



Implantable defibrillator lead extraction with optimized standard extraction techniques

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Abstract

Background Implantable cardioverter-defibrillator (ICD) leads might not be extracted especially in developing countries because of the high cost and lack of specialized tools. We aimed to evaluate transvenous extraction of ICD leads using optimized standard techniques. **Methods** We prospectively analyzed clinical characteristics, optimized extraction techniques and the feasibility of extraction for 40 patients (33 males; mean age 47.9 ± 16.1 years) with 42 ICD leads. **Results** Complete procedural success rate was 95.2% (40/42), and the clinical success rate was 97.6% (41/42). One ICD lead required cardiothoracic surgery. Minor complications occurred in three cases (7.5%), and no major complications or death occurred. Locking stylets were used to extract most leads (34, 81.0%) and almost half of the leads (20, 47.6%) required mechanical dilatation to free fibrotic adhesions; these leads had been implanted for a longer period of time than the others (43.7 ± 18.2 vs. 18.4 ± 13.4 months, $P < 0.05$). Three-quarters of the leads (30, 71.4%) were extracted with locking stylets plus manual traction (12, 28.6%), or mechanical dilatation with counter-traction (18, 42.8%) by the superior vena cava approach and one-quarter of the leads (11, 26.2%) were removed by optimized snare techniques using the femoral vein approach. Median extraction time was 20 min (range 2–68 min) per lead. Linear regression analysis showed that the extraction time was significantly correlated with implant duration ($r = 0.70$, $P < 0.001$). Median follow-up was 14.5 months (range 1–58 months), no infection, or procedure-related death occurred in our series. **Conclusions** Our optimized procedure for transvenous extraction of ICD leads provides a practical and low-cost method for standard procedures.

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1 Introduction

The use of implantable cardioverter-defibrillator (ICD) leads has been exponentially increasing, and ICD lead extraction has become a necessary procedure. But ICD lead extraction has potentially serious complications, including venous or myocardial tear, cardiac tamponade, and even death.^[1] Powered sheaths, such as Excimer laser or a radiofrequency system, have been used for extraction of ICD or pacemaker leads.^[2,3] However, the Heart Rhythm Society (HRS) has stated that “possible predictors of major

complications were implant duration of the oldest lead, female gender, ICD lead removal, and use of the laser extraction technique, multiple leads, and calcified leads.”^[4,5] Consequently, use of powered sheaths may not be optimal.

In addition, powered sheath systems are not available in many countries, especially in developing countries such as China. Furthermore, the high cost prevents their widespread use. To investigate ICD lead extraction in China, we explored the feasibility of transvenous extraction of ICD leads by optimized standard techniques. In our practice, traditional traction, mechanical dilatation, counter-traction, and our innovative extraction methods were synergistic and optimized to dissociate and extract leads, or lead fragments, and may be useful and low cost for clinical practice.

2 Methods

2.1 Patients

Extraction indications were HRS class I and IIa indica-

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tions: infection with a cardiovascular implantable electronic device (CIED) system or CIED pocket; valvular endocarditis without definite involvement of the lead(s) and/or device; occult Gram-positive bacteremia; and lead malfunction. Exclusion criteria were HRS class III indications.^[4,5] The study was approved by the audit department and Research Ethics Committee of Peking University People's Hospital. All subjects gave their informed consent, and patient anonymity has been preserved.

From January 2006 to July 2012, more than 580 leads were extracted from 280 patients in our center. Leads were extracted because of infection or lead malfunction. There were 40 patients with ICD leads, and data collected included patient demographics, type of device and leads, co-morbidities, reason for extraction, procedural information and complications, re-implantation, and outcome.

