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Original Article

Long-term reliability of sweet-tip type screw-in leads

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ABSTRACT

Background: Active fixation leads have provided stable atrial and ventricular pacing; however, long-term follow-up data have not been satisfactory. The purpose of this study was to investigate the long-term reliability of active fixation leads and their electrical characteristic stability.
Methods: A total of 1196 pacing leads were implanted in 830 patients consecutively between 2002 and 2013. In this retrospective study, we were able to trace 1092 leads in 750 patients to investigate the prognosis of implanted leads. The measurement values (including pacing thresholds, sensing amplitudes, and lead impedances of both the atrial and ventricular leads) were obtained from medical records at the time of implantation and during follow up at the outpatient device clinic. All pacing leads were FINELINE II Sterox EZ Leads (Boston Scientific, MN, USA), which are sweet-tip type screw-in active fixation leads, except for the shock leads in patients with implantable cardioverter defibrillator.
Results: The mean follow-up period was 51.3 ± 29.2 months (median, 48 months). A total of 1092 leads were implanted in either the atrium (682 leads) or the ventricle (410 leads). Venous access was achieved through cephalic vein cut down (CVC) method (914 leads) or the subclavian vein puncture (SVP) method (178 leads). The overall lead survival rate was 99.6% at both 5 and 10 years. Lead fracture was observed in 4 of 1092 leads (0.37%), all of which were implanted by the SVP method. No lead fracture occurred among patients wherein CVC method was applied ($p < 0.01$). Device-related infection was observed in four patients (0.53%).
Conclusions: The overall reliability and stability of sweet-tip type screw-in leads were satisfactory throughout the long-term follow-up period (median, 4 years). Because it was associated with less lead fractures, cut-down access from the cephalic vein may be recommended as the first-line approach when considering the importance of long-term durability of pacing leads.

1. Introduction

In recent years, the number of patients with cardiac implantable devices (CID) has increased, including those with pacemakers and implantable cardioverter defibrillators (ICD). CID and pacing leads have been developed as advancements in medical technology. The current generation of CID has already achieved favorable longevity, greater variety, and smaller size compared with previously available devices. Although CIDs still need to be changed every 5–10 years due to battery drain, exchanging pacing leads easily is impossible. Therefore, long-term reliability is essential for pacing leads. It is well known that the longevity of pacing leads is associated with venous approach, insulation materials, and lead structures [1,2]. FINELINE II Sterox EZ Leads (Boston Scientific, Minneapolis, MN, USA), which are sweet-tip type screw-in active-fixation leads, have been used worldwide since 2001. More than one million of these pacing leads have been implanted, and the number is expected to increase because these leads are compatible with magnetic resonance imaging (MRI). The purpose of this study was to investigate the long-term reliability and stability of electrical characteristics in sweet-tip type active fixation leads.

2. Materials and methods

Between June 2002 and July 2013, a total of 1196 leads were implanted in 830 patients at our hospital. Among these cases, 1092

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leads implanted in 750 patients were available for our investigation of lead prognosis. Pacing thresholds, sensing amplitudes of the atrial or ventricular activities, and lead impedances were obtained from the medical records collected at the implantation and from the outpatient device clinic.

2.1. Lead Model

The FINELINE II Sterox EZ Lead (Boston Scientific) is an active fixation screw-in bipolar lead that is one of the thinnest leads as MRI conditional pacing leads. The structure is parallel and incorporates an electrically insulated nickel–cobalt alloy screw-tip with polyethylene glycol capsule coating, titanium-ring electrode tip with oxidized iridium coating, and platinum–iridium sleeve. The distance between the distal and proximal electrodes is 16 mm. Furthermore, mannitol is coated on the top of the helix, and is melted away when the pacing lead is inserted in the blood vessels. Thus, considerable skill is required when the pacing lead is fixed to the myocardial tissue. Six models of these leads are marketed, which differ in length and insulation materials used for their bodies (polyurethane, 4469, 4470, and 4471; silicone rubber, 4472, 4473, and 4474). The lead models were chosen depending on the patient's height or lead positions.

