoned or underwent an attempt at complex extraction, as per operator decision. During a complex extraction, the lead was transected below the anchoring sleeve, a locking stylet (LIBERATOR Locking Stylet, Cook Vascular Inc, Vandergrift, Pa) was inserted in the lumen, and constant traction was applied. If this failed to extract the lead, an appropriately sized stainless steel sheath (Byrd Telescoping Stainless Steel Dilator Sheath Set, Cook) was advanced over the lead and was used to dissect fibrous and periosteal adhesions up to the innominate vein and superior vena cava junction while applying constant traction with the locking stylet. Should the lead remain attached, the stainless steel sheath was exchanged for a radiofrequency-powered sheath (PERFECTA, Electrosurgical Dissection Sheath, Cook). For a small number of patients, a nonpowered polypropylene sheath (Byrd Dilator Sheath Set, Polypropylene, Cook) was used. If the radiofrequency-powered sheath failed to extract the lead or if it resulted in partial lead extraction, a femoral approach was sometimes used that entailed the use of a snare (Byrd Workstation femoral intravascular retrieval set, Cook). All lead extractions were performed in the electrophysiology procedure room, and 2 pediatric electrophysiologists performed all procedures over the study period. No excimer laser-powered sheaths were used during this time period.

Statistics

The data are presented as patient-specific and lead-specific variables. Continuous variables are presented as means with standard deviations or medians with interquartile ranges, depending on the normality of their distribution. Categorical variables are presented as counts and percentages. The 2-sample *t* test and the Wilcoxon rank-sum test were used for normally and nonnormally distributed data, respectively. The Fisher exact test or the χ^2 test was used for categorical data. The Kruskal-Wallis test was used for comparison of multiple samples of nonnormally distributed continuous data.

Data from multiple lead extractions performed on the same patient were considered as nonindependent. Therefore, for multivariable analysis, the logistic regression model was fit using the Generalized Estimating Equation (GEE) with an exchangeable correlation structure to account for clustering of outcomes by patient. Score test probability values are reported for the multivariable GEE models. GEE models were built to examine for predictors of simple extraction for the entire cohort as well as 3 additional nested cohorts: In the first nested cohort, abandoned leads were excluded from the analysis, and the other 2 cohorts consisted of patients either with or without structural heart disease (SHD). Variables included in each of the models were selected based on a priori knowledge and from variables that were significantly differently distributed between the 2 groups ($P \leq 0.1$). Presence of SHD and presence of more than 1 intravascular lead were added to the multivariable analysis because of their clinical relevance. All variables included in the models are listed in Table 3. Additional univariate logistic regression analysis using the GEE model was performed to evaluate for variables associated with procedural complications and failed complex extraction. Two-tailed probability values <0.05 were considered statistically significant. Statistical analysis was performed using SAS 9.1 (SAS Institute Inc, Cary, NC).

Results

Patients and Leads

The cohort included 144 patients with a median age of 14.9 (12.8) years at first lead implant and 21.4 (14.4) years at lead extraction; 42% (61/144) were female and 60% (86/144) had SHD, of which the most common CHD was d-transposition of the great arteries, all of whom were status-post atrial switch procedure (17%), followed by tetralogy of Fallot (11%). There were only 6 patients with cardiac myopathy (5 hypertrophic and 1 dilated). The most common indication for pacing was complete atrioventricular block, whereas ventricular tachycardia was the most common indication for ICD

Table 3. Results of Multivariable Analysis Using the GEE Model for Predictors of Extraction by Simple Traction for the Entire Cohort and for 3 Nested Cohorts

