

Ancillary Tools in Pacemaker and Defibrillator Lead Extraction Using a Novel Lead Removal System

ANTONIS S. MANOLIS,*† THEMOS N. MAOUNIS,† VASSILIS VASSILIKOS,†
JOHN CHILADAKIS,* HELEN MELITA-MANOLIS,‡ and DENNIS V. COKKINOS†

From the *Cardiology Section, Patras University, Patras, and the †Cardiology, and
‡Microbiology Departments, Onassis Cardiac Surgery Center, Athens, Greece

MANOLIS, A.S., ET AL.: **Ancillary Tools in Pacemaker and Defibrillator Lead Extraction Using a Novel Lead Removal System.** *A previous report described our preliminary experience with a highly successful pacing lead removal system (VascoExtor). Extending this experience, we found it necessary to use additional tools to enhance the success of percutaneous lead extraction with this system. In the present series, we used the standard locking stylets (S and K), and recently, one newer type of stylet (Magic) over the last 3 years in 34 patients to extract 48 pacemaker leads in 31 patients and 3 defibrillator (ICD) leads in 3 patients. Lead extraction was carried out in 23 men and 11 women (aged 64 ± 17 years) because of pacemaker infection ($n = 21$), pacemaker ($n = 8$) or ICD ($n = 3$) lead malfunction, or prior to ICD implant ($n = 2$). Leads were in place for 3.5 ± 3.7 years. Infections, involving pocket and lead(s), were due to *S. epidermidis* ($n = 13$), *S. aureus* ($n = 6$), *S. aureus plus E. coli* ($n = 1$), or *fungi* ($n = 1$). Of the 48 pacing leads, 31 were ventricular, 15 atrial, and 2 were VDD leads. The ICD leads were two double-coil leads (CPI) and one single-coil lead (Telectronics). Using the S ($n = 12$), K ($n = 8$), or Magic ($n = 3$) stylets, all pacing leads in 23 patients and the ICD leads in 2 patients were successfully removed from a subclavian approach using the locking stylets. However, in nine (26.5%) patients ancillary tools were required. In four patients, lead fragments were captured with use of a noose catheter, a pigtail catheter, and a biptome from a right femoral approach. In two patients, locking could not be effected and a noose catheter from the right femoral vein was used, aided by a pigtail and an Amplatz catheter and a biptome to remove three leads. In a patient with an ICD lead, a combined subclavian (stylet S) and right femoral approach (noose catheter) was required. In a patient with a dysfunctional ventricular lead 12 years old, a motor drive unit was used to facilitate the exchange of locking stylets, but extraction failed. In another patient, a fragment of a dysfunctional ventricular lead remained intravascularly despite resorting to a femoral approach. Finally, lead removal was completely (32/34, 94%) or partially (1/34, 3%) successful in 33 (97%) of 34 patients for 50 (98%) of 51 leads without complications. In conclusion, to enhance the success of pacing or ICD lead extraction with use of the VascoExtor locking stylets, an array of ancillary tools were required in more than one fourth of patients. (PACE 2001; 24:282-287)*

pacing lead, defibrillating lead, lead extraction, pacemaker infection

Introduction

Extraction of infected or dysfunctional pacemaker leads has been effected with percutaneous techniques using locking stylets.¹⁻⁸ Previous techniques required tedious and exact sizing of the stylet to match the lead lumen. The VascoExtor lead removal system (VascoMed GmbH, Weil am Rhein, Germany) has three types of locking stylets (S/K/L), and lately only one type (Magic), simplifying the sizing process. We have recently reported our preliminary experience with this sys-

tem.⁹ Extending the initial experience with use of this system, this article focuses on the group of patients requiring additional (to the locking stylet) tools for lead extraction among 34 patients, 31 patients with pacing leads and 3 patients with implantable cardioverter defibrillator (ICD) leads.

Patients and Methods

Patients

Over a 3-year period, pacing or ICD lead extraction using the VascoExtor system was attempted in 34 consecutive patients (23 men, 11 women) who were referred for percutaneous lead removal. The patients were 64 ± 17 years of age (range 19-94 years), and had an indication for lead removal, including pacemaker infection ($n = 21$), pacing ($n = 8$), or ICD ($n = 3$) lead dysfunction, or

Address for reprints: Antonis S. Manolis, M.D., Professor of Cardiology, 41 Kourempa St., Agios Dimitrios, Athens 173 43, Greece. Fax: 011-30-61-99 46 82; e-mail: asm@otenet.gr.