2.2 Definitions

Lead extraction, complete procedural success, clinical success, failure, and complications were defined according to the HRS recommendation. Complete procedural success was defined as removal of all targeted leads and lead material from the vascular space, with the absence of any permanently disabling complication or procedure-related death. Clinical success was defined as removal of all targeted leads and lead material from the vascular space, or retention of a small portion of the lead that does not negatively impact the outcome goals of the procedure. Implant duration was the time between initial lead implantation to the time of extraction. Lead extraction time was duration from the time when the head of the lead was cut off to the time of complete removal. Device-related infective endocarditis was defined according to the modified Duke criteria.^[6] Intracardiac vegetation was defined as a discrete, echogenic, oscillating mass found on a valve, lead, or endocardial surface and confirmed in multiple views by echocardiography.^[5-8]

2.3 Current protocol

To prevent the potential risk of septic embolization, pre-operative trans-esophageal echocardiography (TEE) was applied to stratify patients according to risk. Patients with infection and intracardiac vegetation represented a high-risk population with multiple co-morbidities and significantly higher mortality rate regardless of management strategy.^[9] Pacemaker dependency was checked for each patient before lead removal, and temporary pacing was used when needed. After extraction, all patients underwent TEE before device reimplantation. Patients with infection received serial blood cultures and intravenous antibiotic therapy.^[5-8]

2.4 Optimized standard techniques

Strategies were chosen in a step-wise fashion. The superior vena cava approach was preferred. First, the ICD lead was dissected, then manual traction was attempted, and the location of the binding tissue and adhesion extent along the lead was estimated by X-ray. Second, if lead removal failed, the lead was cut off, and a proper-sized locking stylet (Liberator Locking Stylet, Cook Medical, USA) was inserted along the lumen and locked at the distal part of the lead, then manual traction was attempted again. Third, if traction alone was still unsuccessful because of adherent fibrotic tissue, a telescoping dilator polypropylene sheath (LR-PPLBES, Byrd Dilator Sheath Set, Cook Medical, USA) was inserted along the lead to disrupt fibrotic attachments until the lead was free of all binding tissue. Then, the sheath was connected to the endocardium, and counter-traction was used to remove the lead.

If the lead was not accessible from the venous entry, the optimized snare methods by the femoral vein approach were applied. A used and disinfected ablation catheter was typically applied to stretch leads to dissociate them from the vascular wall, endocardium, and/or valve. In some cases, if the lead floated in the right-ventricular and/or pulmonary artery, an ablation catheter was manipulated to and stretch the lead into the right atrium or vena cava. Then, a Gooseneck Snare (Amplatz, USA) was inserted through a 6F Judkin right coronary catheter (Cordis, USA) to grasp and remove the lead or lead fragments. An ablation catheter could be used with the Byrd Workstation Retrieval Set, Dotter Basket Snare and Tip-Deflecting Guide Wire (Cook Medical, USA) to snare the lead or lead fragments.

2.5 Statistical analysis

Data were presented as mean \pm SD, median (interquartile range [IQR]), and/or number and percentage. The unpaired Student's *t*-test or Mann-Whitney *U* test was used to analyze the nonparametric data. Linear regression analysis was undertaken to assess the relationship between extraction time and implant duration. All the statistical analyses were performed using SPSS 17 (SPSS Inc., Chicago, IL) and *P* < 0.05 was considered statistically significant.

3 Results

3.1 Baseline clinical characteristics

We extracted 42 ICD leads from the 40 patients (33 males; mean age 47.9 ± 16.1 years). Patient demographics, indications for extraction (Figure 1) and lead types were listed in Table 1. Before visiting our center, 29 patients with

infection had received enhanced antibiotic therapy (vancomycin, *etc.*); 21 patients with pocket infection underwent pocket debridement for one to six times without lead removal, then, the original ICD devices were reimplanted in 15 patients after disinfection. New pockets or deep burying of original ICD devices under the pectoralis was tried. One patient with infective endocarditis underwent ICD replacement in another medical center despite recurrent fever and lead vegetation; repeated high fever and positive blood culture continued after replacement. Six ICD leads had been cut off and fixed to the chest muscle, but had retracted into the heart or vasculature, over time. All attempts of conservative treatment failed.

