International Journal of Cardiology 199 (2015) 277–281

Contents lists available at ScienceDirect

International Journal of Cardiology

journal homepage: www.elsevier.com/locate/ijcard

Predictive factors of lead failure in patients implanted with cardiac devices

Yoshiyasu Aizawa *, Masachika Negishi, Shin Kashimura, Kazuaki Nakajima, Akira Kunitomi, Yoshinori Katsumata, Takahiko Nishiyama, Takehiro Kimura, Nobuhiro Nishiyama, Kotaro Fukumoto, Yoko Tanimoto, Shun Kohsaka, Seiji Takatsuki, Keiichi Fukuda

Department of Cardiology, Keio University School of Medicine, Tokyo, Japan

ARTICLE INFO

Article history:
Received 24 March 2015
Received in revised form 13 May 2015
Accepted 18 July 2015
Available online 23 July 2015

Keywords:
Pacemaker
Implantable cardioverter defibrillator
Lead failure
Fidelis
Riata
Brugada syndrome
Idiopathic ventricular fibrillation

ABSTRACT

Introduction: Lead failures (LFs) are one of the most common complications in patients implanted with cardiovascular implantable electronic devices. LFs often cause serious secondary complications such as inappropriate ICD shocks or asystole. This study aimed to identify the clinical factors associated with the occurrence of LFs.
Methods: A total of 735 consecutive device implantations (mean age 67 ± 15 years, males 64%) performed at a single university hospital setting from 1997 to 2014 were included. The implanted devices consisted of 421 pacemakers, 250 implantable cardioverter defibrillators (ICD), 9 cardiac resynchronization therapy pacemakers (CRT-P), and 55 CRT defibrillators (CRT-D). The primary endpoint was the development of an LF.
Results: During a mean duration of 5.8 ± 4.3 years, 38 LFs developed in 31 patients (mean age 56 ± 14 years). LFs included 32 ICD (7 Sprint Fidelis, 2 Riata), and 6 pacing leads. Nine patients received inappropriate ICD shocks and 1 had syncope due to an LF. All patients underwent lead reinsertions with device replacements. Eight patients required opposite site implantations due to venous occlusions. The predictive factors of LFs were the age, male sex, taller body length, ICD vs. pacemaker, lesser lead number, extra-thoracic puncture of the axillary vein vs. a cut-down of the cephalic vein, use of recalled leads and patients with idiopathic ventricular fibrillation (IVF) and Brugada syndrome (BrS).
Conclusion: LFs occurred mainly with ICD leads. A lesser age, the puncture method, lead model, and diagnosis of IVF/BrS were associated with the development of LFs.

1. Introduction

Cardiovascular implantable electronic devices (CIEDs) have improved the survival and quality-of-life in patients with various heart rhythm disorders [1]. Indications for CIED implantations have expanded not only for symptomatic bradycardia but also primary or secondary prevention of sudden cardiac death and severe congestive heart failure despite optimal medical therapy. However patients will encounter various device problems or device replacements during their remaining life span [2–4]. Lead failure (LF) is one of the serious problems, which requires an emergent response and invasive procedures such as lead reinsertion and device replacements. In 2007, the Sprint Fidelis (Medtronic) ICD lead and in 2011, the Riata (St. Jude Medical) ICD lead were recalled by the Food and Drug Administration (FDA). The Riata ICD leads are prone to failure by conductor externalization and/or electrical dysfunction [5–7]. Although several risk factors for an LF were identified, predicting its occurrence is difficult in the clinical setting. We assessed the hypothesis that there may be some risk factors for LFs, which have not been fully clarified. The purpose of this study was to disclose the clinical factors for predicting the development of LFs.

2. Methods

2.1. Study population

All 735 consecutive CIED implantations at the Keio University Hospital from January 1997 to June 2014 were included in this study and reviewed retrospectively. The implanted devices consisted of 421 pacemakers, 250 implantable cardioverter defibrillators (ICDs), 9 cardiac resynchronization therapy pacemakers (CRT-Ps), and 55 CRT defibrillators (CRT-Ds). The patients were evaluated at our pacemaker/ICD clinic every 6 months for pacemakers and 3–4 months for ICD/CRT devices with or without remote monitoring. The patients gave their written informed consent prior to the invasive procedures. Leads were inserted from the left cephalic vein as a first choice but if it failed an extra-thoracic puncture was performed using a contrast medium injection from the left superficial vein or by echo-guidance.