Variable	Leads in All Patients (n=203)		Excluding Abandoned Leads (n=168)		Leads in Patients Without SHD (n=83)		Leads in Patients With SHD (n=120)	
	OR (95% CI)	P	OR (95% CI)	P	OR (95% CI)	P	OR (95% CI)	P
Patient characteristics								
Age at first lead implant, y	1.04 (1.00–1.09)	0.064	1.05 (1.00–1.09)	0.050	1.03 (0.93–1.15)	0.579	1.05 (1.00–1.09)	0.069
Presence of SHD	0.75 (0.30–1.89)	0.537	0.93 (0.34–2.54)	0.887	n/a		n/a	
Presence of >1 lead	0.85 (0.34–2.15)	0.736	0.51 (0.18–1.47)	0.211	0.94 (0.17–5.29)	0.949	0.84 (0.31–2.29)	0.734
Lead characteristics								
Lead age, y	0.63 (0.48–0.82)	<0.0001	0.67 (0.51–0.87)	0.0003	0.56 (0.41–0.76)	0.002	0.67 (0.48–0.94)	0.001
Body diameter	0.46 (0.11–1.82)	0.296	0.30 (0.06–1.51)	0.156	0.45 (0.04–5.19)	0.608	0.36 (0.06–2.34)	0.306
Location, ventricle	0.40 (0.20–0.79)	0.015	0.36 (0.18–0.74)	0.010	0.20 (0.05–0.78)	0.022	0.56 (0.24–1.30)	0.200
Steroid-eluting tip	2.32 (0.42–12.8)	0.301	1.73 (0.28–10.52)	0.545	3.18 (0.18–56.34)	0.453	1.26 (0.13–12.57)	0.844
Insulation type, polyurethane	0.34 (0.14–0.80)	0.017	0.25 (0.10–0.66)	0.007	0.35 (0.09–1.33)	0.130	0.26 (0.08–0.93)	0.044

n/a indicates not applicable.

therapy. Patient indications for lead extraction were lead failure in 65% (94/144) and system infection in 8% (11/144). The majority of devices (94%) were implanted on the left side, with 64% being pacemakers and 36% being defibrillators. The majority of patients had only 1 lead (65%), with 3 and 4 leads present in only 3 (2%) patients each.

Lead extraction procedures involved 203 leads, with a mean lead age of 6.2 (4.4) years. Coil-mounted defibrillator leads accounted for 19% (39/203) of all leads. The majority of explanted leads were active-fixation (86%), ventricular in position (59%), had a steroid-eluting tip (78%), and had silicone (63%) as their outer insulation. Detailed patient and lead characteristics are presented in Tables 1 and 2, respectively.

Lead Extraction

Simple extraction was successful in 37 patients or 59 leads, and complex extraction was required in 107 patients or 144 of the remaining leads. Of these, 35 of 144 leads were abandoned and 109 of 144 leads underwent complex extraction. Successful extraction was achieved in 94% (103/109) of the complex group and 80% (162/203) of all leads, with complete extraction in 75% (152/203) and partial in 5% (10/203). Only 6 leads failed complex extraction (see Figure 1).

The distribution of simple and complex extractions and abandoned leads over the 7-year study period is displayed in

Figure 2, showing a steady increase in the number of complex extractions and a relatively stable number of abandoned leads over the last 6 years ($P=0.03$). The sequential technical approach to complex extractions is displayed as a flow diagram in Figure 3. The majority of leads (72%) required the use of a radiofrequency-powered (RF) sheath, with only 12 (11%) requiring the additional use of a snare via a femoral approach. Success rates for each of the complex extraction techniques are presented in Figure 4, with the RF sheath approach contributing to the majority (56%) of successful complex extractions.

Independent variables associated with a simple extraction were identified using the GEE multivariable logistic regression analysis. The results for the entire cohort of 203 leads and for the 3 nested cohorts are displayed in Table 3. Lead age (odds ratio [OR]; 0.63; 95% confidence interval [CI], 0.48 to 0.82; $P<0.0001$) was the only statistically significant variable associated with simple extraction that persisted in all 4 groups. A ventricular lead location (OR, 0.40; 95% CI, 0.20 to 0.79; $P=0.015$) and polyurethane-type insulation (OR, 0.34; 95% CI, 0.14 to 0.80; $P=0.017$) were the other significant independent variables in the main cohort as well as the first nested cohort (which excluded abandoned leads). For the nested cohorts, comparing patients with and without SHD, lead age was a common predictor of simple extraction. Additional predictors included polyurethane insulation in the SHD nested cohort and ventricular lead location in the non-SHD nested cohort. Patient age at the time of first implant closely approached but did not reach statistical significance. Figure 5 is a box plot presentation of lead age distribution comparing leads in the simple and complex extraction groups. The mean lead age was 3.0 (2.9) years in the simple group compared with 7.6 (4.3) years in the complex group ($P<0.0001$).

