Original Research

Transvenous Extraction of Cardiac Rhythm Device Leads: A Report of the Experience from a Single Referral Centre in Greece

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Introduction: As rates of implanted cardiac electronic devices continue to rise, lead extraction procedures are crucial for the management of complications. The optimal method for such procedures has been constantly debated. We sought to review our experience of lead extraction using a conventional technique.

Methods: This was a retrospective study of lead extraction procedures in a major referral centre in Greece. Leads were extracted in a series of 66 consecutive patients (69% men, age range 53-90 years) who visited our centre between August 2008 and June 2012. The extraction procedure was performed in the catheterization lab with a widely used system composed of a locking stylet and sheath.

Results: A total of 120 leads were extracted (51 atrial, 69 ventricular) including 19 defibrillator leads and 9 coronary sinus leads. The most frequent indication for lead extraction was infective endocarditis (28 patients, 42%), followed by generator pocket infection (22 patients, 33%), and lead malfunction (16 patients, 24%). Extraction was achieved through the venous entry-site approach in all procedures. The leads were completely extracted in 65 patients (98.5%). Only one complication was recorded: perforation of the right atrium in one patient (1.5%), who eventually underwent emergency cardiac surgery with a good outcome.

Conclusions: Our data confirm that a conventional mechanical technique is highly effective for successful extraction of all types of implanted cardiac electronic device leads and is associated with very limited complications.

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As the numbers of cardiac implantable electronic devices (CIED) continue to rise worldwide, lead extraction has become a critical procedure in managing device-related complications. Lead removal is the main treatment approach in cases of lead failure or infection, as well as in order to upgrade to new technology.[1,2] During the past two decades, the field of CIED lead extraction has expanded from the use of rudimentary kits delivering simple traction, to the use of complex telescoping sheaths, excimer laser, or radiofrequency energy designed to disrupt adhesions.[3,4] Despite these continuous advances in lead extraction technology, such procedures continue to be associated with considerable morbidity and mortality, while the more recently introduced techniques are available in only a few centres. Furthermore, the benefits of powered sheaths over conventional mechanical extraction tools with respect to success rates and cost-effectiveness have been questioned.[5,6]

Several studies from high-volume

centres have shown that lead extraction, employing various methods, can now be performed with high success and low complication rates. A long lead implantation time and a lack of operator experience have often been associated with extraction failure. Lead extraction is fully reimbursed in Greece and has been since its first clinical introduction in the early 1990s. The aim of the present study was to share our experience in removing pacemaker and implantable cardioverter defibrillator (ICD) leads using the Cook extraction system (Cook Medical Incorporated, IN, USA).

Methods

Study design and population

This was a retrospective, single-centre study that was performed in the Hippokration General Hospital of Athens, which is a major referral centre for lead extraction, managing patients referred from all over Greece. The study population consisted of consecutive patients who underwent lead extraction between August 2008 and June 2012. Collected data regarding patients' clinical characteristics, implanted devices, and the extraction procedure were analysed. Most patients (65%) had received their devices from Hippokration General Hospital services and this was the first extraction procedure for all patients. Over the 4 years of the study, the rate of extraction procedures increased continuously. The Heart Rhythm Society's (HRS) recommendations were generally adhered to.[2]

Our definitions of endpoints were based on the intention-to-treat analysis. Assessment of the success of the procedure was performed with radiographic evaluation. In accordance with the guidelines, clinical procedural success was defined as removing all leads and lead material, or as much of the lead as necessary to treat the indicated condition successfully. Total lead removal, including the lead tip, was needed to qualify for clinical success in HRS Class I indication cases. Clinical success would not be achieved if a non-functional or recalled lead was not totally removed (the intention being total removal). A failure was recorded when clinical success was not achieved or with the development of a major complication. Complications were defined as major or minor and were scored according to the HRS recommendations.

