2017 HRS expert consensus statement on cardiovascular implantable electronic device lead management and extraction

Fred M. Kusumoto, MD, FHRS, FACC (Chair),[1]
Mark H. Schoenfeld, MD, FHRS, FACC, FAHA, CCDS (Vice-Chair),[2]
Bruce L. Wilkoff, MD, FHRS, CCDS (Vice-Chair),[3] Charles I. Berul, MD, FHRS,[4,*]
Ulrika M. Birgersdotter-Green, MD, FHRS,[5] Roger Carrillo, MD, MBA, FHRS,[6] Yong-Mei Cha, MD,[7]
Jude Clancy, MD,[2] Jean-Claude Deharo, MD, FESC,[8] Kenneth A. Ellenbogen, MD, FHRS,[9]
Derek Exner, MD, MPH, FHRS,[10] Ayman A. Hussein, MD, FACC,[11]
Charles Kennergren, MD, PhD, FETCS, FHRS,[12,‡] Andrew Krahn, MD, FRCPC, FHRS,[13]
Richard Lee, MD, MBA,[14,§] Charles J. Love, MD, CCDS, FHRS, FACC, FAHA,[15,¶]
Ruth A. Madden, MPH, RN,[11] Hector Alfredo Mazzetti, MD,[16,#] JoEllyn Carol Moore, MD, FACC,[17]
Jeffrey Parsonnet, MD,[18,**] Kristen K. Patton, MD,[19,‡‡] Marc A. Rozner, PhD, MD, CCDS,[20,†,§§]
Kimberly A. Selzman, MD, MPH, FHRS, FACC,[21] Morio Shoda, MD, PhD,[22]
Komandoor Srivathsan, MD,[23] Neil F. Strathmore, MBBS, FHRS,[24,¶¶]
Charles D. Swerdlow, MD, FHRS,[25] Christine Tompkins, MD,[26] Oussama Wazni, MD, MBA[11]

Document Reviewers: Adrian M. Baranchuk, MD, FACC, FRCPC, FCCS; Carina Blomström-Lundqvist, MD, PhD; Frank A. Fish, MD; James M. Horton, MD; Roberto Keegan, MD; Miguel A. Leal, MD, FACC, FHRS; Nigel Lever, MBChB, FRACP; Aman Mahajan, MD, PhD, MBA; Marc R. Moon, MD; Siva K. Mulpuru, BS, MB, MBBS, MD, FHRS, CCDS

From the [1]Mayo Clinic, Jacksonville, Florida, [2]Yale University School of Medicine, New Haven, Connecticut, [3]Cleveland Clinic Lerner College of Medicine of Case Western Reserve University, Cleveland, Ohio, [4]Children's National Medical Center, Washington, District of Columbia, [5]UC San Diego Health, La Jolla, California, [6]University of Miami, Coral Gables, Florida, [7]Department of Cardiovascular Diseases, Mayo Clinic School of Medicine, Rochester, Minnesota, [8]CHU La Timone, Service de Cardiologie, Marseille, France, and AMU, UMR MD2, Faculté de Médecine Nord, Marseille, France, [9]Virginia Commonwealth

KEYWORDS Lead management; Extraction; Defibrillator; Pacemaker; Infection

ABBREVIATIONS **^{99m}Tc-HMPAO-WBC** = ^{99m}Tc-hexamethypropylene amine oxime–labeled autologous white blood cell; **CIED** = cardiovascular implantable electronic device; **COR** = Class of Recommendation; **CRT** = cardiac resynchronization therapy; **CS** = coronary sinus; **CT** = computed tomography; **ECG** = electrocardiogram; **EGM** = electrogram; **FDA** = Food and Drug Administration; **FDG** = fluorodeoxyglucose; **HR** = hazard ratio; **ICD** = implantable cardioverter defibrillator; **ICE** = intracardiac echocardiography; **INR** = international normalized ratio; **IV** = intravenous; **LIA** = lead integrity alerts; **LNA** = Lead Noise Algorithm; **LOE** = Level of Evidence; **LV** = left ventricular; **LVAD** = left ventricular assist device; **MAUDE** = Manufacturer and User Facility Device Experience; **MR** = magnetic resonance; **MRI** = magnetic resonance imaging; **NCDR** = National Cardiovascular Data Registry; **NIS** = National (Nationwide) Inpatient Sample; **OR** = odds ratio; **PADIT** = Prevention of Arrhythmia Device Infection Trial; **PET** = positron emission tomography; **RA** = right atrium; **RLES** = Riata Lead Evaluation Study; **RV** = right ventricular; **S-ICD** = subcutaneous implantable cardioverter defibrillator; **SVC** = superior vena cava; **TEE** = transesophageal echocardiography; **TR** = tricuspid regurgitation; **TTE** = transthoracic echocardiography; **UDI** = unique device identification; **VF** = ventricular fibrillation; **VT** = ventricular tachycardia (Heart Rhythm 2017;14:e503–e551)

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Address reprint requests and correspondence: Heart Rhythm Society, 1325 G Street NW, Suite 400, Washington, DC 20005. E-mail address: clinicaldocs@hrsonline.org.

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University Medical Center, Richmond, Virginia, [10]*University of Calgary, Calgary, Canada,* [11]*Cleveland Clinic, Cleveland, Ohio,* [12]*Sahlgrenska University Hospital, Gothenburg, Sweden,* [13]*The University of British Columbia, Vancouver, Canada,* [14]*Saint Louis University, St. Louis, Missouri,* [15]*Johns Hopkins Hospital, Baltimore, Maryland,* [16]*Hospital Fernandez, Buenos Aires, Argentina,* [17]*Minneapolis Heart Institute, Abbott Northwestern Hospital, Part of Allina Health, Minneapolis, Minnesota,* [18]*Dartmouth-Hitchcock Medical Center, Lebanon, New Hampshire,* [19]*University of Washington, Seattle, Washington,* [20]*The University of Texas MD Anderson Cancer Center, Houston, Texas,* [21]*George E. Wahlen Department of Veterans Affairs Medical Center, Salt Lake City, Utah,* [22]*Tokyo Women's Medical University, Shinjuku, Japan,* [23]*Mayo Clinic, Phoenix, Arizona,* [24]*Royal Melbourne Hospital, Parkville, Victoria, Australia,* [25]*Cedars-Sinai Medical Center, Los Angeles, California, and* [26]*University of Colorado School of Medicine, Aurora, Colorado.*

†*Deceased (see In Memoriam at the end of this document)*
**Representative of the Pediatric and Congenital Electrophysiology Society (PACES)*
‡*Representative of the European Heart Rhythm Association (EHRA)*
§*Representative of the Society of Thoracic Surgeons (STS)*
¶*Representative of the American College of Cardiology (ACC)*
#*Representative of the Latin American Heart Rhythm Society (LAHRS)*
***Representative of the Infectious Diseases Society of America (IDSA)*
‡‡*Representative of the American Heart Association (AHA)*
§§*Representative of the American Society of Anesthesiologists (ASA)*
¶¶*Representative of the Asia Pacific Heart Rhythm Society (APHRS)*

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1. Introduction and Methodology

Most cardiovascular implantable electronic devices (CIEDs) currently use leads that connect the generator to cardiac tissue. Lead management is an important issue, given the lead failures, generator changes, and clinical conditions that can directly affect CIEDs, such as infection. This document is intended to help clinicians in their decision-making process for managing leads. The document also builds on the 2009 *Transvenous Lead Extraction: Heart Rhythm Society Expert Consensus on Facilities, Training, Indications, and Patient Management* (2009 HRS Extraction) document,[1] which provides detailed recommendations on facilities and training for lead extraction that remain appropriate. The main focus of this consensus statement is to provide practical clinical