Six patients with endocarditis have visible vegetation; two on the lead (0.8 × 0.5 cm, 0.6 × 1.0 cm), one on the lead

and tricuspid valve (1.8 × 1.4 cm), one on the lead and the superior vena cava entry (0.5 × 1.2 cm), and the other two on the tricuspid valve (1.0 × 1.6 cm, 0.5 × 1.4 cm).

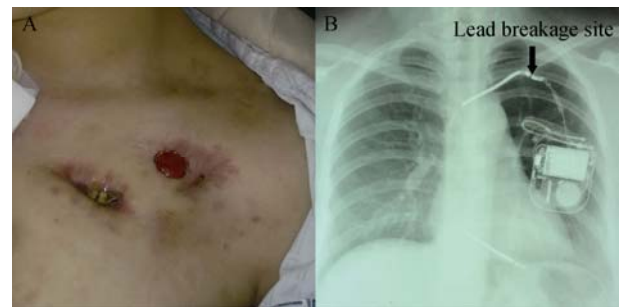


Figure 1. Extraction indications. (A): Pocket infection; (B): Lead breakage under clavicle.

Table 1. Baseline clinical characteristics of patients (n = 40) and implantable cardioverter-defibrillators (ICDs, n = 42).

Characteristics	
Male / female	33 (82.5%)/7 (17.5%)
Age, yrs (mean, range)	47.9 ± 16.1 (range 26–85)
Implantation indication	
Brugada syndrome (ICD)	17 (42.5%)
Long QT syndrome (ICD)	15 (37.5%)
Cardiomyopathy (cardiac resynchronization therapy defibrillator)	8 (20.0%)
Extraction indication	
Infection	29 (72.5%)
Pocket infection	21 (52.5%)
Endocarditis	6 (15.0%)
Gram-positive bacteremia	2 (5.0%)
Intracardiac vegetation, cm (mean ± SD)	(0.9 ± 0.4) × (1.0 ± 0.7)
Lead breakage or damage	11 ± 27.5, n = 42
Defibrillator lead	
Single-coil/dual-coil	4 (9.5%)/38 (90.5%)
Coated/non-coated lead	19 (45.2%)/23 (54.8%)
Active/passive fixation lead	6 (14.3%)/36 (85.7%)
Implant duration, months (mean ± SD, range)	32.5 ± 23.8 (2–96)

3.2 Characteristics of ICD lead extraction

We used specialized extraction equipment for all the 42 ICD leads, including locking stylets, telescoping sheaths, or femoral extraction tools (Figure 2). Locking stylets were used for 34 ICD leads (81.0%), another six leads had fractured and prolapsed into the heart before surgery, and the remaining two leads could not be inserted through by locking stylets due to the breakage. Twenty dual-coil leads (47.6%), including four coated and 16 non-coated leads, adhered to the wall of the vein, tricuspid, and/or myocardium (Figure 3) and had much longer implant duration than the other ICD leads [43.7 ± 18.2 (range 22–96) vs. 18.4 ± 13.4 (range 1–48) months, *P* < 0.05]. In these cases,

telescoping dilator sheaths and counter-traction were used to isolate the leads along the adherent strip organizations for removal. Optimized snare methods by the femoral approach were used if the lead had been cut off and retracted into the heart chamber before surgery (*n* = 6, 14.3%), or could not be removed by the superior vena cava approach (*n* = 6, 14.3%) due to large adherent tissues or disruption during surgery.

In total, complete procedural success rate was 95.2% (40/42), and the clinical success rate was 97.6% (41/42) (Figure 2). One patient required cardiothoracic surgery after failed by the transvenous approach, the 56-month lead was non-coated, passive-fixation, dual-coil, and formed

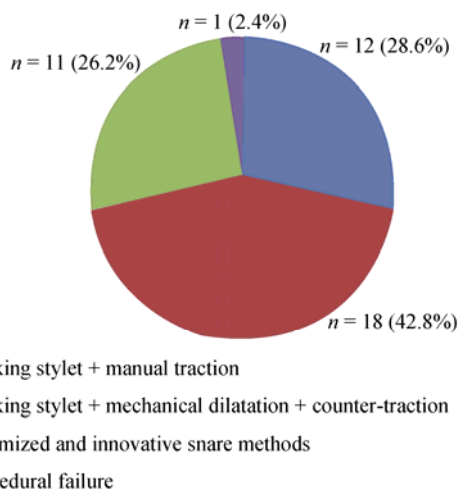


Figure 2. Implantable cardioverter-defibrillator lead-extraction characteristics (leads, $n = 42$).