2.2. Implant procedure

Before the implant procedure, we first performed cephalic vein venography on the implanted side, except for patients who had considerable renal failure. The operation began after we had confirmed the patency or running of the cephalic and subclavian veins. Three experienced operators performed the procedure under local anesthesia. We used a primary approach for lead implantation from the cephalic vein. The approach was changed to subclavian vein puncture (SVP), if necessary. Extrathoracic puncture of the axillary vein method was not performed in this study. Second, we cut the skin of the left or right pectoral region and created pacemaker pockets below the fascia of the pectoralis major muscle after administration of local anesthesia. We exposed the cephalic vein and ligated the distal side with silk thread. Subsequently, we inserted a sheath introducer, followed by the guide wire. It was necessary to insert two leads for a dual-chamber device. Hence, we preferred to use leads with different insulation materials between the atrium and ventricle due to the smoothing operation. Moreover, in each implantation, we attempted to fix the lead at the right atrial septum (for the right atrial lead) and the right ventricular mid-septum (for the right ventricular lead), which were our first choices for the locations. If the septum location was considered unacceptable, the right atrial appendage or free wall was chosen for the right atrial leads, and the right ventricular apex or outflow tract (high septum) was also chosen for the right ventricular leads. After lead fixation, we measured the sensing of atrial and ventricular activities, as well as pacing thresholds in volts (V) at a pulse width of 0.4 ms. Atrial and ventricular lead impedances were measured with a pulse width and amplitude of 0.4 ms and 5 V, respectively. Intra-operative measurements were performed using a pacing system analyzer (Biotronik ERA-300; Biotronik Inc., Berlin, Germany). After confirming all electrical measurements were within permissible range, we ligated the pacing leads alongside the cephalic vein and tissues. Finally, we sutured the subcutaneous and skin after the devices and the leads had been connected.

2.3. Statistical analysis

The overall lead survival rate was estimated by using the Kaplan–Meier method. The log-rank test was used to assess differences in lead survival, based on the use of the venous approach. Data on electrical characteristics are expressed as mean ± standard deviation (SD). The Student *t*-test was used to compare the measurements of pacing, sensing, and lead impedance. Values of $p < 0.05$ were considered statistically significant. Data were collected, and the statistical analyses were performed by using JMP® 11 (SAS Institute Inc., Cary, NC, USA).

Table 1
Study characteristics.

Patients ($n=750$)	Study characteristics
Age	68.8 ± 13.0 years
Sex	464 Males, 286 females
Pacemaker indication	
Sick sinus syndrome (%)	279 (37%)
AV block (%)	253 (34%)
AF with bradycardia (%)	47 (6%)
Others (NMS, HOCM, and CHF) (%)	4 (1%)
ICD indication	
Ventricular tachycardia (%)	167 (22%)

Table 2
The number of pacing leads.

Leads ($n=1092$)	Atrial lead	Ventricular lead
4469 (polyurethane, 45 cm)	97	0
4470 (polyurethane, 52 cm)	166	153
4471 (polyurethane, 58 cm)	3	246
4472 (silicone, 45 cm)	159	0
4473 (silicone, 52 cm)	257	5
4474 (silicone, 58 cm)	0	6
Approach		
Cephalic vein (%)	554 (81%)	360 (88%)
Subclavian vein (%)	128 (19%)	50 (12%)

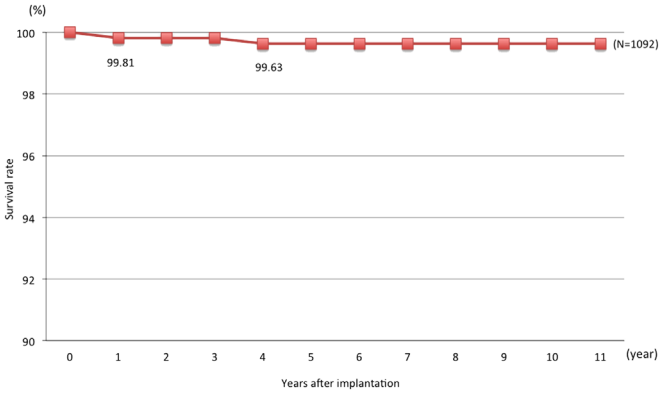

Fig. 1. The overall survival rate of FINELINE II Sterox EZ Leads with verified lead fracture.

3. Results

The mean follow-up period was 51.3 ± 29.2 months (median, 48 months). Seven hundred fifty patients (464 men and 286 women) were included in this study. The mean age of the patients was 68.8 ± 13.0 years (range, 11–94 years). The indications for pacemaker or ICD implantation are provided in Table 1, which included sick sinus syndrome, atrioventricular (AV) block, ventricular tachycardia, atrial fibrillation (AF) with bradycardia, and other conditions (neurally mediated syncope, hypertrophic obstructive cardiomyopathy, or congestive heart failure) in 279 (37%), 253 (34%), 167 (22%), 47 (6%), and 4 patients (1%), respectively. A total of 1092 leads could be traced for investigation in this