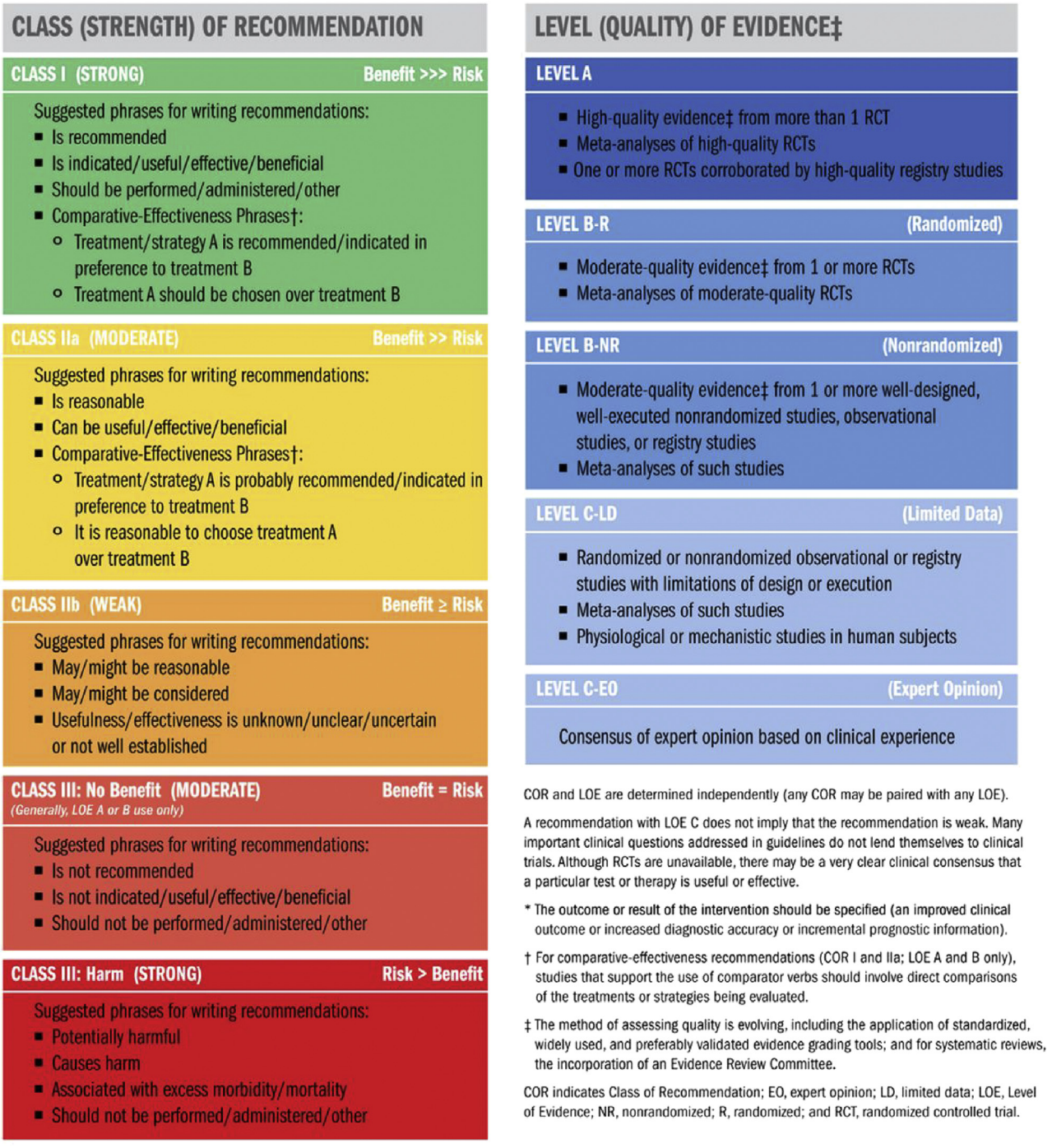

Figure 1 Applying Class of Recommendation and Level of Evidence to clinical strategies, interventions, treatments, or diagnostic testing in patient care (Halperin et al. Circulation 2016;133:1426–1428).

guidance in the broad field of lead management, including extraction.

This consensus statement is the result of an international collaboration among 10 professional organizations, including the Heart Rhythm Society (HRS), American College of Cardiology (ACC), American Heart Association (AHA), Asia Pacific Heart Rhythm Society (APHRS), American Society of Anesthesiologists (ASA), European Heart Rhythm Association (EHRA), Infectious Diseases Society of America (IDSA), Latin American Heart Rhythm Society (LAHRS), Pediatric and Congenital Electrophysiology Society (PACES), and Society of Thoracic Surgeons (STS).

This document follows the policies of the HRS, with the required disclosures from all committee members (Appendix 1), as well as from all peer reviewers (Appendix 2), regarding their industry relationships. Of the writing committee's 29 members, 18 had no or minimal financial relationships (<$10,000) with industry. Literature searches were

performed, and initial drafts were authored by the writing committee members with no relevant industry relationships. Recommendations were developed from the available data, and commonly encountered clinical situations were identified by the writing committee members. The recommendations follow the Class of Recommendation (COR) and Level of Evidence (LOE) system and methodology developed by the AHA and the ACC (Figure 1).[2] The LOE was assessed by the writing committee members with no relevant relationships with industry. All recommendations are supported by a short summary of the evidence or specific reasoning for the recommendation. The recommendations required a predefined threshold of >80% consensus by anonymous vote. The actual average consensus vote was 96%.

The recommendations for this document underwent a public comment period, and the document underwent internal peer review by the HRS Scientific and Clinical Documents Committee and external review by the participating societies.

2. Background

Over the past 60 years, CIEDs have become established as an important therapeutic modality of cardiovascular care for the treatment of patients with bradycardia, tachycardia, and heart failure. Although recent technological advances have eliminated the need for transvenous or epicardial leads for CIEDs used in selected patient groups, lead management remains critical for a variety of reasons. Recent estimates suggest that 1.2–1.4 million CIEDs are implanted annually worldwide (MedMarket Diligence LLC Report C500). Questions on lead management arise in several situations, including when changes in a patient's clinical condition make a different functionality more or less important, if a lead becomes nonfunctional, and if the presence of a lead is thought to interfere with the patient's optimal treatment.

3. Definitions

The definitions used in the document are provided in Table 1. The definitions relevant to extraction are similar to those developed by the 2009 HRS Extraction document.[1] As in that document, lead extraction is defined as any lead removal procedure in which at least one lead requires the assistance of equipment not typically required during implantation or at least one lead was implanted for longer than 1 year. Definition of outcomes also closely follows the 2009 HRS Extraction document.[1] In that document, clinical success could include the retention of a small part of the lead that did not affect the desired outcome of the procedure. After discussion, the writing committee reached consensus and specifically defined "small" as <4 cm for any residual lead portion. In addition, the <4-cm remnant cannot affect the desired outcome of the procedure; thus, an extraction procedure would not be defined as a clinical success if the remnant needed to be surgically removed due to continued concern for infection. More detail on clinical outcomes is provided in Section 12.

Table 1 Definitions

Term	Definition
Nonfunctional lead	A lead that is not usable due to electrical dysfunction, regardless of whether it is connected to the CIED or not.
Abandoned lead	A functional or nonfunctional lead that is left in place and is not connected to the CIED.
Lead removal procedure	A procedure involving the removal of a pacing or defibrillator lead using any technique, regardless of time since implantation.
Lead explant procedure	Lead removal procedure where all leads were removed without tools or with implantation stylets and all removed leads were implanted for less than 1 year.
Lead extraction	Lead removal procedure where at least one lead removal required the assistance of equipment not typically employed during lead implantation or at least one lead was implanted for greater than 1 year.
Definitions for extraction procedures	
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.
Complete procedural success rate	Extraction procedures where there is complete procedural success/total number of extraction procedures.
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.
Clinical success rate	Extraction procedures where there is clinical success/total number of extraction procedures.
Failure	Lead extraction procedures in which complete procedural or clinical success cannot be achieved, or the development of any permanently disabling complication, or procedure-related death.
Failure rate	Failed extraction procedures/total number of extraction procedures.
Lead removal with clinical success	Leads with attempted removal where the entire lead is taken out of 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.
Lead removal with clinical success rate	Number of leads removed with clinical success during a lead extraction/total number of leads with attempted removal.

CIED = cardiovascular implantable electronic device.

4. Lead Survival

COR	LOE	Recommendation	References
IIa	C-EO	**A lead model and clinical scenario-specific strategy of increased surveillance and management can be useful for CIED leads that have been identified with higher-than-expected failure rates.**	

Identifying an acceptable annual performance target should take into account the lead's intended use, complexity, and patient factors that influence durability. Extensive data from currently available pacing and implantable cardioverter defibrillator (ICD) leads are available from real-world registry data and product performance reports, based on extensive remote monitoring data.[3–5] These data, comprising several available leads with robust 5- to 10-year follow-up data, support a target annual failure rate of ≤0.4% for ICD leads and ≤0.2% for pacing leads.

4.1. Historical Background

The integrity and reliability of CIED leads are critical for the proper function of these devices and their ability to deliver life-sustaining therapies. The leads must survive the hostile biological environment of the human host and retain electrical integrity and chemical inertia while enduring repetitive mechanical stress with millions of cardiac cycles each year. As such, improving lead design and performance have been targets of significant scientific and engineering efforts in recent decades, but CIED leads continue to occasionally fail, potentially leading to adverse clinical outcomes.

Multiple studies have addressed lead failure rates and modes of failure[3–11] (Appendix 3). The reported lead failure rates have varied, with certain leads being more prone to failure and certain patient populations more vulnerable to lead failure.[3] The comparison of failure rates across a wide range of manufacturers and lead designs is complicated by varying definitions and study designs, patient and operator characteristics, venous access and implant technique, duration of follow-up, and methods employed to detect lead failure but, most importantly, by the differences in the leads' structural properties.

Lead failure can represent the breakdown of any of the lead components, including insulation, conductors, connectors, terminal pins, electrodes, and coils. The clinical consequences depend on the failure mode and can lead to the system's inability to deliver appropriate therapy or to the delivery of inappropriate and potentially harmful therapy.

The manufacturers' product performance reports indicate a survival probability for most CIED leads in adult patients in the range of 92% to 99% 5 years after implantation.[12–16] The interpretation of these survival estimates is potentially limited by the under-reporting of failures, lack of uniform definitions, reliance on self-reporting, and insufficient follow-up.

Pacing leads have shown better overall survival rates than ICD leads due to a simpler design and fewer components, which reduce the risk of failure. In the 2006 Danish Pacemaker Register (a longitudinal registry of all leads implanted in Denmark), the 10-year survival rates for unipolar and bipolar pacemaker leads were 96.5% and 97.8%, respectively; the data also suggested that pacemaker lead performance had improved over time.[4] Studies from the past decade have reported lower ICD lead survival rates: ranging from 91% to 99% at 2 years, 85% to 95% at 5 years, and 60% to 72% at 8 years.[17–25] However, many of these studies included leads known to have unacceptably high failure rates or leads subject to safety communications or recalls (Sprint Fidelis [Medtronic] and Riata [Abbott]) (Section 6).[6]

Currently, the four most commonly implanted ICD lead families are the Endotak Reliance (Boston Scientific), Sprint Quattro (Medtronic), Protego (Biotronik), and the 7F Durata (St. Jude Medical [now Abbott]) leads. In a recent meta-analysis of 17 studies, which included a total of 49,871 patients with a follow-up of 136,509 lead-years, the failure rates were 0.29% per year for the Quattro lead family, 0.36% per year for the Endotak Reliance lead family, and 0.45% per year for the Durata lead family (P=NS between families).[11] A caveat when interpreting these observations: The mean follow-up duration of the studies included in this meta-analysis was 2 to 3 years, and none of the studies had an average follow-up longer than 6 years. The failure rates with Sprint Fidelis and Riata/Riata ST leads appear to have increased over time.[24,25] Studies with longer duration follow-ups are therefore needed to further assess the long-term performance of currently implanted leads and all future leads. Lead failure might be more likely in children due to somatic growth and high levels of physical activity.[26,27]

4.2. New Technology

Due to the clinical challenges and morbidity inherent in lead management, significant research efforts have focused on improving lead design and developing devices that do not require intravascular leads. The former aims to develop smaller, yet more durable and easily extractable leads. The latter has resulted in the introduction of the subcutaneous ICD and leadless pacemaker systems.