Figure 3. Extracted implantable cardioverter-defibrillator lead with adhesive myocardium.

severe adhesion with the superior vena cava, and there was a vegetation on the lead and the superior vena cava entry (0.5×1.2 cm). In one patient (with a non-coated, passive-fixation, dual-coil lead for 47 months), a small portion of the lead was retained, but did not negatively affect the outcome of the procedure. In total, 30 ICD leads (71.4%) were completely extracted with the use of locking stylets plus manual traction (12, 28.6%), or mechanical dilatation plus counter-traction (18, 42.8%) by the superior vena cava approach (Figure 4). Optimized snare techniques were successfully used to remove 11 leads (26.2%) by the femoral approach (Figure 5, Figure 6). In particular, six ICD leads (14.3%) were active fixation leads (screw-in leads). After being locked with locking stylets and with some applied tension, the leads rotated counter-clockwise and were successfully removed. For five leads, the active fixed spirals have not retracted back to the end of the electrodes.

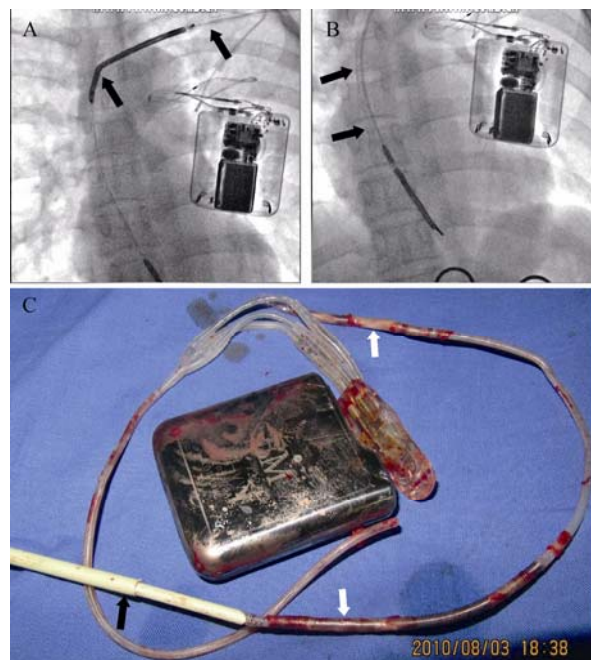


Figure 4. Superior vena cava approach. A female patient with pocket infection and dual-coil ICD lead (96 months). (A): After the lead was locked with a locking stylet, a telescoping dilator sheath (black arrow) was advanced over the lead to free adhesions (polypropylene sheath was fuzzy on X-ray); (B): The sheath was advanced and connected to the endocardium, counter-traction was applied to remove the lead; (C): Extracted ICD and fibrotically encapsulated lead (white arrow). ICD: implantable cardioverter-defibrillator.

The mean extraction time was 21.3 ± 13.9 min (range 2–68 min) (median 20.0 min, IQR 11.3–30.1 min) per ICD lead. It was significantly longer for non-coated leads ($n = 22$) than coated leads ($n = 19$) (28.1 ± 14.1 min vs. 12.6 ± 6.6 min, $P = 0.03$). The extraction time was positively correlated with implant duration ($r = 0.70$, $P < 0.001$), and did not differ significantly between 6 screw-in and 35 passive-fixation leads [22.4 ± 13.8 min (range 2–38 min) vs. 20.8 ± 15.8 min (range 3–68 min), $P > 0.05$].