In the group of leads undergoing complex extraction, a total of 6 leads failed to be extracted. Five leads failed after an attempted RF sheath approach (without an attempt to extract from below), whereas the sixth lead failed after a femoral approach. Among the variables included in the univariate analysis, a device implanted on the right side (OR, 7.14; 95% CI, 2.17 to 25.0; $P=0.001$) was the only one

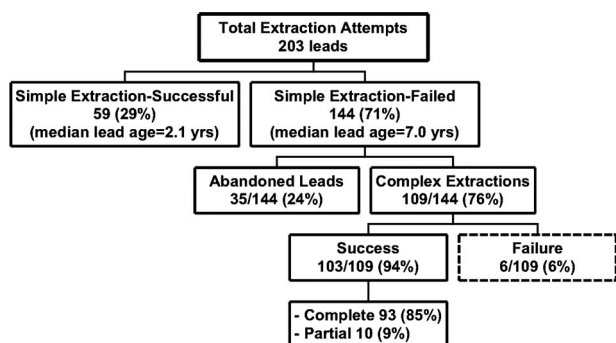


Figure 1. Flow chart for all extraction attempts involving 203 leads.

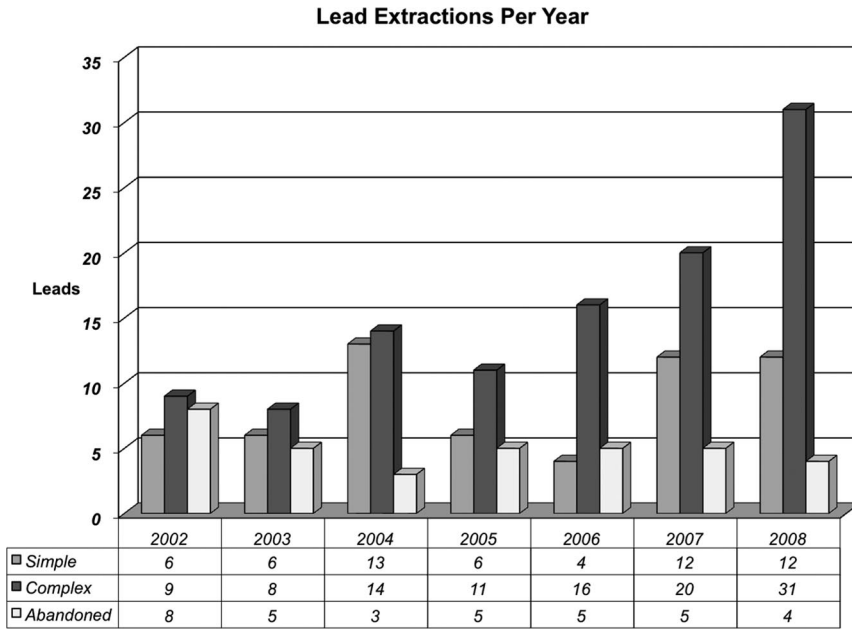


Figure 2. Distribution of lead extractions per study year ($P=0.003$).

statistically significantly associated with failed complex extraction (Table 4).

Adverse Events

Complications occurred in 8 patients, with 4 being classified as major and 4 minor. Major complications included (1) a resusci-

tated ventricular fibrillation arrest occurring in the recovery room in a 49-year-old patient with congenitally corrected transposition of the great arteries and pulmonary hypertension. No etiology was evident for the event other than pulmonary hypertension. The ventricular fibrillation responded to a single DC countershock. (2) Hemodynamically unstable hemopericardium in a 13-year-old patient with long-QT syndrome: The hemopericardium that was due to right atrial perforation with the RF sheath required pericardiocentesis and surgical closure. The ICD was implanted at 9 years of age and the coil had a thick fibrous band noted where it crossed the tricuspid annulus. The patient had no long-term sequelae. (3) In a 17-year-old patient with congenital complete AV block, a retained right ventricular lead fragment eroded through the right outflow tract with a delayed presentation of a significant hemopericardium (syncope and hypotension) requiring only pericardiocentesis. (4) A 33-year-old man with congenitally corrected transposition of the great arteries and severe biventricular dysfunction had pulmonary edema requiring mechanical respiratory support. The pulmonary edema was initiated by postextubation left lower lung collapse secondary to massive left atrial dilatation. He went on to have a successful heart-lung transplant during the hospital admission.

