Extraction of SelectSecure leads compared to conventional pacing leads in patients with congenital heart disease and congenital atrioventricular block

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BACKGROUND SelectSecure™ pacing leads (Medtronic Inc) are increasingly being used in pediatric patients and adults with structural congenital heart disease. The 4Fr lead is ideal for patients who may require lifelong pacing and can be advantageous for patients with complex anatomy.

OBJECTIVE The purpose of this study was to compare the extraction of SelectSecure leads with conventional (stylette-driven) pacing leads in patients with structural congenital heart disease and congenital atrioventricular block.

METHODS The data on lead extractions from pediatric and adult congenital heart disease (ACHD) patients from August 2004 to July 2014 at Bristol Royal Hospital for Children and the Bristol Heart Institute were reviewed. Multivariable regression analysis was used to determine whether conventional pacing leads were associated with a more difficult extraction process.

RESULTS A total of 57 patients underwent pacemaker lead extractions (22 SelectSecure, 35 conventional). No deaths occurred. Mean age at the time of extraction was 17.6 ± 10.5 years, mean weight was 47 ± 18 kg, and mean lead age was 5.6 ± 2.6 years (range 1–11 years). Complex extraction (partial extraction/femoral extraction) was more common in patients with conventional pacing leads at univariate ($P < .01$) and multivariate ($P = .04$) levels. Lead age was also a significant predictor of complex extraction ($P < .01$).

CONCLUSION SelectSecure leads can be successfully extracted using techniques that are used for conventional pacing leads. They are less likely to be partially extracted and are less likely to require extraction using a femoral approach compared with conventional pacing leads.

KEYWORDS SelectSecure pacing lead; Lead extraction; Pediatrics; Congenital heart disease; Pacemaker; Congenital heart block

ABBREVIATIONS ACHD = adult structural congenital heart disease

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Introduction

In recent years, permanent transvenous pacemaker and defibrillator implantation have become therapeutic modalities frequently used in children and young adults with structural congenital heart disease.[1–4] With increasing life expectancy in this subset of patients, lead extraction is inevitable, and a parallel increase in the need for extraction has been observed.[2,5,6] Although transvenous leads are more reliable than epicardial leads, concern remains regarding long-term vascular complications.[4] Removal of dysfunctional leads improves vessel patency, but extraction of chronically implanted leads is a complex procedure associated with significant morbidity and, in some cases, mortality.[4]

The SelectSecure™ (Medtronic Inc, Minneapolis, MN) is a lumenless lead with a smaller diameter (4.1Fr) that has been implanted since 2004.[1,7–9] The smaller lead diameter makes it ideal for transvenous pacing in younger patients.[10,11] Because the SelectSecure has a solid core, the lead must be extracted without the use of a locking stylet.[10] Data on lead extraction in pediatric and adult congenital heart disease (ACHD) patients are limited, particularly in relation to SelectSecure extractions.[2,12,13] An understanding of the outcomes associated with lead extraction, along with the nuances required for each type of lead, is essential to optimize our choice of pacing lead.[2,14] We report our tertiary center experience on extraction of SelectSecure leads compared to conventional (stylette-driven) pacing leads in a cohort of pediatric and ACHD patients.

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Methods

This single institutional retrospective study was conducted with the approval of the Research Ethics Board at University Hospitals Bristol NHS Foundation Trust. Pediatric and ACHD patients who had undergone lead extraction between August 2004 and July 2014 were included in the study. A list of these patients was obtained from the cardiac database at the Bristol Royal Hospital for Children and the Bristol Heart Institute. Patients were included in the study if the initial lead

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was implanted during childhood or if the pacemaker lead was implanted as an adult with structural congenital heart disease. Patients in whom the SelectSecure lead was extracted at the same time as a defibrillator lead were not included.

Echocardiogram reports were reviewed, predominantly looking for postextraction effusions. The reported grade of tricuspid regurgitation was assessed after the extraction and compared to the previously reported grade of tricuspid regurgitation. Clinical details in relationship to the extraction, including any radiographic imaging performed around the time of extraction, also were reviewed. Given the low incidence of major complications, we chose a composite end-point of complex extraction as the primary outcome variable. This was defined as either a partial extraction (leaving some or all of the lead *in situ*) or the need to extract using a femoral approach. The method of extraction was also assessed, examining whether a cutting sheath was required and the type of cutting sheath used. The 2 cutting sheaths used were the polypropylene telescoping sheath (Cook, Bloomington, Indiana) and the Evolution® (Cook, Bloomington, IN). The Perfecta® electrosurgical dissection sheath (Cook) was used for 14 cases before the Evolution was used.