4.2.1. Single-Component Leadless Pacemakers

Two single-component leadless pacemakers have been implanted in humans in recent years: the Nanostim (Abbott) and the Micra Transcatheter Pacing System (TPS) (Medtronic).[28,29] These systems contain the pulse generator and pace-sense electrodes in one unit and are delivered to the right ventricle through a femoral vein. The Nanostim system uses an active screw-in helix and secondary fixation with three angled nitinol tines perpendicular to the helix. The Micra system employs four self-expanding nitinol tines for fixation. Both devices are reportedly retrievable, but available data are very limited.

4.2.2. Subcutaneous Implantable Cardioverter Defibrillators

An entirely subcutaneous ICD (S-ICD) has been recently introduced, which prevents the inherent problems related to transvenous leads.[30] The S-ICD consists of a pulse generator implanted in a left mid-axillary position connected to an entirely subcutaneous lead with a shocking coil electrode that is positioned in a parasternal position.

5. Diagnostic Approach to Suspected Lead Failure

This section discusses the clinical presentation and diagnostic approach to suspected lead failure. The primary focus is on ICD leads due to their higher failure rates compared with pacing leads and the clinical challenges pertaining to lead management in patients with Sprint Fidelis and Riata ICD leads. Generally, the same diagnostic principles apply to pacemaker leads, with the exceptions that oversensing in ICD leads results in inappropriate shocks and pacing inhibition and that high-voltage failure modes do not apply to pacing leads.

5.1. Clinical Presentation

The lead failure modes are pace-sense malfunction and shock component malfunction, with the former accounting for the clear majority (>90%) of diagnosed lead failures in clinical practice.[7] In pace-sense circuits, conductor failure or insulation breach typically present as oversensing of rapid, nonphysiological signals, resulting in inappropriate shocks or pacing inhibition.[24,31]

In the past, the most common presentation of pace-sense lead fracture was inappropriate shocks.[9,32] Due to device diagnostics that incorporate the detection of short intervals and changes in impedance and the widespread use of remote monitoring, an increasing number of patients in recent years are presenting with lead alerts, enabling early recognition of lead failure before the onset of adverse clinical events.[33] Despite these advances, patients can still present with multiple shocks, because fracture might only become apparent after high-voltage therapy. Health care providers who provide initial care for patients should understand the use of magnets for suspending therapy.

The true incidence of shock-component malfunction is difficult to ascertain due to a lack of specific diagnostic tools. These malfunctions typically present with shock impedance change and, less commonly, as failed defibrillation or in association with coexisting pace-sense failures. Insulation failure with shorting of the high-voltage circuit can result in catastrophic failure of the pulse generator. The introduction of remote monitoring and enhanced lead diagnostics will likely improve the early recognition of shock-component malfunction.

5.2. Device Electrograms in Pace-Sense Failures

Device electrogram (EGM) analysis is important in the diagnostic approach to suspected lead failure, especially pace-sense circuit failures, because oversensing (noise) is the most common observation in this failure mode. It is important to distinguish lead failure–related oversensing from other sources, such as electromagnetic interference, myopotentials, P- or T-wave oversensing, R-wave double counting, and lead-lead interactions. Cyclical oversensing, which refers to sensing non-QRS components with every cardiac cycle, typically indicates an intracardiac source of oversensed signals.

The morphology and pattern of typical nonphysiological EGMs in conductor fractures have been validated by returned product analysis of explanted leads.[33] The typical characteristics of conductor-fracture EGMs are signals that are (1) intermittent with a high dominant frequency; (2) highly variable (amplitude, morphology, frequency); and (3) not recorded on the high-voltage or shock channel. The EGMs are typically noncyclical, exhibit extremely short nonphysiological R-R intervals (<160 ms), are unlikely to represent ventricular depolarization, and might saturate the sensing amplifier, resulting in a truncated signal on the near-field sensing channel. Atypical EGM patterns can, however, occur in pace-sense conductor fractures, including oversensing that is precipitated by pacing and cyclical oversensing patterns.[34–36] Lead connection problems present with similar EGM patterns and are difficult to distinguish from conductor fractures. However, connection problems are most often temporally associated with an invasive CIED procedure such as implantation or generator replacement.

Data regarding EGM characteristics in insulation breaches of pace-sense circuits are limited to observational clinical series, and returned product analysis validation is limited to case reports.[19,31] In contrast to conductor fractures, insulation failures do not themselves typically generate abnormal signals but result in sensing of physiological signals from surrounding structures or nonphysiological signals, which are typically generated from the interaction of conductors. As such, EGM patterns in insulation breaches vary, reflecting the signal source.[36]

5.3. Impedance and Impedance Trends in Lead Failure

CIEDs periodically measure the entire circuit's resistance to direct current, which applies Ohm's law (R=V/I) and reflects the electrical circuit integrity. The pace-sense conductors' resistance to current typically contributes less than 15% of the entire circuit's resistance; therefore, impedance assessment and monitoring lacks sensitivity in pace-sense failures. In fact, impedance abnormalities occur in only a minority of pace-sense lead failures before the abnormalities are identified by oversensing diagnostics or inappropriate detection of ventricular tachycardia (VT) or ventricular fibrillation (VF). In contrast, the observation of abrupt, relative changes in impedance trends is more specific and is about as sensitive as an out-of-range impedance.[19,24,33] A single abrupt change could, however, be spurious, and a gradual rise in impedance without oversensing typically reflects increased resistance to current at the lead-myocardium interface, which by itself does not require lead revision in the absence of sensing and pacing abnormalities. A pacing impedance of less than 200 Ω can indicate an insulation breach of the pace-sense component.

Impedance measurements remain the primary diagnostic tool for high-voltage conductors. There are numerous considerations for the low-voltage, painless measurement of shock circuit impedance, including (1) typical low impedances for high-voltage cables and shock electrodes; (2) tissue resistance, which is inversely proportional to voltage, thereby affecting the estimate of high-voltage impedance based on painless measurement; and (3) the greater effect of respiratory

variability with low-voltage measurements. An abrupt increase in shock impedance (typically >75%) or a shock-impedance value greater than 100 Ω likely indicates shock conductor fracture, based on the returned product analysis of Medtronic leads connected to Medtronic generators.[37] The applicability of these specific threshold values for diagnosing conductor fractures in other manufacturers' leads has not been reported. Elevated shock-impedance values could also reflect a faulty connection of shock components. High-voltage insulation breaches result in low impedance values, but shock impedance trends in this setting have not been studied systematically, and no threshold values have been defined. Case reports have shown that shocks can short-circuit despite normal low-voltage painless measurements of shock impedance.[38,39]

5.4. Device Diagnostics to Mitigate Adverse Consequences of Pace-Sense Failure

5.4.1. Counts of Extremely Short R-R Intervals

Intervals near the ventricular blanking period are unlikely to represent successive ventricular activation, even in VF. Some devices keep track of nonphysiological sensed intervals in place of lead integrity. The utility of this feature has been studied systematically with the Medtronic Sensing Integrity Count, which stores the count of R-R intervals that are shorter than 130 ms. However, the most common cause of isolated, extremely short sensed R-R intervals is benign combinations of oversensed physiological signals or detection of environmental electromagnetic interference.[33] A rapidly increasing sensing integrity count is a sensitive indicator of conductor fracture, which in isolation has low specificity. It has been noted that elevated sensing integrity count values are more common with intact integrated bipolar leads than with intact dedicated bipolar leads.[40] Increasing episodes of nonsustained VT, particularly if characterized by rapid rates, should arouse suspicion for possible lead failure.

5.4.2. Algorithms That Incorporate Both Rapid Sensing and Impedance Monitoring

Lead Integrity Alert (Medtronic)

This was the first lead-alert algorithm to incorporate oversensing metrics and is the most extensively studied. The algorithm combines a rapidly increasing sensing integrity count with repetitive rapid oversensing and abrupt impedance changes.[33,40] Monitoring both rapid oversensing and impedance trends provides earlier warning of lead failure than a fixed impedance threshold.[9,40] This algorithm has been validated by returned product analysis, and multiple studies have assessed its clinical utility.[33,40] The false-positive rates have been generally low and even lower for dedicated-bipolar leads compared with integrated-bipolar leads, primarily due to more frequent triggering by electromagnetic interference in integrated-bipolar leads.[31,33,40] Prospective and retrospective observational data indicate that lead integrity alerts (LIA) improve early detection of Fidelis lead fractures and reduce inappropriate shocks compared with monitoring impedance alone.[33,40] Other published studies have indicated that LIA also improve detection of conductor fractures in other models of Medtronic leads, which has been confirmed by returned product analysis.[34] Retrospective, observational, clinical studies have found that this algorithm identifies failures in defibrillation leads from various manufacturers.[19,41]

Latitude Lead Check (Boston Scientific)

This algorithm is qualitatively similar to Medtronic's LIA and alerts for either rapid, repetitive oversensing or out-of-range pace-sense impedance. A potential advantage of this algorithm is that it is incorporated within the remote monitoring system network, not the ICD; thus, it can be regularly updated for all patients. To date, no peer-reviewed publications have assessed this algorithm's clinical performance.

