Extraction of chronically implanted coronary sinus leads active fixation vs passive fixation leads

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BACKGROUND The Medtronic model 4195 (StarFix) left ventricular lead is an active fixation lead that provides additional support within the coronary sinus (CS) via deployable lobes. While this lead has been shown to have excellent stability within the CS, concerns about its extractability have been raised.

OBJECTIVE The aim of this study was to compare the safety and efficacy of the extraction of the model 4195 lead vs other Medtronic CS leads in a prospective cohort study.

METHODS Patients undergoing extraction of this and other CS leads for standard indications were prospectively enrolled and studied. The primary outcomes of interest were the removal success rates and associated complication rates. Patients were followed for a month postprocedure.

RESULTS The overall left ventricular lead extraction success rate was 97.6% (n = 205). Among 40 patients with chronic model 4195 leads, there were 37 successful extractions (92.5%) as compared to 98.8% for the 165 non-4195 leads. However, in 2 of the 3 StarFix lead extraction failures, standard extraction techniques were not used. All 10 of the model 4195 leads that had been implanted for less than 6 months were extracted without incident.

CONCLUSION In this largest study of CS lead extractions published to date, the overall success rate of the extraction of chronically implanted CS leads is high and the complication rate is similar in these lead models. The extraction of the model 4195 lead is clearly more challenging, but it can be accomplished in high-volume extraction centers with experienced operators. It is recommended that the model 4195 lead be extracted by experienced operators.

KEYWORDS Cardiac resynchronization therapy; Lead extraction; LV leads

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Introduction

Cardiac resynchronization therapy (CRT) improves mortality and reduced hospitalization in patients with left ventricular (LV) systolic dysfunction, symptomatic heart failure, and a wide QRS complex.[1–5] Successful achievement of efficacious LV lead pacing in a region that will facilitate early LV activation is critical to the success of CRT.[6–8] The limiting factor in the implementation of successful CRT is often the anatomy of the coronary veins and the association of the cardiac veins with the phrenic nerve.[9–13] Challenges include the unavailability of a good vein position, the possibility of lead movement after implantation, and the problem of patient posture causing a change in the relationship of the LV stimulation site and the phrenic nerve. In 1 study there was a 12% rate of CRT failure postoperatively

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because of either loss of LV capture or phrenic nerve stimulation.[14] The model 4195 LV lead was designed to overcome these challenges and has been shown to aid in the effective delivery of CRT.[15] In many of these cases and in the case of infection, extraction of the coronary sinus (CS) lead is needed. There are few reports on the outcomes of CS lead extraction.

We report the results of a study of the extractability of the CS lead, with special attention to the Medtronic model 4195 StarFix lead (ClinicalTrial.gov ID: NCT00893386). The study was part of the postmarketing evaluation plan that was required at the time of approval of the Medtronic StarFix (model 4195) lead by the US Food and Drug Administration. This lead has been described elsewhere.[15] It is a unipolar lead with an outer push tube that allows for fixation within the body of the tributaries of the CS. The model 4195 lead has been found to be highly efficacious with an extraordinarily low dislodgment rate, in spite of the fact that it is most often placed along the body of a large vein.[15] We enrolled patients with model 4195 leads and a concurrent comparison group of patients with other market available Medtronic CS leads who were undergoing a planned extraction of their CS lead for standard consensus-based indications.[16]

The objective of this study was to describe the extraction of chronically implanted CS branch leads for CRT. Furthermore, this analysis sought to compare the safety and efficacy of the extraction of the model 4195 lead vs other CS leads given the concerns that have been raised about the ability to extract the model 4195 active fixation lead.[17,18]

Methods

Study population

Patients with Medtronic CS leads implanted for at least 180 days requiring lead extraction for standard indications were included in the primary analysis group (Table 1). All patients had a class I or class II indication per the Heart Rhythm Society/American Heart Association (HRS/AHA) 2009 consensus document.[16] Patients were enrolled at 25 centers from July 2009 through July 2014. All decisions on the extraction procedure were based on physicians' judgment. The study protocol was approved by the institutional review board at each participating institution. There was also an additional small cohort of patients who underwent an extraction of the model 4195 leads that had been implanted between 90 and 179 days.

Outcomes and definitions

Data on all extraction procedures and adverse events were reviewed by a committee of physicians with expertise in the extraction of CS leads using the HRS/AHA consensus document on lead extraction.[16] That adjudication committee determined procedural success, clinical success, or failure on the basis of the definitions in the HRS guidelines. These definitions are as follows:

Complete procedural success: Removal of all targeted leads and all lead material from the vascular space, with

Table 1 Indication for extraction procedures

Extraction indication	Model 4195 ≤6 mo (n = 10)	Model 4195 >6 mo (n = 40)	Non-4195 (n = 165)	Total
Class I				
Functional leads – arrhythmias	0	0	1	1
Functional leads – immediate threat	0	1	3	4
Functional leads – implanted cardiac devices	0	1	2	3
Nonfunctional leads – immediate threat	0	1	4	5
Nonfunctional leads – implanted cardiac devices	1	1	1	2
Evidenced by pocket abscess, device erosion	3	10	41	51
Evidenced by valvular endocarditis, lead endocarditis, or sepsis	1	12	27	39
Lead that interferes	0	0	2	2
Obliteration or occlusion	0	0	2	2
Occult gram-positive bacteremia	0	2	5	7
Retained lead	0	1	0	1
Sepsis	2	2	17	19
Class IIa				
Design or failure of lead	0	0	3	3
Leads preventing access	0	1	2	3
Localized pocket infection	1	0	22	22
Treatment of a malignancy	0	0	1	1
Thrombosis or venous stenosis	0	1	0	1
Functional leads – pacemaker or defibrillator, that due to design or failure need to be removed	0	1	2	3
Nonfunctional leads – not immediate or imminent threat	0	1	2	3
Chronic pain	0	1	0	1
Persistent occult gram-negative bacteremia	0	2	1	3
Class IIb				
Nonfunctional leads – indicated CIED procedure	0	0	5	5
Other				
Nonfunctional leads – physician discretion	2	2	22	24