From Diagnosis of Cardiac Device Infection to Complete Extraction of the System

6

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6.1 Introduction

Infection of cardiac implantable electronic devices (CIED) is associated with high mortality [1]. The progressive increase in implantation of CIED together with increased comorbidity in patients receiving them has set the stage for higher rates of CIED infection (CIEDI) and infective endocarditis (IE) [2]. Currently, CIED infection is the most frequent indication for lead extraction, [3] having increased from nearly 30% of extractions in 2006 to 50% in 2012 [4].

6.2 Importance of Complete CIED Removal to Prevent Recurrence of Infection

Medical therapy has been associated with high mortality and risk of CIEDI recurrence (Fig. 6.1) [4–6]. In a large cohort study, a sevenfold increase in 30-day mortality was observed if the CIED was not removed; despite fatal complications related to CIED removal, the mortality associated with delayed removal was significantly higher [7]. Therefore, this risk of recurrent infection makes it essential to remove all hardware [8, 9].

Current guidelines recommend complete CIED removal in all cases of CIEDI, whether systemic or localized in the pocket, and even when occult infection is suspected, with no apparent source other than the device. The only exception to this rule is a minor incisional/suture abscess, not communicating with the pocket, that

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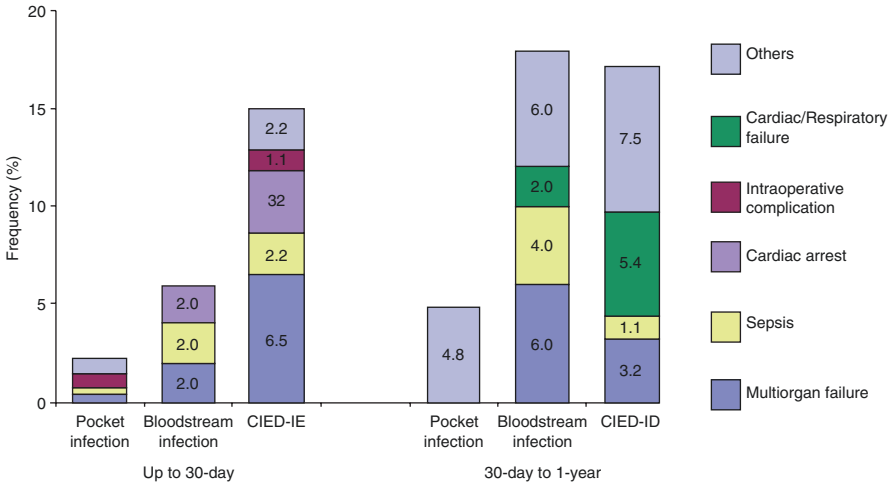


Fig. 6.1 Incidence and cause of death at 30 days and 1 year among three different clinical presentations of CIED infection (Reproduced from Lee et al. with permission) [4]. *CIED-IE*, infective endocarditis involving the CIED

occurs within a few days after implantation; this may be treated with antibiotics and careful follow-up [7] [see Chap. 4 for a complete discussion of this topic].

Considering the inherent risk of an open surgical procedure, transvenous lead extraction has become the preferred method [10]. In experienced centers, procedural mortality rates oscillate between 0.1% and 0.6%, with higher mortality rates associated with systemic infections [11].

Open extractions are generally favored in high-risk cases, in order to avoid life-threatening complications that can be encountered during percutaneous extractions. In general, open extractions are considered when the patient has epicardial leads, some other reason for cardiac surgery, or large lead masses (vegetation or thrombus >2.5 cm), or failed a prior extraction procedure [7, 10].

6.3 Definitions

The concept of "lead removal" includes a broad spectrum of procedures (Table 6.1). Distinction must be made between simple procedures that can be performed via the implant vein without specialized tools and removal of leads involving more complex procedures [10].

