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Original article

Initial experience using Excimer laser for the extraction of chronically implanted pacemaker and implantable cardioverter defibrillator leads in Japanese patients

Hideo Okamura (MD)[a,b,*], Satoshi Yasuda (MD, PhD)[a,b], Shunsuke Sato (MD)[c], Koji Ogawa (BSc)[d], Ikutaro Nakajima (MD)[a], Takashi Noda (MD, PhD)[a], Yusuke Shimahara (MD)[c], Teruyuki Hayashi (BSc)[d], Yoshihiko Onishi (MD, PhD)[e], Junjiro Kobayashi (MD, PhD, FJCC)[c], Shiro Kamakura (MD, PhD)[a], Hisao Ogawa (MD, PhD, FJCC)[a,f], Wataru Shimizu (MD, PhD, FJCC)[a,b]

[a] Department of Cardiovascular Medicine, National Cerebral and Cardiovascular Center, Osaka, Japan
[b] Department of Advanced Cardiovascular Medicine, Graduate School of Medical Sciences, Kumamoto University, Kumamoto, Japan
[c] Department of Cardiovascular Surgery, National Cerebral and Cardiovascular Center, Osaka, Japan
[d] Division of Clinical Engineering, National Cerebral and Cardiovascular Center, Osaka, Japan
[e] Department of Anesthesiology, National Cerebral and Cardiovascular Center, Osaka, Japan
[f] Department of Cardiovascular Medicine, Graduate School of Medical Sciences, Kumamoto University, Kumamoto, Japan

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ABSTRACT

Background: Given the exponential growth in cardiac device implantations, the need for less invasive lead extraction is increasing. The Excimer laser was approved for lead removal in Japan in 2010. The present study reports the initial experience using this novel technique to extract chronically implanted pacemaker and implantable cardioverter defibrillator (ICD) leads from Japanese patients.
Methods and results: We performed a retrospective study of consecutive patients undergoing lead extraction using the laser sheath at a single Japanese center. Patient and lead characteristics, indications, and outcomes were analyzed. From August 2010 to September 2012, a total of 70 leads, including 14 ICD leads, were removed using the laser sheath from 40 patients (26 male, 14 female; age 65.5 ± 18.3 [mean ± SD] years; body mass index 21.8 ± 3.5 kg/m^2). The median implant duration was 87 months (range 13–328 months). Indications were infection (n = 35), venous occlusion (n = 4), and pain (n = 1). The femoral approach was used in combination with the laser technique in five cases. Complete procedural success was achieved with 68 leads (97.1%). Although the electrode tip was left behind in the remaining two leads, the desired clinical outcomes could be achieved; which were defined as clinical success. No cases resulted in failure. There were no major complications, including death and bleeding requiring open-chest surgery.
Conclusions: Laser sheaths appear to provide a feasible and effective means of extracting chronically implanted pacemaker and ICD leads in Japanese patients.

Introduction

The number of implantations of cardiovascular implantable electronic devices (CIEDs), including permanent pacemakers (PPMs), implantable cardioverter defibrillators (ICDs), and cardiac resynchronization therapy devices (CRTs) has been increasing year by year [1]. As the number of patients with chronically implanted CIEDs has grown, the number of lead-related complications requiring total removal of CIED systems has been increasing [2,3]. Leads implanted for longer than one year are likely to have adhered to veins, myocardium, and other leads, making their removal more difficult. The Excimer laser sheath (Spectranetics, Colorado Springs, USA) has been proven to be effective in many studies [4–7], and the laser sheath was approved in Japan in July 2010. Transvenous lead extraction can be associated with serious complications [8]. We sought to investigate the outcomes and complications associated with the use of the laser sheath in extracting chronically implanted PPM and ICD leads, in Japanese patients, an older and lower body mass index (BMI) population.

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* Corresponding author at: 5-7-1 Fujishirodai, Suita, Osaka 565-8565, Japan. Tel.: +81 6 6833 5012; fax: +81 6 6872 7486.
E-mail address: hokamura@hsp.ncvc.go.jp (H. Okamura).

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Methods

Study patients

We performed a retrospective study of 40 consecutive patients undergoing lead extraction using a laser sheath at the National Cerebral and Cardiovascular Center, Suita, Japan, from August 2010 to September 2012. All patients gave informed consent. The indications for transvenous lead extraction were decided based on the Heart Rhythm Society (HRS)/American Heart Association (AHA) 2009 consensus document [9]. Patient characteristics, lead and device characteristics, indications for extraction, and outcomes were analyzed.

Lead extraction technique

The technique of transvenous lead extraction has been reported previously [7]. Briefly, procedures were performed in the operation room under general anesthesia with invasive arterial blood pressure monitoring and transesophageal echocardiogram (TEE). The patient was prepped in a manner to allow for emergent open-heart surgery. There was cardiac surgical back up and a stand-by pump oxygenator.

