Pacing and implantable cardioverter-defibrillator transvenous lead extraction

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During the last 20 years, the transvenous techniques for the extraction of chronically implanted pacing (PL) and defibrillating leads (DL) achieved a high success rate. However the procedures are often complex and are associated with a small but significant risk. The operators' experience and the availability of different approaches for difficult cases seem to affect both the results and the complications. This paper represents a review of indications, techniques and results of a 10-year experience in the field of transvenous lead extraction.

Since January 1997, extraction was attempted in 1330 leads; among these 1137 were successfully extracted with the standard mechanical approach (success rate 85.4%); in 12 leads was performed a partial extraction (0.9%) and 1 was inapplicable (0.07%). The jugular approach was performed in 180 leads (164 PL and 16 DL): 39 were intravascular free-floating leads (38 PL and 1 DL) and 141 were difficult exposed leads (126 PL and 15 DL) allowing extraction in 178/180 (98.8%) cases. After this approach, the final results were: total extraction 98.88%, partial extraction 0.90%, unextracted 0.15%, and not applicable 0.07%.

Major complications occurred in 4 cases (0.3%) and were cardiac tamponade (2 underwent successful pericardiocentesis, 1 surgical repair, and 1 patient died). No complications were directly related to the jugular approach.

In conclusion, transvenous lead extraction is an effective and safe procedure. The success rate and the incidence of complications are highly affected by the staff experience. The use of the jugular approach, in the presence of free-floating or difficult exposed leads, increases both safety and success rate.

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Background

Device therapy involving pacemakers for bradyarrhythmias and implantable cardioverter-defibrillators (ICDs) for tachyarrhythmias have undergone a surprising evolution. System failure and infection, however, are still possible complications. In contrast to the relative frequency of lead failure, either as a result of implantation error or deterioration of the lead materials, primary malfunction of the pulse generator is rare. Infection is another complication of implanted devices; it is reported to occur from 0 up to 19% of the pacemaker patients[1,2] and from 2 to 7% of the ICD patients.

Management of complications ranges from abandonment of a failed lead and reimplantation of a new lead to the removal of all inflammatory tissues, extraction of all implanted devices, and reimplantation of new devices. In the early 1980s, before the development of successful low morbidity techniques for extracting leads, every attempt was made to save the chronic pacemaker site or, at least, to leave the leads in place if the site had to be abandoned. Removing the chronically implanted leads was considered only when the complication was life-threatening. During the past decade, effective, low morbidity techniques have evolved for transvenous lead extraction[3] making the management of chronically implanted lead complications easier.

Pacemaker and implantable cardioverter-defibrillator failure/ infection management: indications for extraction

The management of pacemaker and ICD complications includes several approaches from simply reprogramming in case of pseudomalfunction to removal of the entire hardware; the systematic discussion of all approaches will not be done in this paper while the attention will be fo-

cused on the indications and techniques for transvenous extraction, which require particular facilities and training. The indications for lead extraction have generally been described according to the Byrd classification[4]. The categories of "mandatory", "necessary", and "discretionary" have served well during the developing phase of lead extraction technology and physician skills.

Mandatory indications mean that leads must be removed. Mandatory conditions are those in which leaving the leads in place would be life-threatening or disabling like septicemia, endocarditis, lead migration (e.g., perforating, causing arrhythmia or emboli), device interference (e.g., abandoned implantable defibrillator lead), obliteration of all usable veins.

Necessary indications mean that leads should be removed. Necessary conditions are those in which lead extraction would correct a problem or prevent a life-threatening situation from developing, but the existing problem is not considered life-threatening like pocket infection, chronic draining sinus, erosion, vein thrombosis, lead migration (not presently causing life-threatening conditions), potential device interference, lead replacement (e.g., supernumerary, extract and implant thrombosed vein).

Discretionary indications mean that leads could be removed. Discretionary conditions are those in which it is preferable to remove the leads but in which it would rarely be considered a medical necessity like pain, malignancy, lead replacement (e.g., abandoned lead for < 3 to 4 years).

Today there is a consensus opinion on the treatment of pacemaker/ICD infection (local and systemic): it is the complete removal of the entire stimulating/defibrillating system together with prolonged antibiotic therapy (from 2 to 12 weeks).