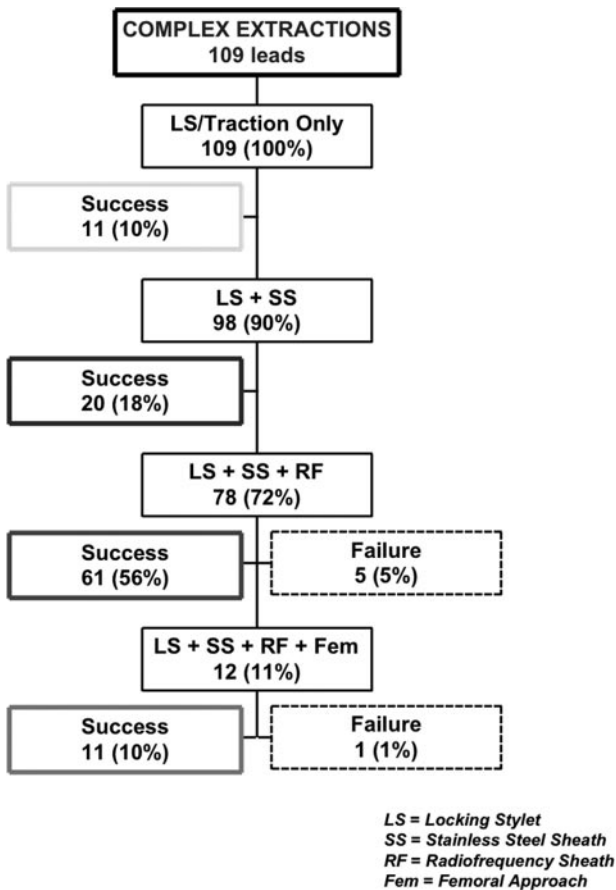


Figure 3. Chronological order of the different techniques used during the complex extraction procedures on 109 leads.

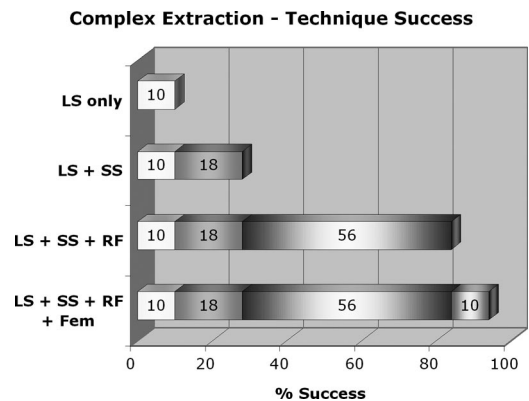


Figure 4. Complex extraction cumulative success by technique.

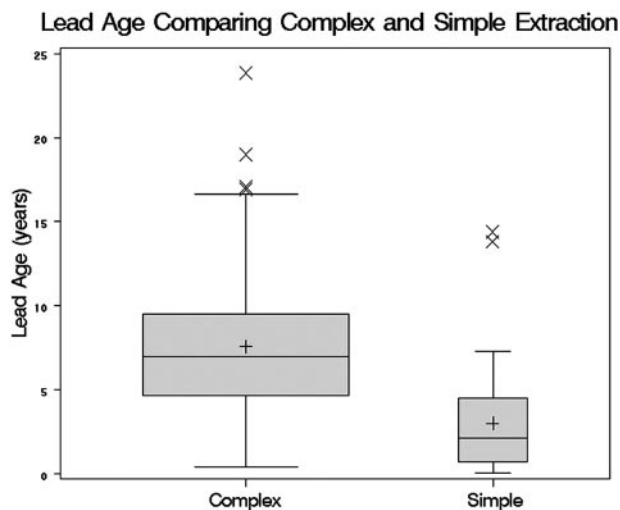


Figure 5. Box plot showing lead age in years compared between the simple and complex extraction groups ($P<0.0001$).

Minor complications included (1) pocket hematoma in 2 patients, (2) excessive but not hemodynamically compromising bleeding during extraction procedure requiring red blood cell transfusion, and (3) superficial pocket infection successfully treated with antibiotic therapy. There were no procedure-related deaths. Considering the limited number of procedural complications, only univariate analysis was performed showing that only lead age (OR, 1.28; 95% CI, 1.09 to 1.50; $P=0.002$) was found to be significantly associated with minor or major complications (Table 5).