5.4.3. Algorithms That Compare Sensing and Shock EGMs

Two currently employed algorithms—Medtronic's Lead Noise Algorithm (LNA) and St. Jude Medical's SecureSense—identify oversensed, nonphysiological, pace-sense signals as those that do not correlate temporally with EGMs on the shock channel. There are differences in the design of LNA and SecureSense, but both withhold shocks if sufficient evidence of oversensing occurs.[42,43] Algorithm failures can be caused by a false-negative assessment, resulting in failure to withhold inappropriate therapies for true lead failure or a false-positive assessment with the algorithm being triggered by conditions other than lead failure. In the latter, failure to deliver appropriate therapy for life-threatening arrhythmia is of greatest concern. Neither algorithm identifies right ventricular (RV) coil fractures in integrated bipolar leads or simultaneous nonphysiological signals on sensing and shock channels, such as those caused by cable-coil abrasions. The differences in design of these algorithms might account for the variability in algorithm failure modes.

In bench testing, SecureSense identified simulated lead failure signals (97.1% of sustained episodes, 90.4% of nonsustained episodes) and did not withhold shocks from 100% of induced VF episodes.[43] A systematic analysis of this algorithm's clinical performance has not been reported. Case reports and small series have documented false positives, mostly for clinically insignificant events.[44]

In bench testing, LNA identified 83% of simulated lead failure signals and did not withhold shocks from 100% of stored EGMs of spontaneous VT and VF episodes.[42] In a prospective clinical study, the maximum delay for detecting 196 episodes of induced VF episodes was 2 seconds.[45] In the PainFree SST trial, this algorithm withheld all shocks from only 3 of 11 patients (27%) with clinically diagnosed lead failure and did not withhold therapy from any of the 3901 adjudicated and treated VT and VF episodes.[46]

5.5. Device Diagnostics to Mitigate Adverse Consequences of Shock-Component Failure

Shock-component failure is monitored primarily by standard shock impedance assessment.[37] In in vitro studies, new high-

frequency measurements of impedance appear to be able to detect partial, high-voltage insulation breaches.[47] One manufacturer (St. Jude Medical [now Abbott]) provides an automatic shock-vector adjustment algorithm (Dynamic Tx) that removes a shorted high-voltage pathway from shock delivery in a dual-coil lead, but no systematic data have been published to date about this feature.

5.6. Role of Remote Monitoring

Devices with wireless telemetry automatically detect and transmit stored data, including lead alerts.[48] Observational studies support the use of remote monitoring to facilitate diagnosis of lead failure.[49] Limited observational data suggest that wireless remote monitoring, when combined with LIA, reduces inappropriate shocks more than LIA alone.[50] The role and importance of remote monitoring in the diagnosis of lead failure and monitoring at-risk leads have been endorsed by consensus statements from the HRS and the Canadian Heart Rhythm Society.[51,52]

5.7. Caveats in Diagnosis of Lead Failure

In suspected lead failure diagnosis, it is important to differentiate true lead failure from other causes of false-positive impedance rises and rapid oversensing that could be mistaken for lead failure.

Swerdlow et al analyzed leads that were clinically diagnosed as failures, were explanted, and were subjected to returned product analysis.[34] Their study analyzed normally functioning leads with impedance rises and compared impedance trends and EGMs in leads that were confirmed to have failed compared with leads that were confirmed to be normal and intact except for explant damage. The study included 40 fractured leads, 30 with connection problems, and 21 functioning leads that triggered high-impedance alerts. An algorithm was developed in this study to distinguish failed leads from both header-connection problems and benign impedance changes at the electrode-myocardial interface. This algorithm was subsequently validated prospectively in a set of 100 leads. Briefly, (1) either extremely high maximum impedance or noise oversensing with a normal impedance trend indicated a fracture; (2) short temporal interval from surgery to impedance rise or prolonged stable impedance after an abrupt rise indicated a connection problem; and (3) gradual impedance increase or stable, high impedance indicated a functioning lead. The algorithm was found to correctly classify 100% of fractures and 87% of connection problems that had been misdiagnosed as fractures.

Case reports have documented rare occurrences of lead interactions and perioperative air in the header, each of which can trigger lead alerts.[53,54] Multiple recent reviews have discussed the approach for patients with suspected lead failure.[31,36]

6. Lead Recalls and Advisories

6.1. Background

6.1.1. Introduction

Lead advisories or recalls refer to notifications to patients, providers, and regulators that a lead has failed to meet the prespecified expectations for performance.[55] Malfunction (or more often failure) exceeding expected rates is based on returned product analysis, customer reported failures, postmarketing registry reports, or remote monitoring. The precise terminology is primarily determined by regulator language, given the vast majority of leads are not extracted from patients and returned to the manufacturer.[55,56] Random component failure is the term used to describe an unavoidable rare failure that does not reflect a systematic failure mechanism over-represented in a particular lead model. Advisories are typically reported when a lead manifests a specific mechanism of component failure, attributed to a component or an assembly flaw that leads to lead failure, which can involve any of the lead components (insulation, conductors, connectors).

6.1.2. Lead Surveillance History

The growth of CIED implants with increasingly complex lead systems has led to a greater need for surveillance and reporting. Lead manufacturers generate product performance reports that have evolved over time to become in-depth online reports that detail lead performance. The degree of rigor of review and reporting has increased over time, often prompted by lead recalls/advisories that have led regulators and physicians to increase the sample size of prospective registries.[55,56] Remote monitoring has transformed the oversight and reporting of lead performance, because the scale of observations has increased exponentially. Rare but life-threatening performance concerns are readily placed in context when information on hundreds of thousands of comparable leads can be readily accessed. Manufacturers have also markedly enhanced their internal quality processes at the component and assembly level and continue to request input from expert physicians at "arm's length" when concern is raised over lead performance metrics.

6.1.3. Historical Lessons

Several notable examples of lead performance advisories have shaped the evolution of lead design and performance management, including the Telectronics Accufix pacing leads, which were recalled in November 1994 after two deaths and two nonfatal injuries were reported.[57] The failure mechanism was protrusion of an electrically inactive J retention wire, which fractured and protruded from the polyurethane insulation, resulting in laceration of the right atrium (RA) and rare embolization to the pulmonary circulation. This landmark recall prompted the formation of a multicenter clinical study and a global registry that tracked clinical failure-related events and complications of interventions when leads were extracted. Notably, more deaths were reported from interventions than from lead-related trauma or embolization.[57]

Around the same time, a widespread lead problem focused on the durability of a type of polymer used in bipolar polyurethane pacing leads such as the Medtronic 4004 model. This polymer was associated with an increased risk of stress

fracture and insulation breach, particularly evident when the subclavian vascular access approach was used.[58] This problem highlighted the roles of lead component materials and surgical technique on lead performance.

Since then, most concerns about leads have stemmed from ICD leads, whose more complex design and high-voltage components have been associated with systematically higher failure rates than those of pacing leads.[31] Kleemann et al reported on 990 ICD leads (from multiple generations and manufacturers) that were implanted between 1992 and 2005, finding a 20% failure rate at 10 years.[8] Ellenbogen et al evaluated the long-term reliability of the Medtronic 6936 coaxial polyurethane ICD lead in the 1990s, reporting a striking 37% failure rate at 69 months of follow-up.[59] This study reported a late failure mechanism after acceptable performance in the first 3 years, thus launching the development of lead failure recognition algorithms characterized by detection of nonphysiological short sensing intervals.[19]

The next major lead advisory took place in 2007, affecting the Medtronic Fidelis lead, whose malfunction was characterized by a higher-than-expected lead failure rate related to conductor fractures attributed to features designed to reduce the lead's size and enhance the lead's flexibility, which permitted bending with a short curvature radius. More than 90% of Fidelis fractures were caused by fracture of one of the two pace-sense conductors, the inner coil near the tie-down sleeve or the cable to the ring electrode near the distal shocking coil.[32,33,50] Initial clinical presentations were characterized by a high incidence of inappropriate shocks, which was markedly attenuated by the LIA algorithm.[19,33] Fracture rate estimates have ranged from 1.5% to 3% per year, a clear excess in relation to several other concurrent lead models.[32,50,60]

The most recent major advisory concerned the St. Jude (now Abbott) Riata ICD leads, characterized by frequent externalization of conductor coils and an increased risk of lead malfunction.[61] The root cause of externalization was attributed to a design that included redundant cables with stiff ethylene tetrafluoroethylene insulation in large channels, which resulted in cable sliding, "inside-out" erosion, and insulation that did not use an outer "jacket." The Riata family of leads exemplifies the decision-making challenges faced by clinicians because the mechanical externalization rate for select models can be as high as 25%–30%, whereas electrical failure rates range from 2% to 4%.[61] The long-term risk for mechanical failure due to extruded cables is unknown. These leads also represent an inherently more complex and high-risk extraction challenge because of the externalization of the coils, although the data suggest that extraction outcomes are comparable to other lead models in experienced hands.[62]

6.2. Thresholds and Targets for Lead Performance

Lead performance has steadily improved over time, and regulators have set targets for the extent of data necessary for prospective lead follow-up to ensure postmarketing surveillance detects evidence of unsatisfactory lead function.[63] Despite these stringent standards, a clear consensus has not arisen regarding acceptable thresholds for annual failure rates for pacing or ICD leads to guide manufacturers, regulators, or clinicians. Defining these targets would benefit all stakeholders when responding to data from surveillance, assisting the decision-making process when notifying the relevant parties and when removing a lead from ongoing use. By definition, these targets are empirical, although they are informed by historical lead performance that sets targets based on currently available lead models. The current long-term lead performance of currently available ICD leads suggests that annual failure rates should not exceed 0.4% per year and that annual failure rates for pacemaker leads should not exceed 0.2% per year in the first 10 years of the leads' implanted life cycle.[3–5,11] Many currently available leads from the range of manufacturers meet these targets, although data beyond 10 years are limited. These data have been generated from leads using DF-1 connectors and not the DF-4 connector that is now in common use. Data on long-term performance of left ventricular (LV) leads are also less plentiful, especially with the advent of quadripolar leads that currently dominate implant practice. These targets therefore primarily apply to right-sided leads, until further data on quadripolar LV leads set target performance standards.