6.4 Perioperative Management for CIED Removal

After blood cultures are completed, i.e., antibiotics should be initiated before hardware removal. No clinical trial data are available to define the optimal duration of antimicrobial therapy. A plan for pre-, intra-, and postoperative antibiotic must be

Table 6.1 Definitions of lead removal procedures and outcomes

Lead removal	• Removal of a pacing or defibrillator lead using any technique
Lead explant	• Lead removal procedure where all leads are removed without tools or with implantation stylets and had been implanted for less than 1 year
Lead extraction	• Removal of a lead that has been implanted for more than 1 year • Removal of a lead, regardless of implant duration, requiring the assistance of specialized equipment that is not included as part of the typical implant
Complete procedural success	• Lead extraction procedure with removal of all targeted leads and all lead material from the vascular space, with the absence of any permanently disabling complication or procedure-related death
Clinical success	• Lead extraction procedures with removal of all targeted leads and lead material from the vascular space or retention of a small portion of the lead (<4 cm) that does not negatively impact the outcome goals of the procedure
Failure	• Lead extraction procedures in which complete procedural or clinical success cannot be achieved • Development of any permanently disabling complication or procedure-related death
Lead removal with clinical success	• Achieving removal of the entire lead from the body or with retention of a small portion of the lead material (<4 cm) that does not negatively impact the outcome goals of the procedure

formulated, including type and duration of the treatment, and will vary according to test results.

CIED removal may have serious and catastrophic life-threatening complications. Therefore, correct perioperative evaluation and patient management are essential to minimize the risk of procedure-related complications. Perioperative management can be divided into three phases: preoperative, procedure, and post-procedure.

6.4.1 Preoperative Phase

The aims of this phase are to confirm appropriate indications for lead extraction, assess procedure complexity, define extraction approach, and optimize the patient's clinical status in preparation for the procedure. This phase includes eight steps.

6.4.1.1 Medical History and Physical Examination

A comprehensive medical history is necessary, including a review of the patient's comorbidities that could worsen the prognosis of CIED extraction (Table 6.2), along with medical treatment, allergies, cardiac device history, CIED indication, and data of first implant. The pocket generator and device site also must be examined for signs of infection. Physical examination should identify signs of heart failure and assess chest wall venous collaterals suggesting venous occlusion or thrombosis.

6.4.1.2 CIED Interrogation

The cardiac device must be interrogated to obtain lead information and to assess pacemaker dependency. Patients who are not pacemaker dependent should have

Table 6.2 Factors associated with extraction procedure complications

Comorbidities	Associated risk
Age	1.05-fold greater mortality
Female sex	4.5-fold greater risk of major complications
BMI < 24	1.8-fold greater risk of 30-day mortality
Cerebrovascular accident	Twofold greater risk of major complications
Severe LV dysfunction	Twofold greater risk of major complication
Heart failure	1.3- to 8.5-fold greater risk of 30-day mortality and threefold greater mortality risk at 1 year
Renal dysfunction (ESRD)	4.8-fold greater risk of 30-day mortality Cr > 2.0 greater risk of in-hospital mortality and twofold greater risk of 1-year mortality
Diabetes mellitus	Increased in-hospital mortality 1.71-fold greater mortality
Low platelet count	Low platelet count: 1.7-fold greater risk of major complications
Coagulopathy	Elevated INR: 2.7-fold greater risk of major complications and 1.3-fold greater risk of 30-day mortality Anticoagulants: 1.8-fold greater 1-year mortality
Anemia	3.3-fold greater risk of 30-day mortality
Extraction for infection	2.7- to 30-fold greater risk of 30-day mortality 5- to 9.7-fold greater 1-year mortality risk

their device reprogrammed to backup pacing modes (VVI 40 bpm) prior to the procedure to confirm lack of dependency.

6.4.1.3 Chest X-Ray

Information regarding type of lead, position, and presence of abandoned leads can be obtained from posteroanterior and lateral chest radiography (X-ray). X-ray should rule out left-side lead implantation or extravascular lead course; otherwise, computed tomography (CT) may be necessary to characterize lead course and plan an appropriate procedural strategy (Fig. 6.2).