Extraction procedure

Our system is composed of the Liberator® Beacon® Tip, locking stylet (Cook Medical), and the Byrd Dilator Telescoping polypropylene sheaths that pass over the electrode to separate the fibrous tissue between the electrodes and the structures of the heart and vessels. All patients provided informed consent. The extraction procedures were performed in the catheterisation-electrophysiology laboratory, under sedation and continuous invasive arterial pressure and pulse oximetry monitoring, while an anaesthesiologist was continuously present and cardiothoracic surgery was readily available. Each extraction procedure was performed by a senior interventional electrophysiologist, accompanied by one of two available trained assistant operators. In cases of pacemaker dependency, temporary pacing was applied.

The same procedure stages were followed for all patients, with small deviations when needed. First, the generator pocket was opened and the device was removed, along with any skin corrosion and inflammatory or necrotic tissue. Then, the electrode was freed from the scar tissue that develops around the pacemaker and pacemaker pocket. The electrodes were then cut from the connector down to about 10 cm from the venous entry site and a locking stylet was passed as close as possible to the tip of the electrode—bypassing most of the conductor and insulation—where it was locked by rotating a lever counterclockwise. Polypropylene telescoping sheaths were used to break up fibrous adhesions to the vascular wall and to yield countertraction at the endocardial surface, while stable traction of the locking stylet was maintained. The sheath was advanced within the vessel until it reached the endocardial surface, or until traction of the stylet alone was sufficient to release the lead from the endocardial surface and vascular adhesions. Movements were carefully coordinated in order to avoid injury to the vessel, and especially to the superior *vena cava*. The tips of the removed leads and the pacemaker case were sent for cultures.

Results

A series of 66 consecutive patients underwent extraction procedures for transvenous removal of 120 leads. The patients' characteristics are summarised in Table 1. Patients were predominantly male (69%) and their age ranged from 53 to 90 years. Only one patient had had two previous pacemaker implantation proce-

Table 1. Patient and lead characteristics (n=66).

Men, n (%)	46 (69)
Mean age, years	64 ± 12 (53-90)
Mean extraction time after 1st implantation, months	62 ± 71 (3-375)
Implanted device, n (%):	
Single-chamber pacemaker	13 (20)
Dual-chamber pacemaker	32 (48)
Biventricular pacemaker	2 (3)
Single-chamber ICD	2 (3)
Dual-chamber ICD	10 (15)
Biventricular ICD	7 (11)
Cardiac leads per patient, n (%):	
One	15 (23)
Two	48 (72)
Three	3 (5)
Pacemaker dependency	18 (27)
Positive blood cultures	35 (53)

Data are given as mean ± SD or as absolute number (percent).

Table 2. Pathogen isolation and selected antibiotic treatment in cases with positive blood cultures.

Pathogen:	n (%)
Staphylococcus epidermidis	25 (71)
Staphylococcus aureus	6 (17)
Candida albicans	2 (6)
Enterococcus faecalis	2 (6)
Antibiotic:	
Vancomycin	17 (48)
Rifampin	15 (43)
Linezolid	6 (17)
Gentamicin	1 (3)
Ampicillin/sulbactam	1 (3)

dures: the first pacemaker system was removed because of infection, but three months after the second device implantation a new infection developed. The remaining patients had had only one implantation procedure. The mean time from initial implantation to extraction was 62 months (range 3-375 months).

In the majority of our patients, the clinical indication for the removal procedure was infection. Specifically, the most frequent indication for lead extraction was infective endocarditis in 28 patients (42%), followed by generator pocket infection in 22 (33%), and lead malfunction in 16 patients (24%). There were 35 cases with positive blood or electrode tip cultures that were treated accordingly with antibiotics (Table 2). In cases with negative cultures, empirical antibiotic treatment was applied.