The baseline demographic and clinical data were collected on all patients using electronic medical records or clinical charts. The detailed device information was collected from printouts obtained during routine follow-up. The primary endpoint was an LF requiring an invasive procedure. The definition of an LF was an abnormal impedance, pacing and/or sensing failure, or non-physiologic high-rate oversensing (noise) detection. The recalled leads were defined as the Medtronic Spring Fidelis (model 6949, 6931, 6948)

* Corresponding author at: Department of Cardiology, Keio University School of Medicine, 35 Shinanomachi, Shinjuku-ku, Tokyo 160-8582, Japan.
E-mail address: yoshiyaaizawa-circ@umin.ac.jp (Y. Aizawa).

http://dx.doi.org/10.1016/j.ijcard.2015.07.055
0167-5273/

Table 1
Clinical characteristics of the patients included in this study.

Variable	Overall (n = 735)	LF (+) (n = 38)	LF (−) (n = 697)	P value
Age, year	66.9 ± 15.0	56.3 ± 14.3 ↓	67.5 ± 14.8	<0.001
Male sex, n (%)	473 (64.4)	31 (81.6) ↑	442 (63.4)	0.023
BL, cm	160.7 ± 10.1	169.5 ± 10.1 ↑	160.2 ± 9.9	<0.001
BW, kg	59.0 ± 13.1	61.2 ± 10.4	58.9 ± 13.2	0.226
BMI, kg/m^2	22.6 ± 4.0	21.2 ± 2.2	22.7 ± 4.1	0.052
Implanted device				
Pacemaker, n (%)	421 (57.3)	7 (18.4) ↓	414 (59.4)	<0.001
ICD, n (%)	250 (34.1)	31 (81.6) ↑	219 (31.4)	<0.001
CRT-P, n (%)	9 (1.2)	0 (0)	9 (1.3)	0.481
CRT-D, n (%)	55 (7.5)	0 (0)	55 (7.9)	0.072
Number of leads, n	1.9 ± 0.5	1.5 ± 0.6 ↓	1.9 ± 0.5	0.004
Material of lead				
Silicone, n (%)	402 (54.7)	27 (71.1) ↑	375 (53.8)	0.038
Polyurethane, n (%)	118 (16.1)	14 (36.8) ↑	104 (14.9)	<0.001
Optim, n (%)	116 (15.8)	0 (0) ↓	116 (16.6)	0.006
Lead diameter, Fr	6.7 ± 0.9	7.2 ± 0.9 ↑	6.6 ± 0.9	0.006
Recalled lead, n (%)	46 (6.3)	9 (23.7) ↑	37 (5.3)	<0.001
Fidelis, n (%)	39 (5.3)	7 (18.4) ↑	32 (4.6)	<0.001
Riata, n (%)	7 (1.0)	2 (5.3) ↑	5 (0.7)	0.005
Lead insertion				
Cut down of CV, n	447 (60.8)	7 (18.4) ↓	440 (63.1)	<0.001
Puncture, n	197 (26.8)	8 (21.1)	189 (27.1)	0.411

BL: body length, BW: body weight, BMI: body mass index, CV: cephalic vein.

and St. Jude Medical Riata (model 1560, 1561, 1570, 1571, 1572, 1580, 1581, 1582, 1590, 1591) ICD leads.

2.2. Statistical analysis

Continuous variables are presented as the mean ± SD and categorical variables as numbers and proportions. Continuous variables were compared using a Mann–Whitney U test. Categorical variables were compared between groups using the chi-square test. A univariate analysis was performed and all variables with a P value of <0.2 were included in the multivariate analysis with a Cox-regression analysis. The survival rate of the leads was evaluated using the Kaplan–Meier method and compared between several parameters using the log-rank test. Statistical analyses were performed on IBM SPSS Statics software (Version 22). A P value of <0.05 was considered statistically significant.