6.4.1.4 Venography with Fluoroscopy

Fluoroscopy is useful to identify regions of venous stenosis or occlusion in venography (Fig. 6.3). In two reports, about 20% of patients had a complete occlusion at the venous entry site [12, 13]. The presence of severe venous stenosis or occlusion increases the complexity of extraction. Moreover, if a new device must be implanted, other vascular access should be evaluated.

6.4.1.5 Transesophageal Echocardiography

In cases of CIEDI, transesophageal echocardiography (TEE) is mandatory prior to CIED removal (Fig. 6.3). TEE evaluates the presence, size, shape, and location of vegetations as well as their relationship with cardiac structures. These results determine the most appropriate approach (transvenous or open surgical) for the

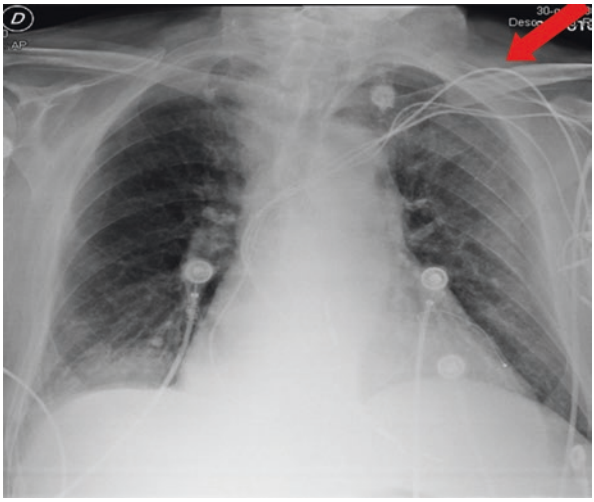


Fig. 6.2 Posteroanterior chest X-ray showing a dual chamber system plus an abandoned unipolar passive fixation PM lead implanted through left jugular vein (red arrow). Leads implanted through atypical accesses should be considered carefully for the increased risk or vein damage

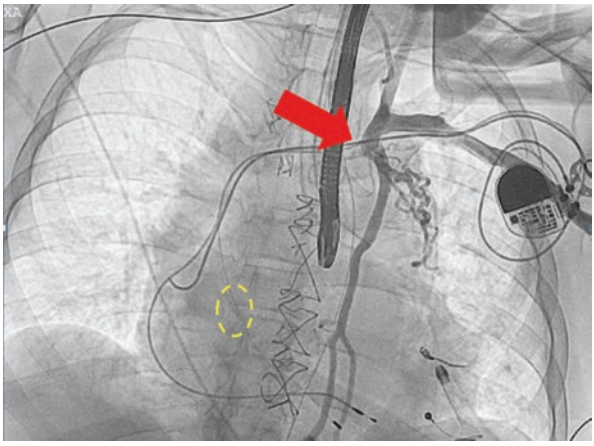


Fig. 6.3 Venography showing complete occlusion of the innominate vein in a GUCH patient (red arrow) with a previously failed lead extraction (dashed yellow circle) and systemic CIEDI

extraction [14, 15]. Decisions regarding percutaneous versus surgical removal of leads with large vegetations (>2.5 cm) should be individualized [10, 16]. Other imaging techniques (e.g., CT scan, ^{18}F-FDG PET/CT), when available, should be considered to properly identify systemic involvement of CIEDI [for a detailed description of imaging techniques applied to CIEDI see also Chap. 5].

6.4.1.6 Perioperative Management of Oral Anticoagulation

Observational studies have shown an increased risk of major complications and death in patients with an elevated international normalized ratio (INR) at the time of lead extraction (Table 6.2). Therefore, oral anticoagulation should be stopped and normal INR values should be achieved on the day of the intervention; the peri-procedural anticoagulation strategies should be individualized according to the patient's thromboembolic risk during non-protected periods [10].