In 2000 a NASPE Policy Conference was held which established indications, facilities and training for transvenous extraction of chronically implanted leads[5]. The indications were categorized as follows:

• class I (conditions for which there is general agreement that leads should be extracted):

a) sepsis (including endocarditis) as a result of documented infection of any intravascular part of the pacing system, or as a result of a pacemaker pocket infection when the intravascular portion of the lead system cannot be aseptically separated from the pocket;

b) life-threatening arrhythmias secondary to a retained lead fragment;

c) a retained lead, lead fragment, or extraction hardware that poses an immediate or imminent physical threat to the patient;

d) clinically significant thromboembolic events caused by a retained lead or lead fragment;

e) obliteration or occlusion of all useable veins, with the need to implant a new transvenous pacing system;

f) a lead that interferes with the operation of another implanted device (e.g., pacemaker or defibrillator);

• class 2 (conditions for which leads are often extracted, but there is divergence of opinion with respect to the benefit vs risk of extraction):

a) localized pocket infection, erosion, or chronic draining sinus that does not involve the transvenous portion of the lead system, when the lead can be cut through a clean incision that is totally separate from the infected area;

b) an occult infection for which no source can be found, and for which the pacing system is suspected;

c) chronic pain at the pocket or lead insertion site that causes significant discomfort for the patient, is not manageable by medical or surgical technique without lead extraction, and for which there is no acceptable alternative;

d) a lead that, due to its design or failure, may pose a threat to the patient, though not immediate or imminent if left in place;

e) a lead that interferes with the treatment of a malignancy;

f) a traumatic injury to the entry site of the lead for which the lead may interfere with reconstruction of the site;

g) leads preventing access to the venous circulation for newly required implantable devices;

h) non-functional leads in a young patient;

• class 3 (conditions for which there is general agreement that lead extraction is unnecessary):

a) any situation where the risk posed by lead extraction is significantly higher than the benefit;

b) a single non-functional transvenous lead in an elderly patient;

c) any normally functioning lead that may be reused at the time of pulse generator replacement, provided that the lead has a reliable performance history.

Transvenous techniques for lead extraction

The difficulty of transvenous lead extraction procedures is the presence of tight adherence above the lead all over the venous tree and inside the heart (Fig. 1).

Up to date the most extensive experiences have been performed by the use of mechanical sheaths and powered sheaths.

Mechanical sheath dissection was introduced in clinical practice by Byrd in the late '80s[6]. The most widely used extraction system is provided by Cook Vascular Inc. This system is provided with locking stylets and dilator sheaths; they are used as a first choice when the proximal end of the lead is exposed (superior approach). The technique in case of superior approach consists of a combination of traction by the locking stylet, mechanical dilation of adherences by the dilating sheaths and countertraction at the tip of the lead by the outer telescopic sheaths. A transvenous workstation with a tip deflecting wire, Dormier basket and loop retriever is the tool of choice in case of total-

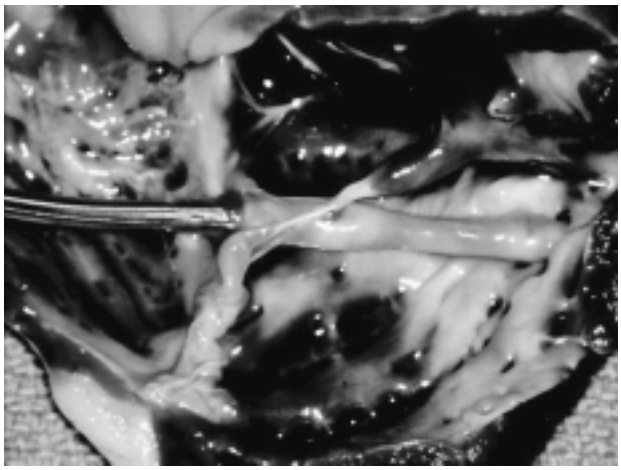

Figure 1. *Autopsy finding of intracardiac adherence above a ventricular pacing lead.*

ly intravascular leads (inferior approach). The most recent results of the US Extraction Database were reported for 6420 leads in 4090 patients[7]; 93% of leads were completely extracted, 5% were partially extracted, and 2% were not removed. Major complications occurred in 1.6% of patients, including a 0.2% mortality rate.