Forty-seven (71%) patients underwent extraction of permanent pacemaker leads and 19 (29%) underwent extraction of dual-coil ICD leads. The leads removed were 51 atrial leads (42.5%) and 69 ventricular leads (57.5%), including 19 defibrillator leads (15.8%) and 9 coronary sinus leads (7.5%). A total of 28 leads were passively fixed and 80 leads were actively fixed. Extraction was achieved by means of the venous entry-site approach in all procedures: specifically, the cephalic vein in 48 procedures and the subclavian vein in 18 procedures. The procedure time ranged from 22 to 67 minutes and the radiation time from 6 to 18 minutes.

The leads were completely extracted in 65 (98.5%) of 66 patients. In one case we failed to remove the electrodes and surgical removal was performed. In this patient the initial implantation was 20 years before, and the tip of the electrode could not be removed because of significant fibrosis within the myocardium. The number of extractions due to infection was greater in the cases that had previously already undergone battery replacement than in those that had not (52% vs. 48%).

Only one complication was recorded: perforation of the right atrium in the above mentioned patient (1.5%), who eventually underwent emergency cardiac surgery with a good outcome. In our patients there were no damaged lead electrodes at all. In two pacemaker-dependent patients, an active electrode was introduced through the external jugular vein, placed at the apex of the right ventricle and connected to a bipolar pacemaker stabilised on the neck. In three cases a permanent epicardial rather than an intravenous temporary pacemaker was placed, because patients were pacemaker dependent but had vegetations on the tricuspid valve.

Discussion

In the present study we report our experience of lead extraction, as documented in a high-volume reference centre in Greece. High success rates have been achieved in a variety of clinical cases using conventional extraction techniques. We were able to completely extract leads in 98.5% of patients. Our data support previous evidence that the operators' experience and the volume of procedures are critical factors that are associated with the success rates of extraction procedures.[7-9] Our institution is developing into a major referral centre for such procedures and our operators consist of one senior electrophysiologist and two assistant electrophysiologists who have been adequately trained in the aforementioned conventional technique. Moreover, the number of procedures in-

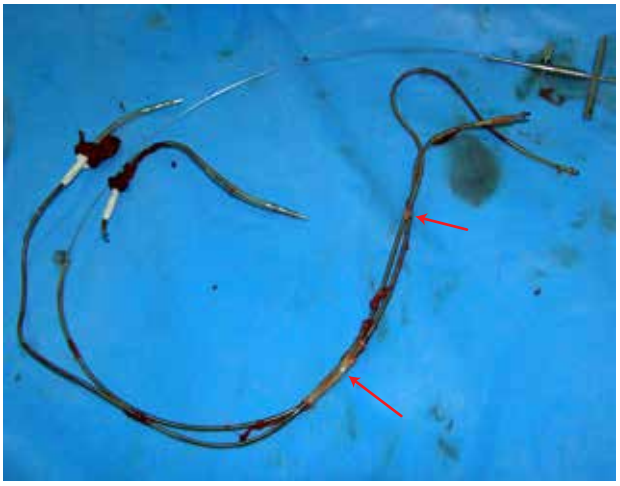

Figure 1. Extracted electrodes with fibrotic adhesions (arrows) in one of our cases.

creased during the observation time – a finding concordant with the increasing rates of device implantation in Greece.

Our data agree with those of other reports that found a widely used tool, such as the Cook extraction system, to be an effective means for extraction procedures, even since the introduction of newer technologies.[5,7,9-11] Applying traction force to the proximal end of the lead has been the earliest and simplest approach to lead extraction, especially in leads that are less than 6 months old. With increasing age of the lead and development of fibrosis around the lead body and between leads, traction alone may not suffice. The strength of the adhesion, the tensile strength of the fibrous tissue, and the tensile strength of the vessel or cardiac wall should further be considered when planning the extraction technique, which may accordingly involve the use of telescoping dilatation, powered sheaths, or a femoral approach. In our series, even in the complex cases (very long implantation time, extensive fibrosis, and multiple leads), the Cook extraction system was successful, with very few complications.