6.4.1.7 CIED Reimplant

Previous to CIED removal, it is necessary to re-evaluate the indication for CIED reimplant. Over time, changes in clinical indications and the patient's clinical status may render CIED therapy unnecessary. About one-third of patients did not have devices implanted after undergoing system extraction for CIEDI [17] [see Chap. 7 for a detailed discussion of post-extraction reimplantation indication and strategies].

6.4.1.8 Informed Consent

A review of the case, including alternatives to extraction and potentially life-threatening complications, should be discussed with the patient and his or her family members and clearly documented in the patient's chart [10]. Surgical approach should be discussed as well as possible conversion to surgical approach in case of complications or failed percutaneous extraction. Also alternative approaches for CIED reimplantation should be discussed with the patient.

6.4.2 Procedure Phase

6.4.2.1 Patient Preparation

Routine preoperative blood work, including complete blood counts and metabolic and coagulation panels, should be obtained, along with the type and cross for 2–4 units of packed red blood cells, which should be available in the procedure room.

Patients should receive sterile preparation for possible emergent sternotomy, creating a sterile field that covers the entire anterior chest and bilateral groin areas. An arterial line should be placed to permit continuous invasive blood pressure monitoring and pulse oximetry to monitor oxygenation. Venous access to permit rapid infusion of fluid, vasopressors, and blood products should be placed in the femoral veins.

External patches that permit transcutaneous pacing and defibrillation should be placed outside of the sterile working field. Once the patient is connected to a cardiac monitor, the CIED may be reprogrammed to inactivate tachycardia therapies and/or asynchronous pacing when appropriate.

CIED removal can be performed under general anesthesia or local anesthesia with sedation. The use of general anesthesia minimizes the patient's discomfort and allows a quick rescue surgery in case of complication.

For transient rate support, temporary pacing using the femoral approach is generally preferred when a superior extraction approach is planned. This will minimize interaction between the temporary pacing catheter and extraction tools. If longer periods of temporary pacing are required after the lead extraction procedure, an external pacemaker (or in selected cases defibrillator) is used, typically placing active fixation leads via the homolateral superior veins (Fig. 6.4) [18].

6.4.2.2 Intraprocedural Imaging

Transesophageal Electrocardiography

Transesophageal electrocardiography (TEE) is helpful for characterizing lead vegetation, evaluating tricuspid valve function, and documenting pericardial effusions