The VascoExtor system by VascoMed consists of a locking stylet equipped with a remote control anchoring mechanism at the tip. A rotating motor can be applied to the stylet in order to facilitate the advancement or the withdrawal of the stylet; the system can be used on a wide range of coil lumen dimensions. A dilator sheath and a transfemoral workstation equipped with a snare-loop catheter for intravascular lead extraction are also available. In a multicenter European study[8], removal attempts were made for 150 leads. Complete extraction was possible in 122 cases (81%), partial removal was possible in 18 cases (12%), and failure to remove the lead in 10 cases (7%). There were no serious complications associated with the procedure. None of the patients died.

Powered sheath techniques were developed in the '90s using a source of energy (excimer laser, radiofrequency) to make dissection of binding sites easier and faster.

Laser energy is delivered at the edge of a special sheath; the circumferential zone of optic fibers at the end of the sheath delivers a 308-nm laser beam that is effective for about 1 mm. In an ideal situation, the sheath is passed over the lead, vaporizing each binding site until the sheath reaches a point about a few millimeters from the heart wall. The lead is then removed from the heart wall using countertraction.

A recent paper reported the US experience with laser sheaths[9]; 2561 pacing and defibrillator leads were treated in 1684 patients at 89 sites in the United States. Of the leads, 90% were completely removed, 3% were partially removed, and the balance were failures. Major perioperative complications (tamponade, hemothorax, pulmonary embolism, lead migration, and death) were observed in 1.9% of patients with in-hospital death in 13 (0.8%). Minor complications were observed in an additional 1.4% of patients. In the European multicenter experience[10], 179 leads in 149 patients were extracted in 11 centers. Complete extraction was achieved in 89.5% of the leads, 6% were partially extracted and 4.5% of the extractions failed. Complications were few but included one ventricular perforation that did not need surgery; two other perforations were related to lead reimplantation and required surgery.

Radiofrequency energy powers the electrosurgical sheaths which are used to ablate the encapsulating fibrous tissue in a manner similar to the laser sheath method. The electrosurgical sheath works as a bipolar electrosurgical cutting instrument, similar to the conventional devices used for hemostasis and cutting. The electrical arc placed at the tip of the sheath cuts the fibrous tissue. An outer sheath is used as a workstation and for counterpressure and countertraction. This technique is to date under clinical evaluation in the United States; early reports showed effectiveness and safety similar to mechanical and laser extraction.

Though the results of mechanical and powered sheath techniques are similar, the duration of the procedures and, consequently, the radiation exposure are shorter using powered sheaths; on the other hand, the use of powered techniques is more expensive. In the next future the cost/benefit ratio of both techniques will require a careful evaluation; probably most procedures could be performed by mechanical techniques while powered sheath techniques should be reserved for selected difficult cases.

Technological advances in transvenous lead extraction can be achieved by modifying the techniques and the approaches as well as improving the materials.

In our personal experience[11,12] and in many reports[13] it was observed that the success rate of removal was strongly affected by the presence of free-floating leads, calcified scar tissue or the impossibility of advancing a stylet into the lead. In the presence of these factors, an approach through the right internal jugular vein presents some advantages. Most of free-floating leads can be exposed via the jugular approach and thus they can be submitted to a standard procedure for exposed leads. In addition the straight course of the lead from the jugular vein to the right atrium or ventricle allows the dilation along the longitudinal axis of the lead, allowing an easier dilation and countertraction. These conditions appeared to increase the effectiveness of mechanical dilation and to reduce the risk of complications. According to these observations we developed a jugular approach (lead extraction from the internal jugular vein) for free-floating and difficult exposed leads[14] (Figs. 2 and 3).