6.3. U.S. Food and Drug Administration

6.3.1. U.S. Food and Drug Administration Determination of Lead Safety and Effectiveness

The Office of Device Evaluation in the Center for Devices and Radiological Health within the U.S. Food and Drug Administration (FDA) is responsible for overseeing the market approval of all pacemaker and defibrillator leads and all CIEDs in the United States. The focus of premarket assessment of any device, including leads, is to ensure that it has a reasonable assurance of safety and effectiveness.

Premarket testing often includes some variation of bench, animal, and clinical investigations. The FDA requires bench testing of all pacemaker and defibrillator leads, which includes standardized testing recognized by the International Organization for Standardization that assesses the leads' mechanical and electrical performance, biocompatibility, and interchangeability. To assess potential failure mechanisms, other bench testing is also performed, such as flex-fatigue testing, which can simulate the stress of a transvenous lead, flexing with each myocardial contraction over several patient years. The required animal studies vary in size and duration, depending on the particular safety or handling issues for a given lead. The FDA is collaborating with a number of stakeholders, including industry, physicians, and the Association for the Advancement of Medical Instrumentation, to provide new lead testing standards.

The FDA requirement for premarket clinical data is determined on a case-by-case basis and is based on design differences with a similar lead that is already market approved. The nature and significance of the lead modifications factor into whether a premarket clinical study is necessary. Although the lack of a blanket requirement for clinical data on every lead prior to approval has been controversial, the size and duration

of a study to detect certain failures, particularly those that occur infrequently or late, can be prohibitive.[64,65] Over the past several years and in part due to the ICD lead recalls during this timeframe, the FDA has continued to adjust both its premarket requirements and postmarketing surveillance data collection requirements for all new ICD and pacemaker leads.

6.3.2. U.S. Food and Drug Administration Postmarketing Surveillance

The FDA is also responsible for postmarketing surveillance to monitor for safety signals in any given device or lead. The focus of postmarketing surveillance is to ensure that all devices, including leads, perform as intended and do not harm the patient. The failure mode for leads is often not entirely new or previously unidentified but rather occurs at a higher rate than with other similar leads. Hospitals and device manufacturers are required to report lead-related failures that clearly caused (or might have caused) death or serious injury. Underreporting can occur, however, because physicians are not required to report these failures, particularly when there was no serious harm. Devices and leads are frequently not returned to the manufacturer to allow for root-cause testing. When the leads are returned, they are often severely damaged from the extraction procedure, limiting the ability to perform a returned product analysis on the leads.[64] The FDA receives several hundred thousand reports annually on device-related adverse events, which are submitted and saved to the Manufacturer and User Facility Device Experience (MAUDE) database.

Postmarketing lead surveillance requirements have changed over the past several years. Since 2008, manufacturers have been required to conduct a 5-year, 1000-patient minimum, postapproval study on all new or substantially modified ICD leads to reliably capture all lead failures in a large patient cohort and to hopefully detect failures that either occur late or occur relatively infrequently.[64]

6.3.3. Unique Device Identification

The FDA has been working to establish the unique device identification (UDI) system, which requires all medical devices and packages to carry a unique numeric or alphanumeric code. The UDI code includes a device identifier, which identifies the model and includes the production identifier, which identifies the manufacturer lot number, serial number, expiration date, and manufacturing date. This requirement will be phased in over the next 5 years. The UDI system will enable a more streamlined and accurate collection of lead-related adverse events and facilitate the use of large registries for postmarketing data surveillance. The UDI system will enhance the management of lead recalls by recording all leads implanted in the United States in a searchable central database.[55,63–65]

6.4. Lead Recalls

If a device manufacturer determines that a device recall is warranted, the FDA will be notified and may issue a public notification along with the manufacturer's notification to ensure widespread awareness of the recall. Information on recalled leads will be posted on the FDA website, the manufacturer's website, and the HRS website.

The FDA classifies recalls as class I, II, or III, depending on the recall's severity and nature.[63–65] The classification depends on the severity and likelihood of the health risk. Both the Fidelis and Riata ICD lead recalls were classified as class I. A recall indicates that the lead model is being removed from the shelf immediately and can no longer be implanted; however, the recall does not necessarily indicate that the lead needs to be removed or replaced. For implanted leads, a recall may involve patient monitoring and management strategies. The FDA does not regulate the practice of medicine. However, the FDA will make general recommendations based on the available information at the time of the recall and will update the recommendations as new information is received. The manufacturers and professional societies will also issue their own recommendations to patients and physicians.

When the Fidelis ICD lead recall was announced on October 15, 2007, the FDA classified it as a class I recall and stated that they concur with Medtronic's recommendations to adjust the ICD settings.[64] Medtronic recommended several specific programming changes to optimize the lead impedance alert efficacy and to turn on the patient alert to reduce the likelihood of an inappropriate shock. The FDA strongly recommended against the routine extraction of these leads and stated in the recall notice that "neither FDA, Medtronic, nor representatives of the Heart Rhythm Society, recommend the routine surgical removal of a fractured lead because removal carries risks."

Occasionally, the FDA will update its recommendations regarding a lead recall or will ask the manufacturer to gather additional information. An example of this is the St. Jude (now Abbott) Riata ICD lead recall in November 2011, which was also classified as a class I recall. The FDA, however, believed there was insufficient information to answer the following important lead management questions: (1) How frequently does the Riata lead insulation fail? (2) What is the typical time to failure? (3) Does externalization of the electrical conductors increase the risk of future ICD lead electrical failure? (4) What are the risk factors that contribute to insulation failure or externalization of the electrical conductors? The FDA therefore released a safety communication in 2012 with updated recommendations and a public notification that Abbott will be conducting a 3-year postmarketing surveillance study. This safety communication recommended that physicians perform baseline imaging of Riata and Riata ST leads to assess externalization. The imaging assessment could also be performed when changing the generator. For patients with known externalized leads, assessment could be performed at repeated intervals to determine progression. This surveillance study, also known as the Riata Lead Evaluation Study (RLES), was intended to gather data on externalization and electrical failures and to enroll a minimum of 300 Riata and 200 Riata ST leads. The study was then expanded in 2013 to include the QuickSite, QuickFlex, and Durata leads (the Cardiac Lead Assessment Study). All

patients enrolled in these studies also underwent annual imaging as a required part of the study.

Similar to the Fidelis recall notice, this safety communication stressed that "the FDA, St. Jude Medical [now Abbott] and the Heart Rhythm Society do not recommend routine removal of any leads due to the risks of explantation surgery." The FDA did not recommend routine replacement of leads with abnormal imaging and normal electrical function. Although an association between externalization of cable conductors and electrical failure has been identified in some studies, the RLES, which was the largest prospective assessment of patients implanted with Riata or Riata ST leads (n=776), showed no association between externalization and electrical failure.[56] The most recent product performance report from St. Jude Medical (now Abbott) stated that as of February 28, 2017, a total of 346 (45%) patients from the Cardiac Lead Assessment Study completed at least 3 years of follow-up with fluoroscopy evaluation. To date, the electrical failure rate for the Riata and Riata ST leads is 5% (10 of 195) for externalized leads and 3% (18 of 581) for leads without externalization (P=.19, NS).[66]

The HRS issues general recommendations regarding lead advisories, recalls, and factors to consider when formulating a plan for individual patients.[66] Professional societies such as the HRS can provide clinical guidance to, as well as partner with, regulatory agencies and industry to help notify its members and educate clinicians on the causes and recommendations for any given lead recall. The current recommendations for Fidelis and Riata leads issued by the FDA and supported by the HRS are listed in Appendix 4.

7. Existing Cardiovascular Implantable Electronic Device Lead Management

COR	LOE	Recommendations	References
I	C-EO	**Leaving the lead in a condition that will permit future extraction and prevents retraction into the vessel is recommended for any abandoned lead.**	

If an abandoned lead is transected and allowed to retract into the vascular system, it could move to the ventricle or pulmonary artery, triggering arrhythmias or thrombosis. If transected, suturing the lead stump in the pocket facilitates future access to the lead and might reduce the risk of retraction into the vessel. In leads prone to developing inside-out erosion, transection could facilitate cable extrusion. If a lead is transected, it might not be possible to subsequently disengage an active fixation mechanism if the lead needs to be removed. Preserving the lead terminal connector could enable future disengagement of the active fixation mechanism but increases the amount of hardware in the pocket.

I	C-EO	**Careful consideration with the patient on the decision on whether to abandon or remove a lead is recommended before starting the procedure. The risks and benefits of each course of action should be discussed, and any decision should take the patient's preference, comorbidities, future vascular access, and available programming options into account.**	

When a lead is replaced due to failure of function, supplanted by an alternate lead (eg, pacemaker advanced to an ICD), or not used due to a change in the clinical situation (eg, atrial lead in atrial fibrillation) or when a lead becomes nonfunctional, a decision needs to be made as to whether the lead should be removed or left in situ, weighing the risks and benefits of each strategy.

The risks of removal include venous or cardiac perforation requiring emergency surgery and depend on multiple factors, including the duration of the lead implant, the number and types of lead (ICD vs pacing), the patient's age and health, the presence of prior sternotomy, and the experience of the operator and their team.