Major complications of pericardial effusion requiring intervention, need for surgical extraction, or death were recorded. Minor complications consisted of bleeding, hematoma formation, infection, prolonged length of stay (>2 days), and hypotension. Bleeding was defined as minor if blood loss was documented in the procedure note (estimated to be <50 mL) and major if it was associated with hypotension or required blood transfusion.

Statistical analysis

Demographic data are presented as mean $\pm$SD. A Fisher exact test was used to test for significance in categorical variables between groups. Outcome variables were all tested at the univariate level using logistic regression. Variables of clinical significance were then entered into a generalized estimating equation (PROC GENMOD), and odds ratios were calculated where appropriate. Given that lead age and lead type were confounding variables (due to the recent trend to implant SelectSecure leads), the interaction between these 2 variables was entered into our final model. $P < .05$ was considered significant. All statistical analysis was performed using SAS (version 9.2, SAS Institute, Cary, NC).

Results

From August 2004 to July 2014, a total of 623 pacemaker leads were implanted in pediatric and ACHD patients at Bristol Royal Hospital for Children and the Bristol Heart Institute. A total of 57 lead extractions were performed during the same time period. Of these, 22 were SelectSecure leads and 35 were conventional pacing leads. Lead extractions were performed by 3 operators (GS, RM, MW). There was no difference between operators for the outcome of complex extraction (partial/femoral extraction) ($P = .58$). Baseline patient demographics are listed in Table 1. Mean age at which patients underwent lead extraction was 17.6 years for both groups. There were 35 males and 22 females. A total of 30 patients who had congenital heart disease underwent explantation; the rest of the patients had congenital complete atrioventricular block. Of the 35 conventional pacing leads that were extracted, 19 were active fixation leads, and all of them were steroid eluting (see Online Supplemental Table 1).

Mean lead age was 4.1 $\pm$ 2.6 years for the SelectSecure group and 6.7 $\pm$ 2.6 years for the conventional pacing lead group, which was significantly different ($P < .01$). The indications for extraction are listed in Table 1. Lead failure (defined as complete failure of sensing/pacing) was an indication in 10 patients. For 14 patients, the indication for extraction was suboptimal sensing/pacing thresholds in addition to the radiographic appearance of lead tension. For 17 patients, the lead was replaced because of radiographic evidence of lead tension in addition to anticipated patient growth in the presence of a normally functioning lead, usually at the time of a generator change. There were no significant differences in the indication for extraction between the 2 groups. The devices were most commonly implanted in the left suprapectoral region, followed by the left axilla, which was not significantly different between the groups. Most patients underwent a single lead extraction; only 4 patients had more than 1 lead extracted, which was not significantly different between groups.

Table 1 Comparison of patient characteristics between conventional pacing lead and SelectSecure lead groups

Variable	SelectSecure (n = 22)	Conventional leads (n = 35)	*P*
Weight at explant (kg)	48.6 ± 20.1	46.3 ± 18.3	.83
Age at explant (y)	17.6 ± 10.5	17.6 ± 10.8	.9
Lead age (y)	4.1 ± 2.6	6.7 ± 2.6	.01
Gender, male	11	24	.17
Congenital heart block	10	17	.9
Congenital heart disease	12	18	.71
Indication			
Lead failure*	3	7	.7
System upgrade†	5	9	.8
Growth‡	7	10	.7
Infection	1	0	.38
Redundant	2	3	.9
Other	4	6	.9
Device position			
Left suprapectoral	14	20	.97
Left axillary	4	7	.9
Other	4	8	.9
No. of leads			
1	21	32	.9
2	1	2	.9
3		1	

*Complete capture/sensing failure.
†Suboptimal sensing/pacing in addition to radiographic appearance of lead.
‡No concerns regarding lead performance; however, significant patient growth anticipated.

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