3.3 Complications

We found three cases (7.5%) with minor complications. Mild pulmonary embolism occurred in a patient with vegetation (1.8×1.4 cm) on the 56-month lead and tricuspid valve. Pneumothorax occurred in one female with lead breakage (96-month duration); the dual-coil lead had solidly adhered to the superior vena cava and subclavian vein. A locking stylet and telescoping dilator sheath were used to remove the lead successfully, with lead extraction time of 20 min. The chest X-ray revealed a left pneumothorax, which cured after closed thoracic drainage. One patient

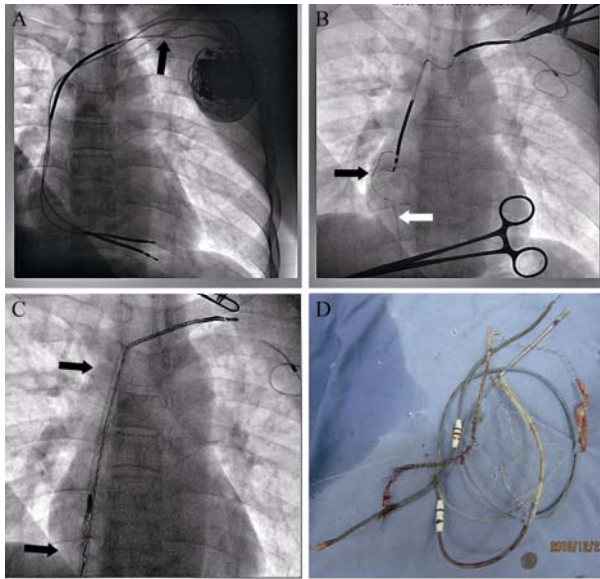


Figure 5. Superior vena cava approach and femoral vein approach (optimized snare technique). A male patient with pocket infection; one single-coil ICD lead (2 months) and one dual-coil ICD lead (breakage under clavicle, black arrow) (28 months). (A): The single-coil lead was extracted successful by use of a locking stylet by the superior vena cava approach; however, the dual-coil ICD lead could not be removed because of severe adhesion and breakage; (B & C): A Gooseneck Snare (black arrow) and a Judkin right coronary catheter (white arrow) were inserted through a long 16 F sheath (Byrd Workstation, (black arrow)) to grasp and extract the dual-coil lead; (D): The intact single-coil lead and fragments of the dual-coil lead.

(pocket infection, 60-month duration) had a small quantity of pericardial effusion after the procedure (extraction time 30 min).

3.4 Laboratory determination

Blood, pocket tissue and leads were cultured to search for infectious pathogens. For 29 patients with infection, the pathogenic organisms were *Staphylococcus aureus* (n = 12, 50.0%), *Staphylococcus epidermidis* (n = 8, 33.4%), *Staphylococcus warneri* (n = 2, 8.3%) and *Streptococcus viridians* (n = 2, 8.3%). Causative organisms for six patients with infective endocarditis were *Staphylococcus warneri* (n = 2), *Streptococcus viridians* (n = 2) and *Staphylococcus epidermidis* (n = 2). In the two patients with Gram-positive bacteremia, *Staphylococcus epidermidis* was isolated. For 21 patients with pocket infection, 16 had positive pocket tissue cultures, including *methicillin-resistant Staphylococcus aureus* in four patients, *methicillin-sensitive Staphylococcus aureus* in eight patients, and *methicillin-sensitive Staphylococcus epidermidis* in four patients. Blood cultures for all patients with pocket infection were negative. No lead fragment gave a positive result.