In our centre, a conventional extraction set is used consistently. Currently, a series of techniques that involve application of laser, radiofrequency energy, or other cutting technologies have been endorsed as possibly more effective compared to mechanical-only means.[12] Still, reports have shown that the use of laser extraction sheaths is not associated with notably higher rates of complete extraction compared to conventional methods.[13] Furthermore, analysis of international registry data has shown that the laser extraction technique, along with lead age, female sex, and defibrillator lead removal, were the main predictors for major complications.[14] In any case, our results are comparable in terms of success rates and complications with those of previous reports in which conventional or powered kits were used.[6,15] It is widely accepted that good training, a high extraction volume, and a well-organised multi-disciplinary team with immediately available surgical support are just as important as the use of a specific extraction method; in our centre we strive meticulously to maintain such standards.[16]

The procedure was partially unsuccessful in one patient, in whom we failed to remove the right atrial electrode of a dual-chamber pacemaker and who finally underwent surgical removal. In this case, the initial implantation had taken place 20 years before and the tip of the electrode could not be removed because of marked fibrosis in the myocardium. The association of unsuccessful lead extraction with a long implantation time has been consistently demonstrated.[7] Nevertheless, we cannot rule out the possibility that the use of a powered sheath might have been more successful in this case of an old and fibrotic lead.

The most common reason for lead removal in our patients was infection. Indeed, infections of CIEDs are the strongest indication for complete CIED system removal.[2,17] Infection may be obvious, presenting with fever, vegetations and sepsis, or insidious, with the patient complaining only of pain in the CIED pocket. Nevertheless, when an infection is identified, this denotes a strong indication for removal of all components of the CIED system, including the device, leads and caps and as much of the infected tissue as possible. In our series, 35 patients presented with positive blood cultures. It is recommended that when blood cultures obtained on different days are consistently positive, even when there is no clear source, transvenous lead extraction should be strongly considered. However, even in patients with documented device-related infection, cultures can be negative, irrespectively of preoperative antibiotic therapy. With respect to antibiotic treatment, although there are limited data on the minimal duration of therapy and when it is appropriate to switch from IV to PO antibiotics, there is now significant experience from using guidelines similar to those for non CIED-related endocarditis. Regarding cases with vegetations, optimal management when these are of a large size (usually greater than 3 cm) is debatable, with some advocating

a surgical approach and others supporting percutaneous lead extraction.[18]

Although lead extraction has developed to be both a safe and efficacious procedure, complications, occasionally life-threatening, are known to occur. In one of our patients, corresponding to 1.5% of the cohort, earnest attempts led to perforation of the right atrium, and eventually this patient underwent emergency cardiac surgery without further complications. Similar incidences of major complications have been reported in conventional and laser extraction registries.

Non-standard leads, such as ICD or coronary sinus leads, can prove a particular challenge, although the same tools and techniques are used as for standard pacemaker leads.[19,20] Regarding ICD leads, extractions are usually more complex and prolonged than in the case of standard leads, because the diameter of ICD leads is larger and defibrillator coils trigger more fibrosis. Long-standing implanted dual coil ICD leads, in particular, are very challenging, as the proximal externalised coil generates additional adhesions at the level of the superior *vena cava*, further enhancing the risk of venous tear during extraction. Nevertheless, in the 19 cases (29%) in which ICD extraction was performed, the procedure was completed successfully.

Our study has, however, several limitations that should be considered. This was a retrospective analysis and therefore it may be possible that clinical events were underreported. However, our institution has a strict policy for the recording of major events and our results resemble those previously reported. We present data on extractions with a conventional technique and have no group of patients who underwent extraction with a powered sheath to compare, but operators were adequately trained for this method, as indicated in current recommendations. The number of extraction procedures during the designated period may not have reached that of other reports; nevertheless, success rates were similar, perhaps as a result of strict compliance with current guidelines.

Conclusions

Extraction procedures for CIED leads require a well-organised and well-trained multidisciplinary team in order to ensure optimal results in terms of removal success and avoidance of complications. Even though developing technology continuously offers new methods, standard conventional techniques remain highly efficient when practice recommendations are carefully followed.

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