Large bore sheaths were placed in the femoral artery and vein. Extraction was performed in a stepwise approach. After a conventional stylet was placed in the lead, an attempt was made to retract the screw in active fixation leads. An initial attempt was made to remove the lead with simple traction. If manual traction was unsuccessful, a SLS II Excimer laser sheath was introduced (Fig. 1).

To pull the lead tip with enough tension, one of two specific locking stylets, Extor (VascoMed, Binzen, Germany) or LLD (Spectranetics) was placed in each lead to be extracted. The SLS II laser sheath was selected from among three different sizes (12, 14, or 16 French) according to the extracting lead diameter. Fig. 2 shows a representative lead extraction case. The SLS II laser sheath was advanced over the targeted lead (Fig. 2A–C) and adhesions were lysed using the laser when required (Fig. 2D and E). The lead tip was freed by performing "counter traction" [7], applying adequate traction to the lead while retaining the sheath in a position close to the atrial or ventricular endothelium (Fig. 2F) (Supplementary Movie 1).

Supplementary data associated with this article can be found, in the online version, at http://dx.doi.org/10.1016/j.jjcc.2013.03.012.

When the laser sheath alone could not be advanced due to calcified adhesions or contact between leads at a point of lead overlap, a mechanical polyamide sheath (VascoMed) was employed. Also, when the subclavian approach did not work well, a femoral approach using a GooseNeck Snare (Covidien, Plymouth, MN, USA) was employed.

Definition of outcome and complications

The definition of outcome has been previously reported in the HRS/AHA 2009 consensus document [9]. Complete procedural success was defined as the removal of all targeted leads and all lead material from the vascular space. Even if a small portion of the lead (e.g. the lead tip or the insulation) remained within the vascular space, it was defined as clinical success when the residual part did not increase the risk of perforation, embolic events and perpetuation of infection, or cause any undesired outcome. Failure was defined as the inability to achieve either complete procedural or clinical success, or the development of any permanently disabling complication or procedure-related death. The definitions of major and minor complications related to the procedure were also specified according to the HRS/AHA 2009 consensus document [9]. Major complications were defined as those that were life-threatening or that resulted in death. Other undesired events related to the procedure that required medical intervention or additional procedural intervention were defined as minor complications.

Statistics

Normally distributed continuous variables are expressed as mean value ± standard deviation. Continuous variables that were not normally distributed are expressed as median with range. Discrete variables are shown as numbers with percentages.

Results

Patients characteristics, indications for extraction, and types of leads

The individual data of the 40 study patients can be found in Table 1. Twenty-six of them were referred to us from other hospitals located in the Kansai region. Patients were implanted with one to four leads each, and a total of 70 leads were extracted using a laser

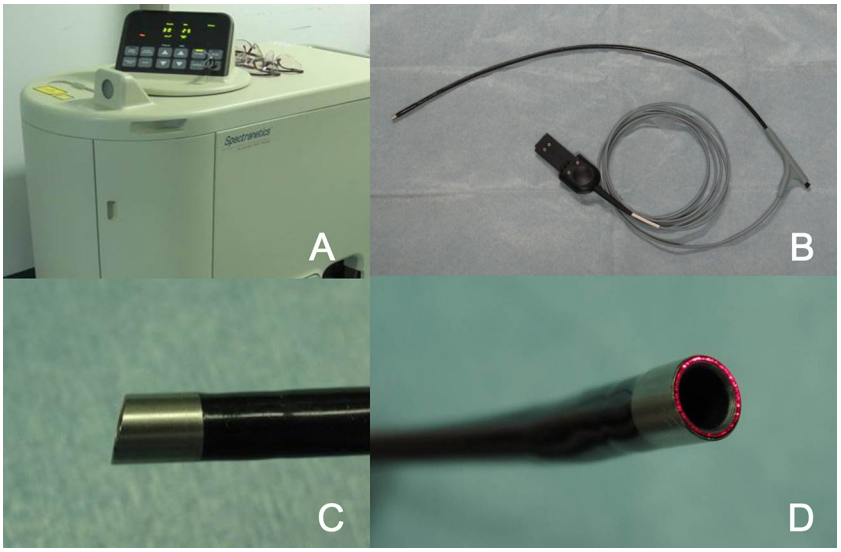

Fig. 1. System and device for lead extraction using laser sheath. (A) Generator of Excimer laser (CVX-300, Spectranetics, Colorado Springs, CO, USA); (B) perspective of laser sheath (SLS II, Spectranetics); (C) side view of laser sheath, showing the oblique shape of the tip; (D) sectional view of laser sheath, showing laser light emerging from the sheath circumference.