Extraction of Sterile Leads Is the Preferred Approach Rather than Implanting a New Lead

The Con Perspective

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KEYWORDS

• Lead malfunction • Implantable cardiac device • Lead extraction

KEY POINTS

- Lead malfunction is a common problem in patients with an implantable cardiac device, and it is expected to increase with the aging of leads.
- There is a weak indication for extraction of superfluous leads with the potential for cardiac implantable electronic device interference and abandoned or redundant leads.
- Lead extraction, although safe in experienced hands, remains a high-risk procedure, especially in lower-volume centers and/or lower-volume operators.

INTRODUCTION

Increased use of the cardiac implantable electronic device (CIED) in recent years has been accompanied by increased complications related to leads and more frequent need for lead extraction.[1]

In the earliest approaches, a simple weight or pulley system was applied to the end of the lead, resulting in significant morbidity and mortality that limited CIED use to life-threatening situations such as infection and sepsis. Device-related infection was the most common indication for lead extraction. With the advent of specific extracting tools, better results are achieved, and the success rates for complete lead removal are higher; therefore, indications for extracting leads have expanded. However, there is still a risk of severe complications such as myocardial avulsion, tamponade, vascular damage, and death.[2]

Indications for transvenous lead extraction (TLE) in the absence of infection remain controversial. Cardiologists are dealing with the difficult choice of extraction or abandonment of sterile, superfluous leads. In these situations, a careful, individualized, risk–benefit evaluation is necessary. Lead extraction is not necessarily the best strategy, and in the absence of randomized, controlled trials of extraction versus abandonment, individual judgment is still a key element in the decision-making process.[3]

COMPLICATIONS IN LEAD EXTRACTION

Lead extraction is a complex surgical procedure with some unavoidable risks. Fibrotic tissue develops over time and entraps the implanted lead in the veins and in the cardiac chambers. Simple traction has been much less effective for chronically implanted electrodes and has been associated with a significant risk of myocardial avulsion

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and tricuspid valve damage. The current conventional techniques include the use of a locking, telescoping, or powered sheath advancement over leads and lead removal through the venous entry site; however, it is sometimes not possible to overcome common procedural difficulties, resulting in failure and/or complications.

Rijal and colleagues[4] published a cohort study that compared the strategy of extracting versus abandoning sterile pacemaker and defibrillator leads. They observed no difference in the primary end point neither of unanticipated CIED-related procedures nor in any of the secondary outcomes, including major or minor procedural complications, risks of hospitalization for any reason or for cardiac causes, or mortality. However, the retrospective observational study design has inherent potential for selection bias; operators may choose healthier patients for lead extraction and unmask higher-risk patients in the lead extraction group.

The most serious risk of lead extraction is potentially life-threatening damage or tearing in the heart or blood vessels, which may result in rapid collapse requiring emergency open chest heart surgery and may result in death. The reported rate of major complications is 1.6% to 2.0%, or approximately 1 major complication per 50 patients. Although mortality in transvenous lead extraction may be low in high-volume extraction centers, postprocedural mortality (30-day) and long-term mortality remain significant. In a large, heterogeneous, unselected cohort, the mortality rate was 2.1% at 30 days, 4.2% at 3 months, and 8.4% at 1 year.[5] Success and complication rates have been correlated to time from implant, presence of infection, female gender, body mass index (BMI) less than 25 kg/m^2, and institutional procedural volume.[6]

In a recent meta-analysis published by Di Monaco and colleagues,[7] which included 66 observational studies, no clear differences emerged in the combined rate of major complications or intraoperative deaths, but both minor complications and mortality at 30 days decreased as center volume increased. Minor complications may be the consequence of less ability to handle even less serious problems in lower-volume centers (or operators), perhaps because periprocedural management differs between centers. In addition, a trend toward older leads in lower-volume centers could be a confounding factor to be considered in explaining differences in the observed results.

Multicenter trials have confirmed the effect of operator experience on outcomes; complication rates with TLE directly parallel operator experience. Lower volume (<60 cases) in the centers studied was also associated with procedural and clinical failure. Therefore, patients should be referred to high-volume centers.[8]

WHAT HAPPENS WITH ABANDONED LEADS?

Most studies on abandoned leads are small registries or observational reports with a relatively short follow-up. Bongiorni and colleagues recently published the European Heart Rhythm survey on Management of malfunctioning and recalled pacemaker and defibrillator leads, which demonstrated that the main concern (61%) about lead abandonment was the increased potential for difficult lead extraction in the future. Other concerns included potential interference with other leads (68%), the formation of a bulk in the pocket (62%), worsening of tricuspid regurgitation (59%), risk of venous thrombosis (56%), and infections (50%).[9]

Glikson and colleagues[10] followed 78 implantable cardiac device (ICD) patients with 101 abandoned leads for a mean of 3.1 plus or minus 2 years and observed no complications in terms of infection, clinically apparent thromboembolism, or sensing malfunction. These data would suggest relatively low rates of complications related to abandoned leads.

In an interesting single-center retrospective review of the removal of infected leads, Huang and colleagues[11] compared outcomes and TLE complications of 123 procedures caused by superfluous leads. They found highly successful outcomes at the time of device upgrade or lead revision; however, most patients were young, and lead dwell time was less than 5 years.

One of the reasons suggested for defibrillator lead extraction is the possibility that the abandoned lead will create noise in contact with the new lead. However, actual reports of such noise are scarce. Cooper and colleagues[12] showed that only metal–metal lead interactions can generate electrical artifacts that may result in ICD oversensing and that mechanical shielding by an intact isolative lead coating can prevent the generation of conductor contact noise. Positioning the new lead's electrode at a site remote from the abandoned lead's conductive elements (**Fig. 1**), and use of dedicated bipolar replacement leads may further diminish the slight chance of lead-related noise.

Similarly, the potential for venous-related complications following lead abandonment seems relatively small. Multiple leads may contribute to venous thrombosis, but this is a rather infrequent complication, even with a first implant, and in general is managed conservatively. Suga and colleagues[13] noted a high risk associated with the