The benefits of removal include removal of unnecessary hardware that might be harder to remove in the future for a mandatory extraction indication such as infection; allowing magnetic resonance imaging (MRI), which is generally contraindicated in the presence of abandoned leads; and creation of an access channel through an occluded vein to allow a lead to be implanted.

IIa	B-NR	**Lead abandonment or removal can be a useful treatment strategy if a lead becomes clinically unnecessary or nonfunctional.**	67–69

Single-center observational studies have compared outcomes in patients undergoing lead abandonment vs extraction in the setting of lead malfunction.[67,68] Over average follow-up times of approximately 3 years, there were no differences in the complication rates or clinical outcomes. In an analysis of the National Cardiovascular Data Registry (NCDR), there was a small increase in risk of procedural complications and mortality in the extraction group compared with patients who underwent a lead abandonment strategy.[69] Data are limited by the observational nature and limited follow-up.

7.1. Lead Management during Cardiovascular Implantable Electronic Device Replacement

In the setting of planned CIED generator replacement or exchange, expectant management of normally functioning, nonrecalled leads is usually preferable to routine lead revision or extraction procedures due to the comparatively lower risk of complications in generator exchange procedures compared with lead extractions. Nevertheless, as in any area of medicine, the unexpected does occur, and the proceduralist should be prepared to respond to unexpected findings that require lead revision or extraction.

7.1.1. Complications of Generator Exchange

Substantial clinical data over the past decade have revealed a surprisingly high risk of complications associated with generator exchange procedures, particularly when systematically assessed, or when including a several-month follow-up (Appendix 5). Direct periprocedural complications occur in 1%–2% of cases, but the overall short-term complication rate is substantially higher (approximately 4%; range 0.6%–8.2%).[70–73] Common major complications include lead dislodgement requiring revision (0.07%–3.2%), infection (0%–5.2%), and hematoma requiring evacuation (0%–1.6%).[70–73] Procedure-related death is rare, occurring in only 0%–0.4%.[70–73] Minor complication rates range from 2.3% to 7.4%, and include infections treatable with

antibiotics, hematoma, pain, and other minor surgical wound problems. It is important to note that not only is generator exchange associated with a 2.2-fold increased risk of pocket-related complications compared with an initial CIED implant, a marked increase in the complication rate occurs over subsequent procedures, ranging from 1.5% for the first to 8.1% for the fourth implanted ICD generator.[74]

These findings highlight the importance of minimizing adverse events by making every effort to reduce overall generator exchanges per patient. This goal can be best accomplished by choosing devices with superior battery longevity, ensuring best possible thresholds at lead implant, avoiding placement of unnecessary leads, and using programming strategies that decrease current drain and minimize unnecessary pacing and the use of ICD therapies.[75,76] Determining the optimal battery choice can be challenging; there are significant differences in battery longevity among manufacturers, and past battery longevity from one manufacturer does not necessarily predict future performance in another.[76]

7.1.2. Risk Factors for Complications and Mortality

Patient, proceduralist, and CIED system factors influence the risk of complications. Adverse periprocedural events are associated with patient comorbidities such as worsening angina, heart failure, antiarrhythmic drug use, valvular disease, renal failure, diabetes, anticoagulation or antiplatelet use, corticosteroid use, chronic pulmonary disease, cerebrovascular disease, prior CIED infection, malignancy, fever, and dermatologic disorders.[72,77]

There are a considerable number of procedural factors that increase the complication rate for generator exchange and include reoperation for dislodgement, hematoma, lack of antibiotic prophylaxis, temporary pacing, low implanter volume (<60–70 CIED procedures per year), procedural complications, greater number of leads, the use of defibrillators compared with pacemakers, and the use of biventricular devices.[71,72,77] Unsurprisingly, comorbidities influence the mortality risk for generator exchange. Older age, atrial fibrillation, heart failure, diabetes, renal dysfunction, lung disease, and cerebrovascular disease are associated with an increased risk of death.[73]

7.1.3. Evaluation of Defibrillator System at Generator Exchange

The *2015 HRS/EHRA/APHRS/SOLAECE Expert Consensus Statement on Optimal Implantable Cardioverter-Defibrillator Programming and Testing* provided recommendations on the intraprocedural analysis of ICDs, including the use of defibrillation threshold testing.[78]

7.1.4. Risk of Lead Failure after Generator Exchange

There are limited data on whether the risk of lead failure increases after generator exchange. In a large series of 60,219 ICD patients followed on the Boston Scientific's LATITUDE platform, the incidence of lead alerts markedly increased after generator exchange compared with the control population (hazard ratio [HR] 5.19 [95% CI 3.45–7.84]), many within the first 3 months of generator exchange.[79] Two series of patients with Fidelis leads reported conflicting results associated with generator exchange (20.8% failure rate after generator exchange vs 2.54% in matched controls, $P<.001$ in one study, and in another study a 3.6% incidence of lead failure after generator exchange compared with 3.5% in controls, $P=.962$).[80,81] The lead failure rate did not increase in the first year after generator exchange in a series of patients with Riata leads (1.5% vs 2%, $P=.32$).[82]

7.1.5. Shared Decision Making

It is increasingly clear that ICD generator replacement should not be an automatic decision but one that warrants careful thought and discussion with the patient about values and goals. This is of particular relevance in the elderly ICD population, in which age and increasing comorbidities might reduce the benefit of sudden death prevention, and neither the operative risks of the procedure itself nor the short-term risk of complications is small.[83]

7.2. Lead Management during Cardiovascular Implantable Electronic Device Upgrade

7.2.1. Upgrade Procedure Preparation

Many of the clinically important circumstances described in the generator exchange section above are applicable to CIED upgrade and revision procedures, particularly awareness of the risks of complications and ways to avoid adverse events. This section focuses on clinical issues specific to procedures in which a lead is added to an existing CIED system. These procedures include upgrading single-chamber systems to dual chamber, pacemakers to ICDs, and either pacemakers or ICDs to systems that provide biventricular pacing, as well as lead revision procedures that require addition of a new lead due to lead malfunction or dislodgement.

7.2.2. Complications of Lead Upgrade and Revision Procedures

The risk of immediate procedural and short-term adverse events in upgrade procedures is strikingly higher than in generator exchange procedures. In the REPLACE Registry, the overall risk of major and minor complications at the 6-month follow-up in the 713-patient upgrade cohort was 15.3%, compared with 4% in the 1081-patient generator exchange cohort, and the rate was higher in procedures involving an LV lead (18.7%).[71] The most frequent complication was lead dislodgement (7.9%), followed by prolonged hospitalization (2.5%), hematoma (1.5%), death (1.1%), hospital readmission (1.1%), infection (0.8%), and perforation (0.7%).[71] Similarly, in a large two-center series of new implants (n=1511), generator exchange (n=1034), and upgrade (n=126), pacemaker implantation and generator exchange had a similar risk of major complications (1.7%), with higher complication rates for ICD implantation (3.5%) and upgrade procedures (6.1%), particularly if an LV lead was implanted (9.5%).[84]

Likewise, increased and unexpectedly high complication rates in pacemaker upgrade procedures (when compared with initial implantation) have been reported for patients with pacemakers, although focused studies were reported in the late

1990s, when upgrade procedures were less common.[85] The incidence of major complications was high (16.7%) in patients undergoing atrial, ventricular, or LV lead upgrade in the Danish Multicenter Randomised Study on AAI Versus DDD Pacing in Sick Sinus Syndrome (DANPACE).[86]

7.2.3. Venous Occlusion

A relatively high rate of subclavian venous occlusions has been reported for patients with chronically indwelling leads. Single-center observational series of up to 356 patients undergoing planned upgrade CIED procedures have shown complete occlusion rates of 3%–26%, a >75% stenosis rate of 10%, and moderate (50%–75%) stenosis rates of 6%–37%.[87–89] Clinical factors associated with stenosis include number of leads, ICD leads vs pacemaker leads, lead dwell time, and multiple procedures. A preparatory venogram or noninvasive ultrasound prior to opening the pocket to assess venous patency should be considered.[87–89]

7.2.4. Lead Choices

When choosing to add a lead to an already existing CIED system, there are numerous clinical decisions regarding the type of lead, whether to include a single- or dual-coil ICD lead, whether to use a passive or active fixation mechanism, whether to add a pacing lead or a new ICD lead in the setting of a pace-sense component malfunction, and the optimal positioning of a new lead in the chamber.[78]

7.2.5. Incorporating Preexisting Leads

Given the limitations of venous access and space in both the central venous system and the heart, a minimalist strategy aimed at reducing the risks of lead additions is practical, and previously placed functioning leads should be integrated into new systems. Data suggest a low risk of lead-related complications when suitable preexisting leads are combined in an upgrade procedure.[89]

7.2.6. Addition of a Pace-Sense Lead

If an ICD lead failure can be localized to the pace-sense portion and the high-voltage component is known to be reliable, the addition of a pace-sense lead would be a potentially viable strategy that reduces complexity and bulk in the ICD pocket. An observational comparison of 24 patients who underwent a pace-sense lead addition and a contemporaneous group of 13 patients requiring addition of a new ICD lead had no substantial differences in outcomes. However, the long-term recurrent lead failure rate was high in both groups (16% of patients at 3 years of follow-up).[7] In a series of 151 patients undergoing ICD revision with the addition of a pace-sense lead in localized defects, 28% of patients experienced a lead-related complication, and the event-free cumulative survival rate of the added lead was 89.6%, 82.0%, and 60.0% at 1, 2, and 5 years, respectively, for pectoral leads.[90] A follow-up study from this group comparing the outcomes of a nonrandomized series of patients undergoing pace-sense lead addition to those undergoing lead extraction and ICD lead replacement in 85 patients showed no statistically significant differences in complications, mortality, or lead survival after up to 3 years.[91] Long-term lead survival rates of 100%, 93%, and 87% at 1, 2, and 3 years, respectively, were reported in a series of 45 patients undergoing pace-sense lead addition.[92] Single-center studies have reported that ICD lead abandonment does not appear to be associated with an increased risk of overall complications, lead defects, defibrillation failures, or venous occlusion.[93] These older studies evaluated this strategy in nonadvisory leads. Recent modeling studies suggest that, due to the progressive failure rate, implanting a new ICD lead in patients with Sprint Fidelis leads (with or without extraction) is cost-effective and associated with fewer adverse outcomes than adding a pace-sense lead.[94,95]