Finally, another recent technological improvement in the field of transvenous extraction is the use of intracardiac echography (ICE), performed using

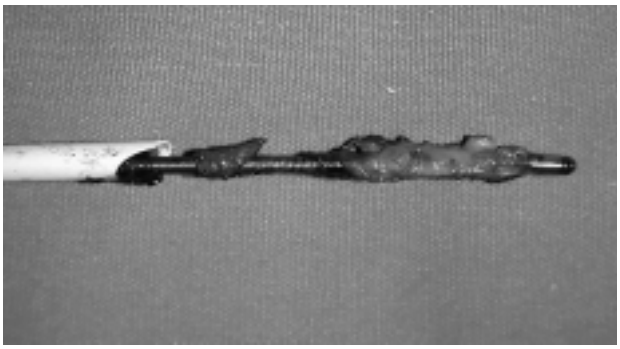

Figure 2. *Mechanical dilator with inside a pacing lead extracted from the internal jugular vein.*

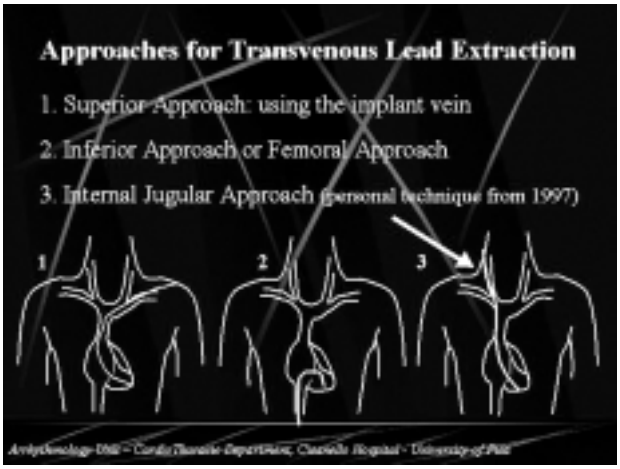

Figure 3. *Approaches used for transvenous lead extraction.*

catheters equipped with an echo-transducer at the tip. The use of ICE during transvenous extraction procedures allows to determine the relationships between leads and most anatomical structures better than fluoroscopy; it can be very useful either to detect the presence of vegetations and their outcome during dilation, or to monitor the possible occurrence of complications. However, because of the costs, the need of an additional venous puncture and a dedicated operator, we may suppose a great utility of ICE in selected cases, such as: difficult leads, multiple leads, suspicion of vegetations, old leads, free-floating leads[15].

Lead extraction: personal experience

We have been performing lead extraction since 1989. Since 1997 we have been using a personal method characterized by: 1) single progressive sheath with mechanical dilation (Cook Vascular Inc.); 2) ICE in case of systemic infections and patients with fever to assess the presence and size of vegetations and their relation with the cardiac structures; 3) a personal technique using an approach through the internal jugular vein in case of free-floating leads or when the removal through the implant vein is not possible (difficult exposed leads).

Since 1997 we managed 787 patients (592 males, 195 females, mean age 65.0 years, range 6-95 years) with 1330 leads (mean pacing period 68.0 months, range 1-336 months). Pacing leads (PL) were 1192 and defibrillating leads (DL) were 138. Ventricular leads were 828, 465 were atrial, 12 superior vena cava leads, and 25 coronary sinus leads (Table I).

Indications for removal were class I in 34.22% (455 leads) and class II in 65.78% (875 leads) of the leads. We performed mechanical dilation using the Cook Vascular extraction kit and, if necessary, other intravascular tools (Catchers and Lassos, Osypka). Since 1996 we developed a new approach using the internal jugular vein in case of free-floating leads or when the removal through the implant vein is not possible (difficult exposed leads).

Transvenous removal was attempted in 1330 leads; 1137 were successfully extracted with the standard mechanical approach (success rate 85.4%); 12 leads underwent partial extraction (0.9%). In 1 case (0.07%) the transvenous lead extraction technique was inapplicable. The jugular approach was performed in 180 leads (164 PL and 16 DL): 39 were intravascular free-floating leads (38 PL and 1 DL) and 141 were difficult exposed leads (126 PL and 15 DL) allowing the removal of 178/180 (98.8%). After this approach the final results were: total extraction 98.88%, partial extraction 0.90%, unextracted 0.15%, and not applicable 0.07% (Fig. 4).

Major complications occurred in 4 cases (0.3%) and were cardiac tamponade (2 underwent successful pericardiocentesis, 1 surgical repair, and 1 patient died). No complications were directly related to the jugular approach.