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Table I.

Clinical Characteristics of 34 Patients Undergoing Percutaneous Lead Extraction Using a New Lead Removal System

Men/women	23/11
Age, years (range)	64 ± 17 (19–94)
Indication for extraction	
Pacemaker infection	21
<i>S. epidermidis</i>	13
<i>S. aureus</i>	6
MRSA	1
<i>S. epidermidis</i> + <i>E. coli</i>	1
fungi	1
Lead dysfunction	11
pacing lead	8
ICD lead	3
Prior to ICD implant	2
Skin erosion	17
Time since initial implantation (years)	3.5 ± 3.7 (0.3–15)
Number of leads	51
Type of leads	
Ventricular	33
Unipolar	12
Bipolar	19
active fixation	1
Single pass unipolar VDD	2
Atrial	15
Unipolar	4
Bipolar	11
active fixation	2
ICD	3

ICD = implantable cardioverter defibrillator; MRSA = methicillin-resistant *S. aureus*.

prior to an ICD implantation (n = 2) (Table I). Infections involved both pocket and lead(s) and were due to *Staphylococcus epidermidis* (n = 13), *Staphylococcus aureus* (n = 6), *Staphylococcus aureus* plus *Escherichia coli* (n = 1), or fungi (n = 1). Skin erosion was present in 17 patients. Positive blood cultures were detected in five patients. Echocardiography revealed small vegetations on the right ventricular pacing leads in two patients. No patient had evidence of pulmonary embolism. The indication for permanent pacemaker implantation had been sinus node dysfunction in 12 patients and second degree Mobitz type II or complete heart block in 19 patients.

Chronically Implanted Leads

Single ventricular pacing leads had been implanted in 15 patients, while 15 patients had two endocardial leads, and 1 patient had three leads in place. Leads had been in place for a mean of 3.5 ± 3.7 years (range 0.3–15 years). The fixation mech-

anism of implanted leads was passive in 45 leads and active (screw-in) in 3 leads. Of the 48 pacing leads, 12 were unipolar ventricular, 18 bipolar ventricular, 4 unipolar atrial, 9 bipolar atrial, 2 unipolar single pass VDD, all tined, and 3 bipolar screw-in atrial (n = 2) or ventricular (n = 1) leads. The ICD leads were tined double coil leads (Endotak, Cardiac Pacemakers, Inc. [CPI], St. Paul, MN, USA) in two patients and single-coil lead (EnGuard, Telectronics Pacing Systems Inc., Englewood, CO, USA) in one patient.

Locking Stylets

The VascoExtor locking stylet system initially included three types of locking stylets (S, K, L), a noose catheter, outer sheaths, and a motor drive unit. More recently, the Magic type of locking stylet was added. The K stylet is used for pacing leads with a conductor coil design of less than four coiled wires and an inside lumen <0.7 mm. For pacing leads with a conductor of quadrifilar coil design and an inner diameter < 0.9 mm, the S (small) stylet is used, while for leads with a larger inner coil diameter (> 0.9 mm) the L (large) stylet is used. The Magic stylet has been designed for pacemaker and defibrillator lead removal. The locking mechanism for stylets S and L consists of anchor flanges that spread by manipulating the stylet handle and fix the stylet directly in the coil in the area of the lead tip. Locking for stylet K is effected by lateral parallel displacement of the split flanges at the tip of the wire. The Magic stylet has a fixation tip that is spread by bending and, thus, gets fixed directly in the coil.

Ancillary Tools

For exchanging the locking stylet, if needed, the VascoExtor system includes a motor driving unit. For applying countertraction, a set of sheaths is available. For extracting leads or intravenous fragments using the transfemoral approach, a noose catheter is available with this lead removal system. Other ancillary tools not included in this system but used during the procedures in the present study included pigtail or Amplatz (Becton Dickinson and Co., Franklin Lakes, NJ, USA) catheters, guidewires, bioptomes, and forceps, mostly used during a transfemoral approach, when the locking stylets were not sufficient or failed.