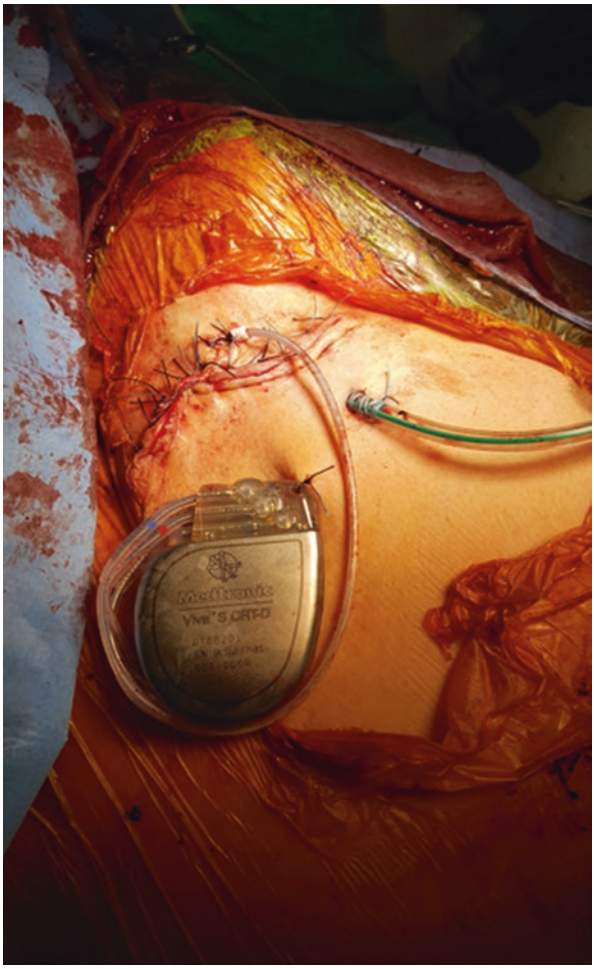


Fig. 6.4 After lead extraction for systemic CEDI this patient received a homolateral dual coil active fixation lead connected to an externalized ICD (after disabling can form shock vectors) to provide both continuous pacing (PM-dependent patient) and backup shock. This approach was in line with a previous report [18]

during lead extraction [19]. TEE allows a prompt identification of cardiovascular causes of hemodynamic instability during lead extraction [20].

Intracardiac Echocardiography

Intracardiac echocardiography (ICE) is more sensitive than TEE to detect vegetations in patients with endocarditis. ICE offers an excellent visualization of cardiac leads and related areas of adherence and may improve the efficacy and safety of the procedure [21, 22].

6.4.2.3 Techniques and Tools for CIED Extraction

The major obstacle to lead removal is the inflammatory and fibrotic response of the body to an intravascular foreign object. Within a few months postimplantation, the lead is surrounded by fibrous tissue. The fibrous lead encapsulation increases over time. The binding is most likely to be present at the point of lead insertion at the

Table 6.3 Tools for CIED lead extraction

Simple traction	• Non-locking stylets • Fixation screw retraction clips
Non-powered extraction tools	• Locking stylets • Snares • Mechanical dilator sheaths composed of metal, Teflon, polypropylene, or other materials that require manual advancement over the lead and rely on the mechanical properties of the sheath to disrupt fibrotic attachments
Powered extraction tools	• Laser sheaths • Electrosurgical dissection sheaths • Rotating threaded tip sheaths

subclavian vein, the junction between innominate vein and superior vena cava (SVC), right atrium, the lead tip, and, in ventricular leads, the tricuspid valve [10].

Extractions can be successfully completed using a variety of tools designed to disrupt fibrous adhesions (Table 6.3, Fig. 6.5). Optimal tool selection is based on factors such as lead-tissue interface, characteristics of the lead, characteristics of the fibrotic lesions, lead dwell time, and operator experience. To date, no unique tool is available to disrupt all types of fibrous adhesions during lead extraction, often requiring the operator to switch between extraction tools and approaches.

Femoral snares and telescoping sheaths tend to fail in the presence of densely fibrotic or severely calcified lesions. Laser sheaths are very effective against fibrous lesions but less effective with severely calcified lesions; however, mechanical cutters more efficiently traverse these lesions [23].

6.4.2.4 Approaches for Lead Removal

CIED leads are most commonly extracted through the original implantation site, where they are connected to the pulse generator. At times, the lead breaks or is free-floating, becoming inaccessible from the original implantation site. In such cases, extraction is performed from a remote site, such as via the femoral vein or the internal jugular vein [24].

Most operators begin the procedure using the venous entry approach and switch to femoral or jugular if necessary. Clinical success has been increased by applying approaches other than the superior approach for CIED extraction [24–26].

6.4.2.5 Lead Preparation

An incision is made over the device and, in cases of pocket infection, the device is dissected out in its entirety before proceeding with lead extraction. This avoids introducing infected material into the intravascular space. The lead must be free all the way to the venous entry site. In case of active fixation leads, the tip must be unscrewed.