A particular subgroup with a 100% success rate and no major complications is represented by DL: from 1994, 128 consecutive patients having 155 leads were referred to our institution with an indication for ICD lead removal. In 22 patients (17%) a previous unsuccessful extraction was attempted. The mean implant period of the leads was 43.9 months (range 2-144 months). We removed completely all the 155 leads

Table I. Patient and lead characteristics.

No. patients	787
Age (years)	65.0
Sex (M/F)	592/195
No. leads	1330
Pacing period (months)	68
Pacing leads/defibrillating leads	1192/138
Location of leads	
Atrial	465
Ventricular	828
Superior vena cava	12
Coronary sinus	25
Exposed/intravascular	1261/69

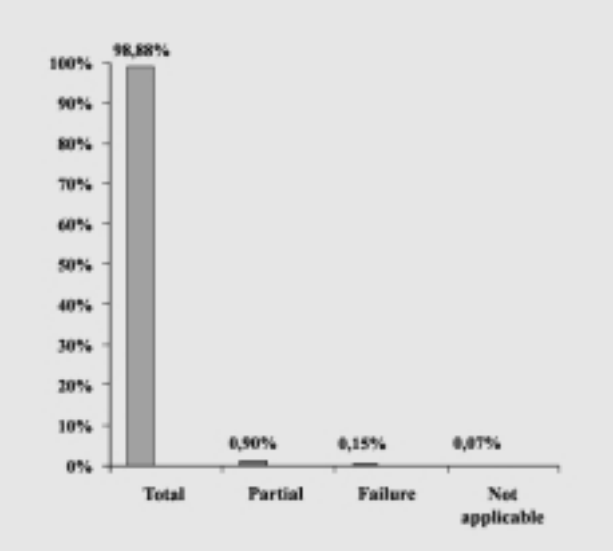

Figure 4. *Success rate.*

(success rate 100%) and no major complications were observed. With the standard procedure, using mechanical dilation, we removed 137 leads (88.4%). By crossovering to the internal transjugular approach we extracted the other 18 leads (11.6%) reaching the complete success in 100% of patients (lead extraction and clinical benefit).

Since 1999, we apply ICE in selected cases of extraction procedures. We use a 9F/9 MHz catheter (Ultra ICE™, Boston Scientific Corp., San José, CA, USA), which is a "direct view" mechanical ultrasound catheter with a rotating transducer mounted on the tip, connected to the motor unit through a flexible drive shaft. The piezo-electric transducer is constructed with a special angle, allowing an optimal scanning of the surrounding structures. At the tip of the catheter, a filling port is used to fill the space around the piezo-electric transducer with distilled water, because the ultrasound waves are not well transmitted in the air. It provides a 360° and a 4 cm depth penetrating two-dimensional image, perpendicular to the transducer and, therefore, the shaft of the catheter. The images are viewed in real time and recorded on S-VHS videotape by connecting the catheter to the Clearview Ultra™ console (Boston Scientific Corp.).

The ICE catheter is introduced into the right femoral vein using the 10F braided soft tip sheath and dilator kit (Boston Scientific Corp.), designed to support the catheter positioning in specific locations of the heart and the vascular system. The catheter is advanced along the sheath to study most of the lead course from the superior vein system to the right ventricle.

ICE is very useful during extraction procedures, giving important information and allowing to monitor possible complications. In our experience ICE resulted superior to transesophageal echocardiography in easiness and in site and size evaluation of the vegetations.

Conclusions

Managing pacemakers/ICD-related complications covers a spectrum of knowledge and techniques. When a malfunction or infection is present the solution may range from replacement of devices and repositioning or insertion of a new lead to the extraction of the leads. Some of these procedures have the potential for tearing the heart and veins, precipitating a life-threatening complication.

Transvenous lead extraction is an effective and safe procedure. The success rate and incidence of complications are highly affected by the staff experience. The use of the jugular approach, in the presence of free-floating or difficult exposed leads, increases both safety and success rate.

The use of ICE is very helpful and effective in the diagnosis of vegetations, in guiding the procedure and monitoring the possible complications. ICE in extraction procedures is mandatory in case of septicemia or any suspicion of possible vegetations and it is useful also in the presence of multiple, long-lasting and free-floating leads.

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