Percutaneous Lead Extraction Procedure

All procedures were performed after informed, written consent was obtained from the patients. For those who were pacemaker dependent, a temporary pacing wire was introduced usually from the internal jugular vein or occasionally the subclavian vein that was contralateral to the site of

the implanted pacemaker. Subsequently, using a sterile and aseptic technique under local anesthesia, the pacemaker pocket was exposed and the pulse generator was retrieved and disconnected from the lead(s). The lead connector was then severed. A test stylet was advanced under fluoroscopic guidance to the tip of the lead to free the lumen of any material and facilitate the passage of the locking stylet through the inner coil. The test stylet was then exchanged for the locking stylet, which was advanced to the tip of the lead where it was fixed by the locking mechanism described above. Positioning and fixation of the extractor (locking stylet) was confirmed by gently pulling under fluoroscopy. Then lead extraction was attempted by slowly pulling on the traction cord of the extractor under x-ray visualization.

For leads that could not be extracted from above (subclavian route), the transfemoral approach was used. The same approach was also used to extract any lead fragments that were not removable from above. After lead extraction was completed, the wound in the infraclavicular area was debrided if infected, the pacemaker pocket was plicated, and wound closure was effected in layers with use of absorbable sutures allowing healing by primary intention. After the procedure, the patients were monitored overnight in the cardiac care unit. For those patients afflicted by infection, a course of intravenous antibiotic therapy was completed before a new pacing system was implanted, usually on the contralateral side. After hospital discharge, all patients were followed-up at the pacemaker clinic. All data are reported as mean \pm SD.

Results

Procedural outcome

In preparation for the extraction procedure, a temporary pacemaker wire was inserted in eight patients who were pacemaker dependent. Lead extraction was attempted in 34 patients for a total of 51 leads (48 pacemaker and 3 ICD leads). Complete removal of all leads was successful in 32 (94%) patients for 49 (96%) leads; partial lead removal with retention of a lead fragment was effected in 1 patient, while extraction failed in a patient with a 12-year-old dysfunctional unipolar ventricular lead. The type S stylet was useful in 13 patients, but 2 of them required additional tools. The K stylet was used in eight patients with two of them needing other tools as well. The S and K stylets were tried in four patients. One of the stylets succeeded in two of these patients, while both stylets failed in the other two patients; in one patient lead extraction failed despite use of other extra tools, while in the other patient a transfemoral approach was successful. The newer

Magic stylet was used in six patients, but ancillary tools were needed in two of them. In one patient, all three stylets (Magic, S, K) were used in succession, and the K stylet succeeded. In two patients, the test stylet of the Magic system sufficed to detach the lead from the right ventricular apex, and lead extraction was aided by an outer sheath that facilitated lead passage in the subclavicular space in one of these patients. Through the transfemoral approach, the noose catheter was successfully used in four patients, aided in one patient by an Amplatz catheter used to capture the proximal end of the lead in the superior vena cava. Successful removal was effected from a right (n = 20), left, (n = 5) right plus left (n = 1) subclavian, or subclavian plus femoral (n = 7) approach. Lead extraction was accomplished by simple traction for six atrial and four ventricular leads (only test stylet inserted), sole use of the locking stylets for 31 leads and via a femoral approach for 2 atrial leads, 7 ventricular leads, and 1 ICD lead.

Ancillary Tools

In addition to the locking stylets, an array of ancillary tools to aid lead extraction were required in nine (26.5%) patients (Table II). The transfemoral approach was needed in seven patients. In one patient with a dual chamber pacemaker and two unipolar leads, the K stylet was used successfully to remove the ventricular lead, but during attempts to remove the atrial lead, the distal part was broken off after the lead was detached from the myocardium and migrated to the

Table II.

Ancillary Tools Used for Percutaneous Extraction of Pacemaker and Defibrillator Leads in 9 (26.5%) of 34 Patients

Pigtail catheter (RFV)	1 patient (A lead fragment)
VascoExtor motor drive unit (RSV)	1 patient (1 V lead)*
VascoExtor noose catheter plus pigtail and Amplatz catheters and a biptome (RFV)	1 patient (2 leads)
VascoExtor noose catheter, plus pigtail catheter (RFV)	1 patient (ICD lead)
Biptome (LFV)	1 patient (V lead)
Magic stylet plus sheath (RSV)	1 patient (V lead)
VascoExtor noose catheter (LFV)	1 patient (V lead)
Sheaths plus forceps (RSV)	1 patient (V lead)
Noose catheter plus Amplatz catheter (RFV)	1 patient (V lead)

* extraction failed.