6.4.2.6 Techniques for Lead Extraction

Simple Traction

After lead exposure and control, an attempt to withdraw the active fixation mechanism is undertaken, followed by gentle manual traction (pulling) of the lead,

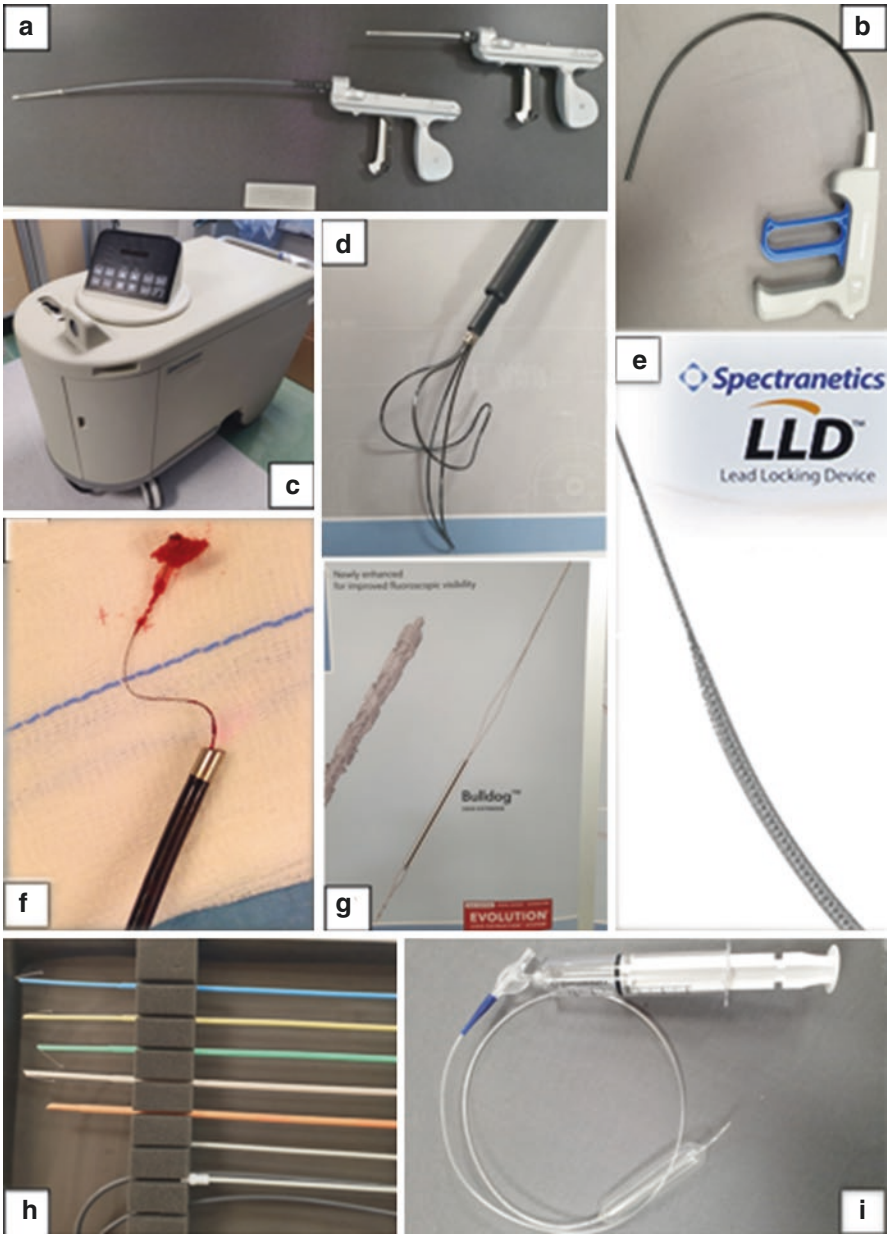


Fig. 6.5 Principal tools for lead extraction. Mechanical rotational sheaths: Evolution RL™ (Panel **a**; Cook Medical, USA) and TightRail™ (Panel **b**; Spectranetics Corp., USA); laser generator and laser-powered sheath (Panel **c** and **f**; Spectranetics Corp., USA); the Needle's Eye retrieval tool for either femoral or superior approach (Panel **d**; Cook Medical, USA); locking stylets to provide a stable support to advance extraction sheaths, LLD™ (Panel **e**; Spectranetics Corp., USA) and Bulldog™ (Panel **g**; Cook Medical, USA); standard Teflon mechanical sheaths (Panel **h**); the Bridge Balloon™ to be inflated in case of upper vein damage to decrease bleeding during the beginning of surgical backup (Panel **h**; Spectranetics Corp., USA)