3.5 Clinical follow-up

The mean follow-up was 22.5 ± 18.4 months [range 1–58 months, median 14.5 months (IQR 7.3–41.8)]. Three patients died due to cardiac sudden death, heart failure, or traffic accident. Recurrent fever decreased within 24 h after extraction in patients with infection. In total, 31 patients (77.5%) underwent re-implantation with new devices during hospitalization at a median time of eight days after

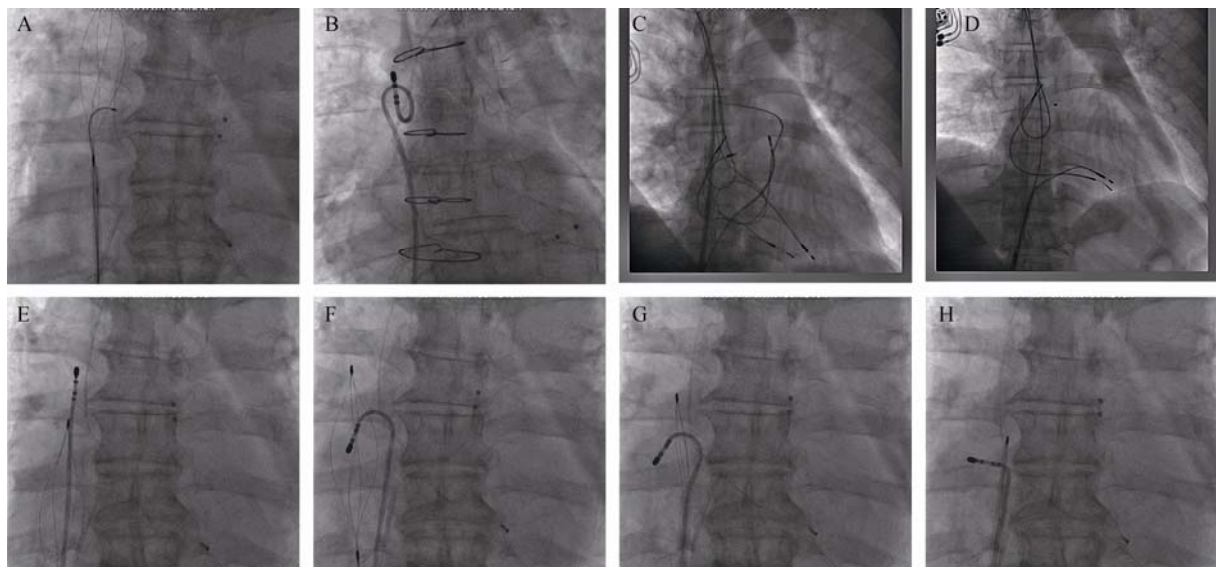


Figure 6. Optimized/innovative extraction techniques by femoral vein approach. (A): Standard snare with Dotter Basket Snare and Tip-Deflecting Guidewire; (B & C): A used and disinfected ablation catheter was adopted to twine, stretch and dissociate leads; (D-H): An ablation catheter was used with a 16 F sheath and Dotter Basket to remove leads.

extraction (range 1–22 days), including 21 with infection and 10 with lead malfunction. Twenty patients underwent contralateral re-implantation, including seventeen patients with pocket infection and three patients with endocarditis. Ten patients with lead malfunction and one patient with infective endocarditis underwent re-implantation ipsilateral to the extraction site. Antibiotic prophylaxis was administered for 3–5 days during re-implantation for uninfected patients. The remaining 11 patients did not receive re-implantation due to high cost (six patients), or severe anxiety (five patients). During follow-up, two patients (one with lead breakage, one with endocarditis) exhibited fever at six and seven months, respectively, after re-implantation on the ipsilateral side, with confirmed infective endocarditis and bacteremia (*Staphylococcus aureus* and *Staphylococcus epidermidis*). The two patients underwent successful second transvenous extraction surgery and contralateral re-implantation.

4 Discussion

Relevant clinical research about ICD lead extraction in China and many other developing countries is rare, which could be due to the limited number of implantations, lack of auxiliary tools, physician knowledge about ICD lead extraction, and also high costs. We described our single-center experience with transvenous extraction of ICD leads by optimized standard techniques.

In this study, the conservative therapy before lead extraction may partially reflect the current management of ICD infection and malfunction in China and other developing countries. In these countries, conservative treatment predominates, and most cardiac electrophysiologists are unfamiliar with ICD lead extraction. Before patients are referred for lead extraction, many interventions would generally be considered inappropriate, such as prolonged antibiotics, pocket debridement, disinfection, and re-use.