A = atrial; ICD = implantable cardioverter defibrillator; LFV = left femoral vein; RFV = right femoral vein; RSV = right subclavian vein; V = ventricular.

right ventricular outflow tract. This fragment was then captured and removed with use of a pigtail catheter passed through the right femoral vein, as the noose catheter was not available at that time. In another patient with a dual chamber device and two bipolar leads, locking of either the S or K stylet could not be effected in the atrial or the ventricular lead. Both leads were then removed during the same, and at a subsequent, session with use of additional tools, including the noose catheter, a pigtail, and an Amplatz catheter and a bioptome. All were introduced via the right femoral vein. The pigtail and Amplatz catheters were used to pull the proximal ends of the leads and redirect them from the superior to the inferior vena cava, where they were captured and trapped by the noose catheter and finally pulled out through the femoral vein. The bioptome was used to capture and detach lead fragments from the endocardial site where the lead tips were anchored. Similarly in four patients, lead fragments were captured with a noose or a pigtail catheter or a bioptome introduced via the femoral vein. In a patient with an ICD lead, a combined subclavian with stylet S and transfemoral approach with a noose catheter was required to extract the lead. A fragment of a dysfunctional ventricular lead remained intravascularly despite resorting to a femoral approach in another patient.

Attempts failed to extract a dysfunctional unipolar ventricular lead (with insulation fracture) that had been implanted 12 years earlier. To facilitate the exchange of locking stylets (types S and K) in this patient, a motor drive unit was used. Finally, the old lead was capped and left in place, and a new pacing system was implanted. In this and in another three patients with difficulties in lead extraction, use of the VascoExtor telescoping sheaths to effect countertraction was attempted, but sheath advancement over the leads through the subclavicular space was not possible. Only in one patient was the outer sheath useful in facilitating lead passage through the subclavicular space where it was initially trapped.

Complications

No complications occurred in this series of patients during the procedures of percutaneous lead extraction. Two deaths occurred that were, not related to the procedure. A 70-year-old man with a pacemaker infection due to *S. aureus* died of a myocardial infarction 5 weeks after the extraction procedure; his hospital course had been complicated by hepatic failure, possibly related to a suspected antibiotic drug idiosyncrasy. Another patient, an 87-year-old woman who had an infected VVI pacemaker system extracted, also died

of a recurrent cholangitis 6 weeks after the extraction procedure, a few days after her discharge from the hospital.

Discussion

Implantation of a transvenous pacemaker is one of the most commonly performed procedures in cardiology. The surgical technique is rather simple, but caution should be exercised to avoid complications. Pacemaker infection remains one of the most serious complications of this procedure.^{10,11} Reported infection rates are around 1%–2%. The most common causative agents are *S. aureus* and *S. epidermidis*, as confirmed in this series as well. Although conservative measures have been used for infections considered localized to the pacemaker pocket, aggressive management with explantation of the pacing system and completion of antibiotic therapy is usually necessary to eradicate the infection.¹⁰

During explantation of the pacing system, removal of the pacing leads is challenging, particularly for those leads implanted for longer periods of time.^{1–8} This is because endocardial leads tend to develop encapsulation by fibrous tissue of their distal tip that is in contact with the endomyocardium, but fibrous adhesions also develop along the endovenous or endocardial course of the lead(s).¹² Removal of chronically implanted transvenous pacing leads can be achieved by surgical or percutaneous methods.^{1–10,13,14} When dealing with infection, some have suggested to base selection of the technique of lead removal on the presence and size of vegetations, proceeding with surgery for large (> 10 mm) vegetations and with percutaneous methods in all other cases.¹⁰ This policy is based on prior studies indicating more frequent embolism with large vegetations.^{10,15} In recent years, newer percutaneous techniques have been proven effective and relatively safe and have practically supplanted cardiac surgery and older methods with manual or weighted traction with their attendant risks.^{1–10} Among these, the most widely used lead extraction system is the Cook retrieval system (Cook Vascular, Inc., Leechburg, PA, USA).⁸

Using the Cook system, lead extraction has been reported as complete for 87% of 2,195 pacing leads from 1,299 patients and partial for 7.5% of the leads.⁸ Success was higher for physicians with greater experience, for shorter implant duration, active fixation, and atrial leads. A femoral approach was used overall in 18% or 31% for leads implanted longer than 8 years. Thoracotomy was used in 3.4%, including 1.3% for complications and 2.1% for extraction failures. The complication rate was 3.9%, including hemopericardium and tamponade (1.2%), hemothorax (0.5%), pul-

monary embolism (0.2%), migrating lead fragment (0.3%), bacteremia (< 0.1%), stroke (0.1%), ventricular tachycardia (< 0.1%), and various other complications (1.4%). Procedure related deaths occurred in eight (0.6%) patients.