combined with the use of tools typically supplied for lead implantation. Some authors suggest adding five to ten lead rotations to increase the effectiveness of the simultaneous gentle traction [27]. The success rate of transvenous lead extraction by simple traction ranges from 9% to 31% (19%) of patients and 28% of leads [28]. Most of these leads have a short dwell time. Despite a low success rate, simple traction could be performed as a first step for lead removal. However, when applying traction to chronically implanted leads, force will be distributed over the fibrotic binding sites and weakened at the distal end of the lead and may facilitate the elongation and fracture of the lead.

Counterpressure and Countertraction

If manual traction is unsuccessful, more advanced tools allowing counterpressure or countertraction are required to direct the force of traction along the length or at the distal end of the lead or to disrupt and dilate the encapsulating fibrotic tissue (Fig. 6.5). The locking stylet is advanced until reaching the tip of the lead. The different lead components are secured to the locking stylet with suture ties or a compression coil (One-tie; Cook Vascular Inc. USA) to convert all these components into one unit, allowing use of the lead as a "rail" for dissection by powered or non-powered extraction sheaths.

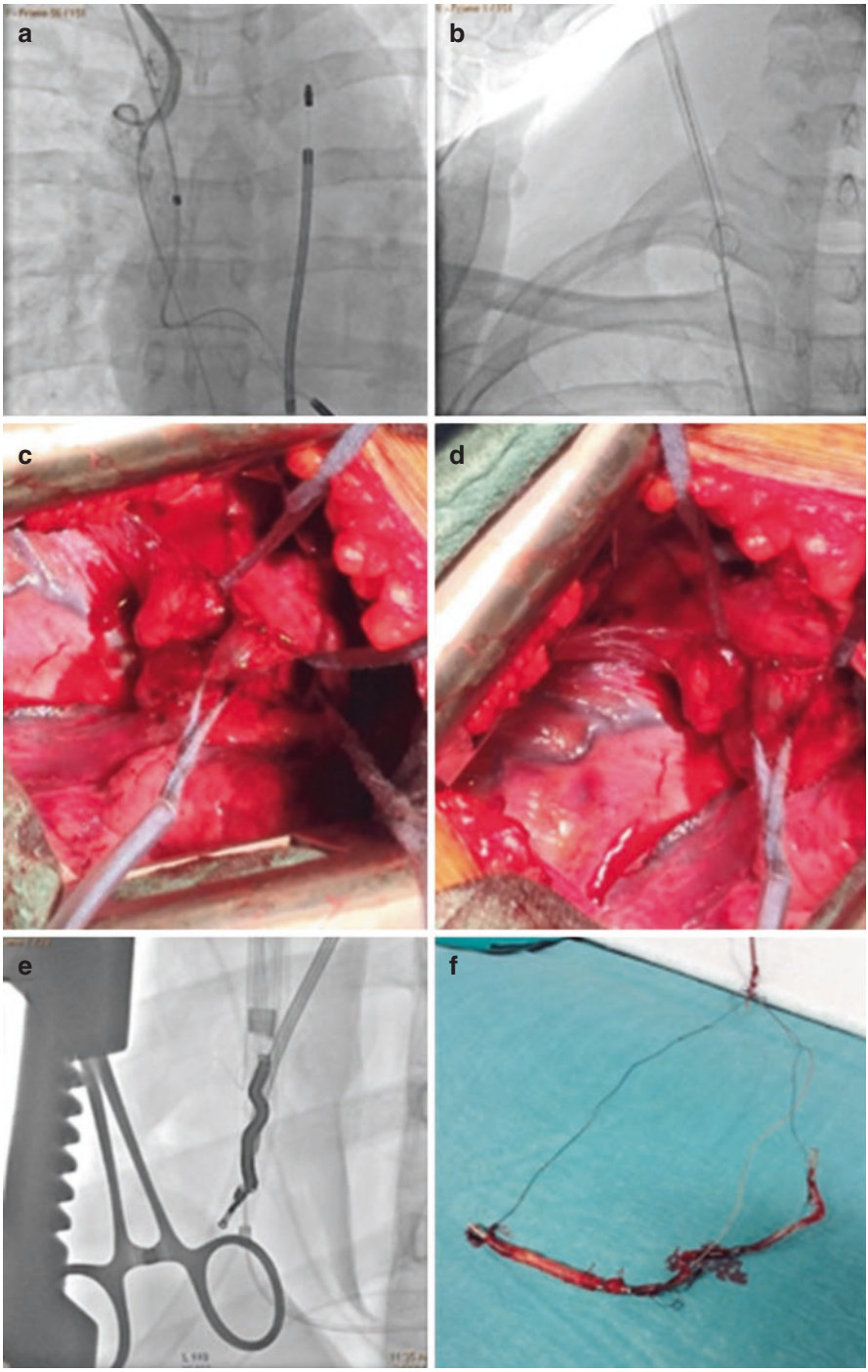
Counterpressure is the application of a forward pressure to the sheath and traction to the lead. These two forces must be balanced to avoid complications. Countertraction occurs when the traction applied on the lead is opposed and counterbalanced by pushing the overlie sheath on the endocardium, thus limiting myocardial invagination or avulsion.