Discussion

Over the past decade, transvenous pacemaker and defibrillator implantations in pediatric and CHD patients have markedly increased.²⁴ Several important factors have contributed to this change. The increasing availability of pediatric-compatible transvenous devices with reduced diameter leads and smaller size generators as well as the accumulating evidence of their superiority to epicardial systems^{19,25–27} have led to an increasing frequency of transvenous device implants in younger pediatric patients.^{28,29} In addition, of the ever-growing population of

Table 4. Results of Univariate Analysis Using the GEE Model for Predictors of Failure (n=6 Leads) During Complex Extraction (n=109 Leads)

Variable	OR (95% CI)	P
Patient characteristics		
Age at lead extraction, y	0.98 (0.90–1.07)	0.635
Weight, kg	1.01 (0.97–1.05)	0.793
Recent era, 2006 to 2008	0.29 (0.05–1.59)	0.156
Presence of SHD	1.53 (0.28–8.42)	0.627
Device sidedness, right	7.14 (2.17–25.0)	0.001
Presence of >1 lead	1.15 (0.21–6.38)	0.877
Lead characteristics		
Lead age, y	1.02 (0.82–1.26)	0.867
Type, ICD	3.69 (0.71–19.36)	0.122
Location, ventricle	2.65 (0.33–21.19)	0.358

Table 5. Results of Univariate Analysis Using the GEE Model for Predictors of Any Major or Minor Procedural or Postprocedural Complication (n=8 Patients) for All Patients Having Undergone a Lead Extraction (n=116 Patients and 168 Leads Analyzed), Excluding Those With Only Abandoned Leads

Variable	OR (95% CI)	P
Patient characteristics		
Age at lead extraction, y	1.03 (0.96–1.10)	0.410
Weight, kg	1.00 (0.97–1.03)	0.935
Sex, male	2.59 (0.52–13.02)	0.249
Recent era, 2006 to 2008	0.45 (0.11–1.92)	0.283
Presence of SHD	1.06 (0.25–4.46)	0.942
System infection	0.98 (0.12–8.13)	0.988
Presence of >1 lead	2.13 (0.42–10.81)	0.360
Lead characteristics		
Lead age, y	1.28 (1.09–1.50)	0.002
Type, ICD	0.53 (0.06–4.48)	0.562
Location, ventricle	0.23 (0.05–1.18)	0.078
Insulation type, polyurethane	0.57 (0.12–2.86)	0.500

young adults with repaired or palliated CHD, a significant proportion eventually have heart rhythm complications requiring pacemaker or ICD placement.^{24,30–32} These combined patient groups are expected to continue to grow, and a subset will ultimately face the need for lead revision for a variety of reasons.²³ Several studies have documented the high incidence of lead failure in pediatric and CHD patients,^{19–22,33} and complications with abandoned leads have also been reported.^{34,35} Lead revisions and replacements may also be anticipated to occur several times over the extended lifespan of a patient implanted at a young age. Therefore, knowledge around the specialized process of pediatric lead extraction including patient selection, techniques, and anticipated outcome is essential in providing comprehensive care for this group of patients. To our knowledge, this is the largest reported series on lead extraction in this young patient population and the first report studying the efficacy and safety of non-laser lead extraction in these patients.

In our center's experience, successful lead extraction was achieved in about one third of patients, using simple traction with a nonlocking stylet, an outcome similar to that reported in several large series on older adult patients with simple extraction success rates ranging from 16.4% to 31.2%.^{1–5,7,12} Of the leads undergoing a complex extraction in our study, about three quarters required the use of an RF-powered sheath, which was successful in more than half, for a cumulative success rate of 94%. There are no reports on the use of RF-powered sheaths in pediatric or adult CHD patients. A randomized trial on the use of RF sheaths versus conventional lead extraction techniques involving 120 adult patients demonstrated the superiority of RF with complete extraction achieved in 93% versus 73% ($P<0.01$).¹⁰ The overall complication rate was 6.7%.¹⁰ The 4 small pediatric and adult CHD series on lead extraction reported success rates for complete extraction ranging from 91% to 95%.^{15–18} Locking stylets and flexible sheaths were used in the earlier series,¹⁵ whereas laser-powered sheaths were used in the subsequent series.^{16–18}

In the present study, older lead age, ventricular lead position, and polyurethane lead insulation were identified as variables independently associated with the lower likelihood of a simple extraction on multivariable analysis. The odds of an extraction by simple traction decreased by 37% with every additional year of lead age; it also decreased by 60% for a lead anchored in the ventricle compared with the atrium and by 66% for a lead with polyurethane compared with silicone as its effective outer insulation. Patient age at first lead implant was clinically suspected to be an important predictor, but the study may have been underpowered, and patient age did not reach statistical significance when included in the model ($P=0.064$).