The Cook retrieval system comprises a variety of locking stylets that increase the expense and the effort involved for exact size matching for each pacing lead to effect locking. A universally applied locking stylet is, therefore, desirable to simplify this tedious process of stylet selection during the procedure and also to reduce the cost of the extraction system. A European multicenter study¹⁶ recently reported the results obtained from the use of a locking stylet (VascoExtor) in 105 patients for 150 leads with 81% complete and 12% partial success in lead extraction. This type of stylet could fit a large number of different leads with a variety of internal lumen diameters. Since then, this extraction system has been improved further with new features and tools. Instead of one stylet version, three types of stylets became available (S, L, and K) to accommodate a greater number of pacing leads. More recently, newer versions of the locking stylet have been introduced, like the Magic stylet that was used during the latter part of the present study for pacing and defibrillating leads. In addition to their universal applicability, another major advantage of these locking stylets over other existing types of stylets is that the locking mechanism is reversible with use of a motor drive unit that renders feasible the removal and exchange of stylets. This system also comes (unavailable with earlier versions) with a transfemoral kit that includes a noose catheter for lead extraction from the femoral vein.

Using the newer version of this lead extraction system, in the present study we were able to completely extract 49 (96%) of 51 leads having a mean implant time of 3.5 years. Although during our preliminary experience with this system, 81% of patients had the leads removed with sole use of the locking stylets,⁹ subsequently it was found that in a significant percentage of patients (26.5%), an array of ancillary tools were required during the procedure to effect successful lead extraction. Among these tools, we used the motor drive unit to facilitate exchange of stylets, and the transfemoral kit with the noose catheter for removal of leads or lead fragments not extractable from the subclavian approach. All these enhancements were useful, except for the outer plastic sheaths that were impractical; difficulty in advancing them over the lead rendered it unfeasible to apply effective countertraction. In addition to the VascoExtor accessories, a variety of other extra tools, including guidewires, pre-

shaped curved catheters (pigtail or Amplatz), bioptomes, and forceps, were also needed. The universally applicable locking stylet greatly simplified the extraction process in 74% of our patients. Most importantly, the use of this system was safe with no complications observed during the procedures. A potential advantage of the newer version of this system is that it can also accommodate ICD lead extraction,¹⁷ although in one of our three ICD leads, a transfemoral approach was needed.¹⁸ With both the earlier and latest versions, we have occasionally encountered locking failure occurring with any type of stylet, which may culminate into a major drawback if other types of stylets or other ancillary tools are unavailable during the procedure.

Although there were no complications in our study, percutaneous lead extraction techniques may pose a significant risk with potentially life-threatening complications, as confirmed by the data reported by the US Lead Extraction Database.⁸ Recently, laser sheaths have been added to our armamentarium and the preliminary results appear promising, although it is worrisome that significant complications, including one death, occurred in five patients having the laser extraction and in only two patients having mechanical techniques.¹⁹ Furthermore, cost appears to be a significant drawback of this newer laser technology, and simpler and less expensive mechanical systems, like the one used in the present study, might offer an important alternative solution. Finally, the two (mechanical and laser) techniques could be potentially combined and a tiered approach might be considered by reserving the laser sheath method for more demanding cases when the mechanical system initially fails.

In conclusion, the new pacemaker and defibrillator lead extraction system with a universally applicable locking stylet appears simple to operate, safe, and quite successful in chronically implanted lead extraction. Sole use of the locking stylet was successful in 73.5%, however, ancillary tools were required in 26.5% of cases. Among the ancillary tools accompanying these stylets, the snare system was useful, but the countertraction sheaths were impractical, necessitating the use of other extra tools. Finally, using this system and aided by an array of ancillary tools, we were able to completely remove 49 (96%) of 51 chronic pacing or defibrillating leads in 32 (94%) of 34 patients. Further studies in larger patient populations are needed to confirm these results and randomized comparative studies are necessary for the currently available lead removal systems, such as the one recently reported.¹⁹

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