7.3. Device Downgrade

When the generator is exchanged due to battery depletion, there is an opportunity to review the indication and appropriateness of the device in relation to the patient's current clinical status, prognosis, and wishes. Discussion with the patient and, if appropriate, his or her family is important to achieve shared clinical decision making.[1,78,96]

When considering replacement of a primary prevention ICD with no history of relevant ventricular arrhythmias, the patient's prognosis, original indication for the ICD, and current LV function should be considered. There are data suggesting that our current significant dependence on LV ejection fraction for assessing risk has limitations.[97,98] Patients who receive an ICD for primary prevention and subsequently have a significant improvement in ejection fraction experience reduced mortality and appropriate ICD therapies, but not complete freedom from significant ventricular arrhythmias.[97–100] If there have been no ventricular arrhythmias and the ventricular function has significantly improved or if the patient has a prognosis of less than 1 year or has developed significant comorbidities, it might be appropriate to not replace the ICD generator or, for pacemaker-dependent patients, replace the ICD with a pacemaker.[97–100] For patients with an ICD that also provides cardiac resynchronization therapy (CRT-D) and who have severe, intractable symptomatic heart failure with no prospect of transplantation or a ventricular assist device, it might be appropriate to downgrade the device from CRT-D to a device that provides cardiac resynchronization therapy without ICD capabilities (CRT-P).

When changing from an ICD to a pacemaker, the issue of lead compatibility should be carefully considered before the operation. The ICD lead connector should be identified as DF-1 or DF-4. For a CRT device, the terminal connector of the LV lead should be identified. With a DF-1 ICD lead, the

ICD coil terminal pins can be capped, and the IS-1 pace-sense terminal pin connected to a replacement pacemaker. There is currently no DF-4 to IS-1 connector for a DF-4 lead. Alternatives are to implant a new IS-1 pace-sense lead, use the DF-4 lead in the left ventricle port with a CRT-P device, or replace with a DF-4 ICD generator with the shock function disabled. Given that the device is being downgraded because of the patient's condition, it might be reasonable to avoid a new lead implant, particularly if the venous system is occluded. In these cases, replacing with a new ICD (with shock function disabled) might be simpler, safer, and possibly cheaper overall, even though the device cost will be higher.

In general, a pacemaker should be replaced with a similar generator. However, for patients with a dual-chamber device, who have developed permanent atrial fibrillation, the alternatives when replacing the generator due to battery depletion are to implant a single-chamber device and cap the atrial lead (which can affect access to MRI) or to implant a new dual-chamber device programmed to a ventricular pacing mode (which might be more expensive but could have a larger battery with a longer interval until the next generator change).

7.4. Nonfunctional and Abandoned Leads

With older ICD lead models, failure is increasingly common over time, with reported failure rates of 7%–16% at 8–10 years.[8,101] Implantation of a new lead might be indicated, particularly if, at the moment when the generator is exchanged, the existing indwelling lead has not failed if the risk of future failure of that lead outweighs the risks of a new lead implant. The clinician should also consider the patient's age, physical and mental condition, prognosis, and wishes. If a lead does fail, is replaced for some other reason, or becomes nonfunctional, a decision needs to be made as to whether the lead should be removed or remain in situ, weighing the risks and benefits of each strategy.

The risks of removal include venous or cardiac perforation requiring emergency surgery and depends on multiple factors, including the lead implant technique, duration of the lead implant, the number and types of lead (ICD vs pacing), the patient's age and health, the presence of prior sternotomy, and the experience of the operator and that of their team.[1] Nomograms to estimate the risk of removal have been developed, and the factors that affect the extraction risk are detailed in Section 10.[102] The benefits of removal include removal of unnecessary hardware that might be harder to remove in the future for a mandatory extraction indication such as infection ("a lead will never be easier to extract than it is today"), preservation of access to MRI, and creation of an access channel through an occluded vein to allow a lead to be implanted.

The risks of abandonment include inability to implant a new lead due to lack of venous access, lead-lead interaction, tricuspid valve damage, and traditionally contraindication to MRI.[1] An experimental study reported excessive heating of an abandoned lead with MRI, although preliminary clinical studies have reported no adverse effects associated with MRI and abandoned leads or remnants.[103–107] Interactions between an abandoned lead and a functional lead rarely cause oversensing, although leads can rub together causing an insulation break. The incidence of tricuspid insufficiency can increase with more than one transvalvular lead.[108] The mechanical consequences of extruded cables in Riata leads is unknown. The major benefits of abandonment are the prevention of risks from removal and that of a simpler procedure, which can be performed by an operator who is not trained in extraction in an environment that is not set up for extraction.

Both present and potential future vascular access issues could affect the decision as to whether to abandon a lead or extract. Venous stenosis and obstruction due to leads is generally asymptomatic because it occurs gradually and collaterals develop, although severely limiting symptoms due to obstruction of the superior vena cava (SVC) or the large central veins do occur and are difficult to resolve. Venous obstruction to any degree has been found in 25% of patients at their first ICD generator replacement, with complete occlusion in 9%.[109] There is an association between the number of leads and the sum of their diameters in contributing toward venous stenosis.[110] However, no study has directly linked abandoned leads to venous thrombosis. The maximum number of leads that can be implanted in a vein with an acceptably low risk of complications is controversial. In a recent survey, European electrophysiologists had a wide variety of responses to the question of how many leads could be implanted in a vein, depending on the patient's age, with three to four leads considered reasonable in the SVC of a younger patient and up to five in the SVC of an older patient, with as many as three to four leads implanted in the subclavian vein.[111]

Single-center studies have reported their experience with abandoning leads and have found either a low rate of complications for abandoned leads or no difference in outcomes between abandoning and extracting.[67,68,110,112,113] Several authors have addressed this controversy, and surveys of pediatric electrophysiologists and European extraction centers have shown a wide divergence of opinion.[114,115] A recent analysis of the NCDR linked to the Medicare database using propensity matching found a higher in-hospital complication rate with lead explantation when compared with lead abandonment, with no significant differences in mortality detected at 1 year.[69] The decision on whether to abandon or extract a lead is complex, and some of the nuances that should be considered in individual patient care are highlighted in Table 2. Some of the most important clinical considerations affecting the decision are the patient's age, projected longevity and comorbid conditions, the number of leads currently implanted, the leads' physical characteristics, the battery status, and the strength of the indication for surgical intervention.

Table 2 Lead abandonment clinical scenarios

Patient scenario	Management strategies	Key points
An 86-year-old man with complete heart block who underwent dual-chamber pacemaker implantation 14 years ago, with most recent generator replacement 3 years ago. Two leads are in place. His medical history is significant for chronic lymphocytic lymphoma and recently diagnosed prostate cancer. He presents with noise on the right ventricular lead and inhibition of ventricular pacing consistent with lead malfunction.	• Assess possibility of reprogramming to unipolar. • Consider likelihood of ipsilateral venous occlusion, which would require contralateral lead placement for addition. • Management options discussed included extraction of 14-year-old pacemaker lead with new lead implantation vs abandonment of old lead and placement of new right ventricular lead. • Values elicited in discussion included patient's desire to avoid hospitalization and not wanting to be dependent on his children. • Although the risks of lead addition and lead extraction are comparable in the literature, the risk of major complications and a more prolonged hospital stay appear higher for an extraction procedure, particularly given the patient's advanced age, comorbidities, and older leads. The decision was made to add a new pace-sense lead and abandon the previously placed lead.	• Age and medical comorbidities contribute to the lead management decision making. • Lead type and dwell time contribute to the risk and benefit analysis in lead management decision making. • Abandoned leads are a contraindication for MRI, which is often used in the follow-up of cancer.
A 46-year-old woman with a history of mechanical mitral valve replacement complicated by complete heart block, who underwent placement of a dual-chamber pacemaker 3 years ago. She presents with dislodgement of the atrial lead associated with symptoms of loss of AV synchrony.	• Management options discussed included extraction and replacement of atrial lead, attempt to reposition, and addition of a new atrial lead. • Values elicited in discussion included the desire to have the best possible functional CIED system and not have abandoned leads, even if this resulted in a longer hospital stay due to anticoagulation management. • Despite the mechanical mitral valve, the ease of extraction of a 3-year-old pacemaker lead is reasonable. The decision was made to extract and replace the lead.	• Young age and long-term need for functional CIED therapy and the desire to avoid an abandoned lead contributed to the decision-making process.
A 25-year-old man who underwent a secondary prevention ICD placement with a dual-coil lead 14 years ago for a ventricular fibrillation cardiac arrest. His ICD lead fractured 6 years ago, and he underwent addition of a new ICD lead and abandonment of his first ICD lead. During the follow-up, the new ICD lead was found to be fractured, with inappropriate detections due to noise.	• Management options discussed included adding a third lead; abandoning both transvenous ICD leads and implanting a subcutaneous ICD; extracting both leads and adding a new ICD lead; extracting both leads and implanting a subcutaneous ICD. • Primary concerns elicited were the potential for long-term complications from the ICD leads and the possibility of needing an MRI in his lifetime. The decision was made to extract both leads and implant a subcutaneous ICD lead, after discussing the risks and benefits of a subcutaneous ICD system vs a transvenous ICD system.	• The lead extraction procedure was higher risk due to the previous decision to abandon a malfunctioning lead in a young patient.

