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Original article

Transvenous extraction of advisory implantable cardioverter defibrillator leads with a relatively long implant duration

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ABSTRACT

Background: Optimal management of advisory implantable cardioverter defibrillator (ICD) leads has not been established. Several studies were reported concerning the lead extraction of advisory ICD leads, but the implant duration of those studies was short. We estimated the efficacy of lead extractions of advisory ICD leads with a relatively longer duration in Japanese patients.
Methods: We retrospectively analyzed 28 patients who underwent a lead extraction at Kokura Memorial Hospital and Tokyo Medical and Dental University Hospital [Fidelis (Medtronic, Minneapolis, MN, USA): $n = 19$, Riata (St. Jude Medical, Sylmar, CA, USA): $n = 8$, Isoline (SORIN CRM SAS, Clamart, France): $n = 1$]. The mean implant duration was 63.3 ± 19.3 months. The indications were device related infections in 3, electrical lead failures in 18, electrical lead failures and venous obstructions in 3, and prophylactic reasons in 4 patients. Inappropriate shocks because of electrical lead failures were observed in 9 patients.
Results: Complete removals were achieved of all 28 advisory leads. In 23 out of 28 patients, new ICD leads were implanted during the same procedure. In one patient, open chest surgery was performed for a hemothorax that occurred during a new ICD lead implantation just after successfully removing the advisory ICD lead. There were no other major or minor complications.
Conclusion: Transvenous extractions of advisory ICD leads with relatively long implant duration were performed with a high success rate and low complication and mortality rate in Japanese patients.

Introduction

In these past few decades, implantable cardioverter defibrillators (ICDs) and cardiac resynchronization therapy (CRT) have been introduced. ICD therapy has been established for prophylaxis of sudden cardiac death due to lethal ventricular tachyarrhythmias. Expanding indications for ICD therapy, such as primary prevention, have resulted in many patients depending on ICD systems. Failure of high-voltage leads can compromise the ICD function, followed by inappropriate shocks, loss of pacing, failure of defibrillation, fatal proarrhythmias, and finally even death.

The Sprint Fidelis (Medtronic, Minneapolis, MN, USA) lead was found to be prone to high- and low-voltage conductor fractures. In 2007 the Food and Drug Administration (FDA) in the USA announced a class I device recall [1]. The Riata and Riata ST (St. Jude Medical, Sylmar, CA, USA) revealed a propensity to externalize conductors via an inside-out abrasion through the silicone insulation followed by a higher incidence of electrical malfunction and lead failure, therefore, the FDA announced a class I device recall in 2011 [2]. Moreover, in 2013 the FDA announced a class II recall for the Isoline defibrillation leads (SORIN CRM SAS, Clamart, France) because of a potential lead insulation problem followed by a device malfunction.

There is currently no consensus on how to manage the patients with these advisory leads. Several studies [3–7] concerning the extraction of advisory ICD leads have been published but the implant duration of the leads are relatively short (2–4 years).

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Furthermore, there has been only one case report [8] concerning the management of recalled ICD leads in Japan. The purpose of this study was to estimate the efficacy of the transvenous extraction of advisory ICD leads with a longer implanted duration in Japanese patients.

Methods

Study patients

Five hundred seventy-four leads in 282 patients were extracted transvenously, mainly using an excimer laser sheath from July 2009 through March 2014 at Kokura Memorial Hospital, and from April 2014 through October 2015 at Tokyo Medical and Dental University Hospital. One hundred and one of them were ICD leads and 28 were advisory leads.

All advisory leads were attempted to be extracted after obtaining written informed consent. The indications for the lead extraction were device infections, lead failures, or prophylactic extractions during generator replacements. A device infection was defined as previously described [9–12]. A pocket infection was defined as the presence of local warmth, erythema, swelling, edema, pain, or discharge from the device pocket, or an erosion or impending erosion of the device. A bloodstream infection was defined as occult bacteremia despite appropriate antibiotic therapy.

Electrical lead failures were defined by absolute limits and relative changes since baseline: pacing threshold >5 V or >100% increase; R wave sensing <3.0 mV or >50% reduction; pacing impedance outside the interval 200–2000 Ω or >100% increase or >50% decrease; high voltage lead impedance outside the interval 20–200 Ω or >100% increase or >50% decrease; non-physiologic noise; and previous lead failure with implant of supplementary leads.