3. Results

The baseline clinical characteristics of the patients included in this study are shown in Table 1. The mean age was 66.9 ± 15.0 years and 64.4% of the patients were men (Fig. 1A). The proportion of each device is shown in Fig. 1B. Bradycardia devices were implanted due to atrioventricular block (48%), sick sinus syndrome (45%), and atrial fibrillation with slow ventricular response (4%) (Fig. 1C). The proportion of underlying cardiac diseases in the patients implanted with tachycardia devices was similar to that in the other reports in our country (Fig. 1D). Briefly, that proportion was about 40% of cardiomyopathy, a quarter of coronary heart diseases, and about 20% of ion channelopathies including Brugada syndrome. During a mean follow-up period of 5.8 ± 4.3 years, 38 leads (31 patients) failed. The failed leads were 32 ICD leads and 6 pacemaker leads. A further detailed lead profile is summarized in Fig. 2, and includes the number of leads, lead material, method of the lead insertion, and use of recalled leads.

The incidence and timing of the LFs according to the underlying heart disease are summarized in Table 2. In the patients with idiopathic ventricular fibrillation (IVF) and Brugada syndrome (BrS), a higher incidence of LFs compared with other underlying diseases was observed (31.3% and 43.8%).

We compared the clinical and lead characteristics between those with and without the development of an LF. The patients that developed LFs had a younger age, male predominance male, taller body length, small number of pacemakers despite a large number of ICD patients, smaller number of leads implanted, high proportion of silicone or polyurethane but none of Optim material, high proportion of recalled leads, and lesser incidence of cut-down procedures of the cephalic vein. A univariate Cox regression analysis demonstrated that there was an increased risk for an LF in patients with a younger age, male sex, taller body length, ICD vs. pacemaker, small lead number and presence of a recalled lead (Table 3). After we analyzed the patients implanted with recalled leads, a univariate Cox regression analysis demonstrated that there was an increased risk for an LF in taller patients and in those a puncture method vs. a cephalic vein

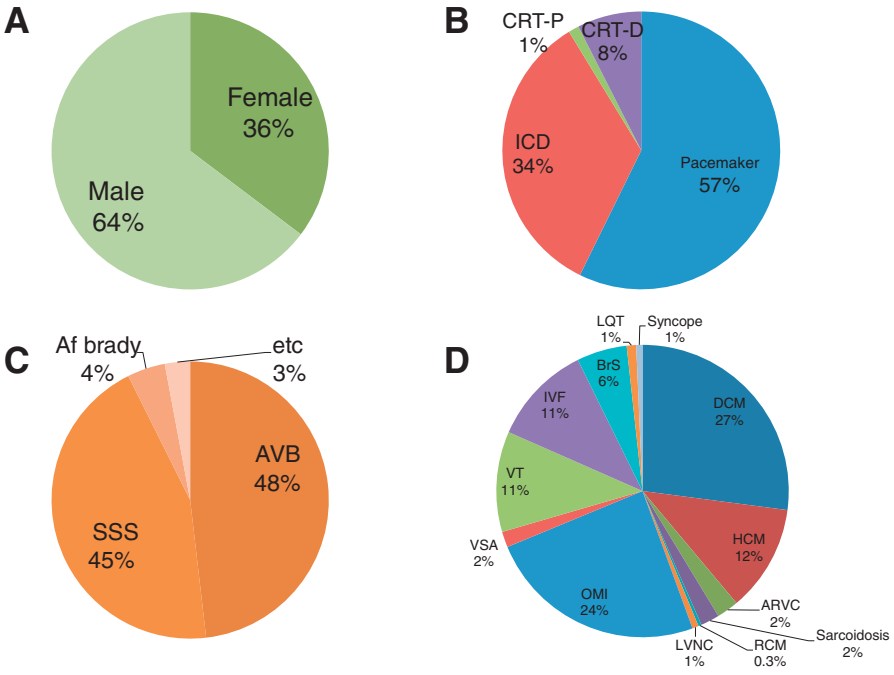

Fig. 1. Clinical characteristics of the patients and the implanted devices in this study. A: proportion of males and females in this study. B: proportion of implanted devices in this study. C: underlying heart diseases in the patients implanted with pacemakers. D: underlying heart diseases in the patients implanted with ICD/CRT devices.