In cases of failure of the superior approach or if the position of the targeted lead is completely intravascular, alternative approaches such as femoral or jugular can be applied [10]. In these cases, a snare is used to grasp the leads, usually in the right atrium. Once the lead is snared, it is pulled into the sheath, which is advanced over the leads to free them, until the tip is reached.

Additionally, in case of failure of a percutaneous approach even with advanced tools, cardiac surgery with sternotomy may be avoided adopting a hybrid approach with minimally invasive surgical access for completion of the procedure (Fig. 6.6) [28].

A stepwise extraction approach results in clinical success in up to 100% of CIED extractions, with a relatively low risk of procedure-related mortality and complications [29].

Fig. 6.6 "Hybrid" approach for lead extraction. (**a**) Fluoroscopy at the start of the procedure. (**b**) Advancement of the sheath (transjugular approach). (**c**) and (**d**) Surgical exposition of the venous vessels with minimally invasive approach. (**e**) Completion of lead extraction by percutaneous approach. (**f**) The lead after extraction. (Reproduced with permission from Bontempi et al. with permission) [28]


a
b
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6.4.3 Post-Procedure Phase

The main goal is to monitor the patient for post-procedure complications. Hemothorax or pneumothorax after CIED extraction can be ruled out by a thorax X-ray. Transthoracic echocardiogram is useful to detect adverse events such as tricuspid valve injury or pericardial effusion or to document remaining intracardiac masses (either retained fragments or so-called ghosts), which are most commonly observed in patients with CIED endocarditis or positive blood cultures. Although the presence of ghosts was associated with high mortality, no specific therapy is indicated for these patients, [30].

In CIED infection the post-procedure phase also is focused on wound care, selection and duration of antibiotics and appropriate timing for device reimplantation [10].

6.5 Reimplantation

The new device should be implanted on the contralateral side. There is no clear recommendation concerning the optimal timing of reimplantation. Factors such as persistent bacteremia, persistent vegetation, and pacemaker or implantable cardioverter defibrillator dependency should be considered and the decision adapted to the individual patient.

Immediate reimplantation should generally be avoided, owing to the risk of new infection. Blood cultures should be negative for at least 72 h before placement of a new device. In cases of evidence of remnant valvular infection, implantation should be delayed for at least 14 days [7]. New devices like subcutaneous ICD (s-ICD) or transcatheter pacemaker may be a good option for these patients [see Chap. 7 for detailed discussion of different approaches for CIED reimplant after extraction].

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