Indications for lead removal in HRS consensus include infection, chronic pain, thrombosis, or venous stenosis in functional and non-functional leads. In this study, infection (72.9%) was the major reason for extraction, which was consistent with previous research.^[5] Previous studies of CIED infection have shown that for patients with infection, conservative treatment was almost always ineffective,^[10–12] and delaying the removal of the CIED system could be lethal.^[5,7,13–15]

In the present study, ICD leads were extracted in 11 patients because of lead malfunction. For such patients, our center tended to extract leads as soon as possible. With prolonged implantation duration, extraction risks increase as

the inter-lead fibrosis thickens and covers more of the surface of the lead, especially with multiple leads. Lead fragility is also proportional to implant duration, which reduces the likelihood of complete lead removal. Therefore, in relatively young patients, implanting new leads without extracting the old ones is usually inadvisable. Alternatively, in older patients with one failed lead or an occluded vessel, conservative treatment may be advisable. Old and new leads together may lead to interference of ICD diagnostic function and may affect defibrillation because of “noise”.^[16,17] In addition, abandoned leads may lead to fatal arrhythmias and increase the chance of infection.^[10,11,18]

ICD leads have special characteristics, with lead extraction risk greater than general pacemaker leads. ICD lead extraction often requires specialized devices and sometimes electrosurgical sheaths or laser sheaths.^[3,19,20]

In our practice, a step-by-step selection of different extraction techniques is routine. The auxiliary tools we used were all available currently in China. When using telescoping dilator sheaths, the dilator sheath must stay “in line” with the lead at all times. If the sheath seems to be moving off-axis, it must be immediately retracted and then carefully advanced again from a different angle, or with more traction on the lead to guide the sheath to the right direction. Then the sheath is advanced to a point within millimeters of the heart wall, with counter-traction used to remove the lead. A key to safe extraction of the lead at this point is not advancing the sheath any further, but rather pulling the lead up to the end of the sheath. If the sheath is pushed further, it might penetrate through the myocardium. If the femoral vein approach is necessary, we use our optimized/innovative snare methods, which have many advantages, such as flexible operation and incurring minimal damage and low cost. This would save money and decrease the medical burden to patients, which is especially important in developing countries.

We could remove all but one ICD lead by the transvenous approach. Our optimized/innovative snare methods by the femoral vein approach proved to be effective and low cost in 26.2% patients, which may have special clinical implications because the femoral vein approach is essential in many cases. An additional indication for the femoral vein approach is in patients with infected leads.^[15]

Previous multivariate analysis by the North American Society of Pacing and Electrophysiology showed that the major complication rate is 1.6%, and removal of the ICD lead itself has high risk.^[4,5] In our study, we observed no major complications or death with lead removal, except for minor complications in three patients (7.5%). During the same period, removal of non-ICD leads (540 leads) showed

96.0% complete procedural success and 98.0% clinical success rate, 2.8% minor complications, and 1.6% major complications, which was in line with previous lead-extraction studies.^[2,4,5,19] Also, there was no significant difference in extraction time between ICD and non-ICD leads.

4.1 Study limitations

We could only provide data for patients who underwent extraction in our center. Secondly, the low complication rates could be due to the care, well-trained staff and small sample size. Finally, because powered sheaths, such as electrosurgical sheaths,^[2] laser sheaths,^[3] or evolution mechanical dilator sheaths,^[20] are expensive and not available in China, therefore we used only optimized standard techniques in our study.

4.2 Clinical implications

Under scientific risk assessment and an experienced surgical team, a high clinical success rate and a low complication rate of transvenous ICD lead extraction can be achieved by making full use of the standard and our modified lead extraction technique and tools. Our optimized standard techniques remains a practicable clinical option for transvenous ICD lead extraction, especially in countries lacking powered sheath systems, and where the low cost of the assisting tools is advantageous. Indeed, pre-procedural assessment should be made carefully with respect to surgical risks. Long lead implant duration and large vegetation increase the risk of complications.

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