The study was approved by the ethical committees of Kokura Memorial Hospital and Tokyo Medical and Dental University Hospital.

Lead extraction procedure

The procedures were performed in the cardiac catheterization laboratory or operation room under general or venous anesthesia according to the patient's condition. Careful monitoring with surface electrocardiograms and, invasive arterial blood pressure monitoring were performed. Transesophageal or intracardiac echocardiography were additionally performed. Cardiac surgical back up and stand-by percutaneous cardio-pulmonary support were provided.

The lead extraction procedure has been described in detail previously [9,10]. Concisely, the lead was prepared by inserting a locking stylet (LLD, Spectranetics, Colorado Springs, CO, USA) into the inner coil lumen when possible. A suture was then tied onto the insulation and the locking stylet. The laser sheath was then advanced over the lead. A laser application was performed at binding sites and the laser sheath was gradually advanced from one binding site to another until the tip of the lead. Once abutting the myocardium, a combination of traction and counter-traction was performed and the lead was freed. The definitions published in the 2017 Heart Rhythm Society consensus statement [12] on transvenous lead extraction were used to adjudicate the procedural success, clinical success, and complications. Major complications were defined as "any of the outcomes related to the procedure that were life-threatening or resulted in death," or, "any unexpected events that caused a persistent or significant disability, or any events that required a significant surgical intervention to prevent" such an outcome. Minor complications were defined as "any undesired events related to the procedure that required a medical intervention or minor procedural intervention to remedy, and did not persistently or significantly limit the patient's function, nor threaten their life or cause death". Examples include a pocket hematoma, upper extremity swelling, and the need for a blood transfusion.

Statistical analysis

The continuous variables are expressed as the mean ± SD, and were compared using a Student's *t*-test. A value of $p < 0.05$ was considered significant. The analyses were conducted using StatView 5.0 software (SAS Institute Cary, NC, USA).

Results

Baseline characteristics

Twenty-eight patients (22 males, mean 59.4 ± 17.6 years old) underwent transvenous extractions of advisory ICD leads (Fidelis: $n = 19$, Riata: $n = 8$, and Isoline: $n = 1$) were analyzed. The baseline patient characteristics are shown in Table 1. The mean left ventricular ejection fraction was 47.0 ± 18.7%. The procedural characteristics are listed in Table 2. The mean implant duration was 63.3 ± 19.3 months (longest 93 months). The indication for the procedure was a device-related infection in 3, electrical lead failure in 18, electrical lead failure and venous obstruction in 3, and prophylactic reasons in 4 patients. Inappropriate shocks because of electrical lead failures were observed in 9 patients. Seven leads (RA: 4, RV pacemaker: 1, RV ICD: 1, LV: 1) were extracted concomitantly.

Lead extraction procedure

The patients were implanted with one or two leads each, and a total of 35 leads including 28 advisory leads were extracted. The summary data of the extracted leads are shown in Table 2. Complete removal was achieved for all 28 advisory leads. Three ICD leads were successfully extracted manually, and the remaining leads were extracted with the aid of a laser sheath. The total laser time was 52.4 ± 43.8 s and total laser pulse 2203 ± 1804. There was no statistically significant difference in total laser pulse in patients with Fidelis and Riata leads (1768 ± 1638 vs 1880 ± 1420). In this patient group no other

Table 1
Summary data of the baseline characteristics of the study patients.

Baseline characteristics	
Number of studied patients	28
Age (years old)	59.4 ± 17.6
Sex (male, %)	22/28 (78.6)
Height (cm)	162.3 ± 9.5
Body weight (kg)	59.9 ± 11.8
Body mass index	22.5 ± 3.1
Hypertension (%)	12/28 (42.9)
Ischemic heart disease (%)	4/28 (14.3)
Diabetes (%)	1/28 (3.6)
Anti-coagulation therapy (%)	11/28 (39.3)
Serum creatinine (mg/dl)	0.95 ± 0.35
LVEF (%)	47.0 ± 18.7
Medtronic Fidelis (%)	19 (67.9)
SJM Riata (%)	8 (28.6)
Sorin Isoline (%)	1 (3.6)
ICD (%)	27/28 (96.4)
CRT-D (%)	1/28 (3.6)

LVEF, left ventricular ejection fraction; ICD, implantable cardioverter-defibrillator; CRT-D, cardiac resynchronization therapy-defibrillator.
Values are given as the mean ± SD or *n* (%).

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