In comparison with our findings, several large series have identified lead age to be associated with a more complex lead extraction.^{1,3–5,7,12,13} In the study by Mathur et al,⁷ a lead in the atrial position was also found to be correlated with simple extraction by traction. Although others^{4,12} have identified defibrillator leads to be predictors of failed simple extraction, when we included defibrillator versus pacemaker lead type in our model, it did not reach statistical significance. The presence of a system infection has fared out as a predictor of simple extraction in certain adult patient series^{5,12,13}; however, in the present study, it did not reach statistical significance on multivariable analysis. It is important to note that system infection was rare (8%) in our series compared with being the predominant indication for lead extraction in most series on older adults. Repaired or palliated CHD was not found to be associated with the probability of a simple extraction.

Major acute procedural complications occurred in 2.8% of patients and minor complications occurred in another 2.8%, giving an overall complication rate of 5.6%. There was no resultant significant disability and there were no periprocedural deaths. The 4 pediatric and adult CHD series reported per-patient complication rates ranging from 6% to 21% and no procedural mortality.^{15–18} Complication rates reported in the large adult series range from 1% to 17%.^{1–4,6–8,10,11,14} In our series, only lead age was associated with the incidence of complications, probably reflecting the complexity of the extraction process. Two studies on adult patients also identified lead age as a predictor of procedural complications,^{3,7} while Agarwal et al¹ identified multiple extracted leads and ICD leads to be associated with complications.

The results of the present study should be interpreted in the context of the single-center design and the heterogeneity of the patient population. In addition, the data analysis did not account for the learning curve of the electrophysiologists performing the lead extractions. The relatively small sample size limited the multivariable analysis model size and the extent of subgroup analysis. The results of RF sheath lead extractions cannot be compared with that of laser-powered sheaths because they were not contemporaneously performed at our institution.

One major limitation of the present study is that it examines lead extraction as a 1-time event and does not take into account the long-term effects of device therapy in pediatric and CHD patients. Though a lead may be extracted relatively safely using readily available tools, when and if the lead should be extracted remains an unknown. Our approach has been to embrace the logic that most individuals with expected longevity >20 years should have nonfunctioning leads removed to leave room for the

future and avoid a more difficult procedure down the line. However, single nonfunctional pacemaker leads have been left capped and abandoned in selected patients, based on individual physician preference and decision-making. This logic remains untested, and further study is needed of this patient cohort followed long-term to look at the ramifications of extracting or abandoning leads.

Conclusion

One third of leads implanted in pediatric and CHD patients can be extracted by simple traction, and the majority can be extracted with the use of additional non-laser-assisted techniques. The use of RF-powered sheaths is effective and relatively safe in this patient population. Older lead age, a lead in the ventricular position, and polyurethane lead insulation were found to be independent predictors of the decreased likelihood of a simple extraction. Although the complication rate was relatively low, this unique patient population presents a challenge because of the small patient size and vascular structures and/or complex cardiac and vascular anatomy. Hence, a comprehensive understanding of anatomy and physiology as well as proper equipment, experienced staff, and cardiac surgical backup are necessary to safely perform these complicated procedures in young patients.

Disclosures

None.

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CLINICAL PERSPECTIVE

Transvenous pacemaker and defibrillator implantation is increasingly common in pediatric and congenital heart disease patients. Given the finite longevity of current leads, extraction is an eventuality for many patients. We report a single-center cohort study with a retrospective review of prospectively collected data on all lead extractions performed between 2002 and 2008, including a total of 144 patients and 203 leads. Successful simple extraction with a nonlocking stylet was achieved in 59 (29%) leads. Of the remaining leads, 35 were abandoned and 109 underwent complex extraction techniques, including a radiofrequency-powered sheath used in 78 of 109 leads. Successful extraction was achieved in 80% of all leads and 94% of leads undergoing a complex extraction. Older lead age, ventricular lead position, and polyurethane insulation were independent predictors of decreased likelihood of an extraction by simple traction. There were 4 major and 4 minor procedural complications and no procedure-related deaths. Thus, the majority of leads implanted in pediatric and congenital heart disease patients can be extracted successfully. This unique patient population presents challenges because of the small patient size and complex cardiac and vascular anatomy. Understanding of the anatomy and physiology, proper equipment, experienced staff, and cardiac surgical backup are necessary to safely perform these complicated procedures in this population.