Table 2 (*Continued*)

Patient scenario	Management strategies	Key points
A 40-year-old woman with familial LQT2 who underwent primary prevention ICD placement with a dual-coil lead 8 years ago due to pregnancy, concerns about increased risk of arrhythmias during the postpartum setting, and strong family history of peripartum sudden death. She has two children, will not have future pregnancies, and has never had ICD therapies. ICD generator is ERI, and she no longer wants ICD therapy.	• Management options discussed included abandoning lead and generator; removing generator and abandoning lead; and extracting lead and generator. • Values elicited included a desire to not have a prolonged hospitalization or recovery and not wanting a generator in the pocket. • The patient did not want to undergo extraction. At her request, the decision was made to remove the generator and abandon the lead.	• The option of removing only the generator would leave the patient with a contraindication for MRI. • The patient remains at ongoing risk for lead infection, which would require a higher risk extraction in the future. • Opening the pocket to remove the generator exposed the patient to a risk of infection.
A 52-year-old man with a history of complete heart block, leading to a diagnosis of cardiac sarcoidosis, underwent dual-chamber ICD with a single-coil ICD lead 4 years ago. He has had ATP therapy for VT. Remote interrogation shows impedance of 150 and episodes of noise on RV lead. Noise is reproducible on exam with pocket manipulation.	• Management options discussed included addition of new RV pace-sense lead and ICD lead extraction and replacement. • Values elicited during discussion included his desire for a reliable system, concerns about the effect of more leads in his vasculature, and his desire to be able to easily undergo MRI in the future. • The decision was made to extract and reimplant a new ICD lead.	• Should the strategy of an additional lead be applied, vein patency would need to be considered. In case of extraction and reimplantation, the lead's original insertion point would need to be evaluated in case this represents damage from the costoclavicular ligaments. • Adding a pace-sense lead is sometimes a suboptimal choice, because the ICD shock coil can also be at high risk of failure in the setting of a pace-sense component fracture.

ATP = antitachycardia pacing; AV = atrioventricular; CIED = cardiovascular implantable electronic device; ERI = elective replacement indicator; ICD = implantable cardioverter defibrillator; MRI = magnetic resonance imaging; VT = ventricular tachycardia.

8. Indications for Lead Extraction (Infectious)

8.1. Cardiovascular Implantable Electronic Device Infection

COR	LOE	Recommendations	References
I	C-LD	**If antibiotics are going to be prescribed, drawing at least two sets of blood cultures before starting antibiotic therapy is recommended for all patients with suspected CIED infection to improve the precision and minimize the duration of antibiotic therapy.**	116

Microbial growth can be suppressed by antibiotics and can mislead or mask CIED-related bloodstream infection. Early identification of the pathogen will guide appropriate selection and duration of antimicrobial therapy. Blood culture should include two sets of aerobic and anaerobic bacterial cultures. Multiple positive blood cultures might be needed to distinguish bloodstream infection vs contamination in cases of infection due to skin flora, in particular, coagulase-negative staphylococci.[116]

COR	LOE	Recommendations	References
I	C-LD	**Gram stain and culture of generator pocket tissue and the explanted lead(s) are recommended at the time of CIED removal to improve the precision and minimize the duration of antibiotic therapy.**	117

Collecting device pocket tissue for Gram stain and culture at the time of device removal is useful for identifying the causative organism. The sensitivity of tissue culture (69%) is higher than that of the swab culture (31%) of the pocket.[117] The entire explanted leads or lead tips should also be sent for culture, although lead contamination can occur when leads are extracted through the generator pocket. Pathogen-guided therapy enhances antimicrobial drug selection by targeting the causal microbe, guiding appropriate treatment duration to minimize recurrent infection, and identifying potential drug resistance.

COR	LOE	Recommendations	References
I	B-NR	**Preprocedural transesophageal echocardiography (TEE) is recommended for patients with suspected systemic CIED infection to evaluate the absence or size, character, and potential embolic risk of identified vegetations.**	118–122

TEE is a useful imaging modality for establishing the diagnosis of CIED-related endocarditis and/or lead infection. The sensitivity of TEE for endocarditis and perivalvular extension of infection is superior to that of transthoracic echocardiography (TTE). The sensitivity of TTE for detecting endocarditis was only 32%, and the specificity was 100% when compared with TEE.[118] TEE benefits include the confirmation of native or prosthetic valve endocarditis and identifying the presence and the size of vegetation(s) on the valve or lead(s), valvular malfunction, and perivalvular abscess. This information can help guide antibiotic therapy and provide additional information on the risk of CIED removal.[119–122]

(*Continued*)

(*Continued*)

COR	LOE	Recommendations	References
I	C-EO	**Evaluation by physicians with specific expertise in CIED infection and lead extraction is recommended for patients with documented CIED infection.**	
When the diagnosis of CIED infection is documented, consulting physicians who have the expertise in CIED infection (including infectious disease specialists, cardiologists, and surgeons who specialize in managing device-related infection and/or performing lead extraction) is beneficial. Delayed, inappropriate, or incomplete therapy can result in significant morbidity and mortality for patients with CIED infection.			
IIa	B-NR	**TEE can be useful for patients with CIED pocket infection with and without positive blood cultures to evaluate the absence or size, character, and potential embolic risk of identified vegetations.**	[123]
Device pocket infection might or might not be accompanied by bloodstream infection. In one study, intravascular lead involvement was present in 88% of patients presenting with pocket infection despite lack of symptoms of systemic infection.[123]			
IIa	C-EO	**Evaluation by physicians with specific expertise in CIED infection and lead extraction can be useful for patients with suspected CIED infection.**	
When CIED infection is suspected, consulting physicians who have expertise in CIED infection (including infectious disease specialists, cardiologists, and surgeons who specialize in managing device-related infection and/or performing lead extraction) can be useful for facilitating the diagnosis and further management.			
IIb	C-LD	**Additional imaging may be considered to facilitate the diagnosis of CIED pocket or lead infection when it cannot be confirmed by other methods.**	[124–129]
18-Fluorodeoxyglucose (^{18}F-FDG) positron emission tomography (PET)/computed tomography (CT) scanning might provide helpful evidence when diagnosis of CIED pocket or lead infection is doubtful.[124–126] One study showed that PET/CT had a high sensitivity of 87% and a specificity of 100% for device pocket infection but a low sensitivity of 31% and a specificity of 62% for endocarditis.[127] In another single-center, prospective, controlled study of 86 patients, patients with suspected generator pocket infection requiring CIED extraction had significantly higher ^{18}F-FDG activity (4.80 [3.18–7.05]) compared with those who did not have the infection (1.40 [0.88–1.73]) and compared with controls (1.10 [0.98–1.40]).[128] The diagnostic performance of ^{99m}Tc-hexamethypropylene amine oxime–labeled autologous white blood cell (^{99m}Tc-HMPAO-WBC) scintigraphy had a sensitivity of 94% for both detection and localization of CIED-associated infection.[129]			

With the increase in CIED clinical applications for bradycardia, tachyarrhythmia, and heart failure, CIED infection has become increasingly prevalent in cardiac disease management[130–137] (Appendix 6). Among Medicare beneficiaries, the prevalence of cardiac device infections increased from 0.94 to 2.11 per 1000 beneficiaries between 1990 and 1999, a 124% increase during the study period.[130] Similarly, in a community-based study of Olmsted County, Minnesota, from 1975 to 2004, the incidence (defined as the probability of occurrence of a given medical condition in a population within a specified period of time) of CIED infection was 1.9 per 1000 device-years, with an incidence of pocket infection alone of 1.37 per 1000 device-years and an incidence of pocket infection with blood stream infection of 1.14 per 1000 device-years.[131] The probability of CIED infections was higher among patients with ICDs than among those with pacemakers.[132] Using the National (Nationwide) Inpatient Sample (NIS) discharge records from the United States, Greenspon et al reported that during the study period between 1993 and 2008, the incidence of CIED infection was 1.61%. The annual rate of infections remained constant until 2004, when a marked increase was observed, coinciding with an increase in the incidence of major comorbidities in patients undergoing CIED procedures.[136] Furthermore, another report from the same data source indicated an increase in lead extraction for CIED infection from nearly 30% in 2006 to 50% in 2012, while lead extraction for non-CIED infection decreased from approximately 70% to 50% in the same period of time.[137] Developing effective means for preventing device infection and early diagnosis are therefore important in reducing the mortality, morbidity, and medical cost related to CIED infection.

8.1.1. Diagnosis

8.1.1.1. Definitions of Cardiovascular Implantable Electronic Device–Related Infection

A correct definition for CIED-related infections will guide diagnosis and appropriate management. CIED-related infections can be categorized as follows[138,139]:

- Isolated generator pocket infection: localized erythema, swelling, pain, tenderness, warmth, or drainage with negative blood cultures
- Isolated pocket erosion: device and/or lead(s) are through the skin, with exposure of the generator or leads, with or without local signs of infection
- Bacteremia: positive blood cultures with or without systemic infection symptoms and signs
- Pocket site infection with bacteremia: local infection signs and positive blood cultures
- Lead infection: lead vegetation and positive blood cultures
- Pocket site infection with lead/valvular endocarditis: local signs and positive blood cultures and lead or valvular vegetation(s)
- CIED endocarditis without pocket infection: positive blood cultures and lead or valvular vegetation(s)
- Occult bacteremia with probable CIED infection: absence of alternative source, resolves after CIED extraction

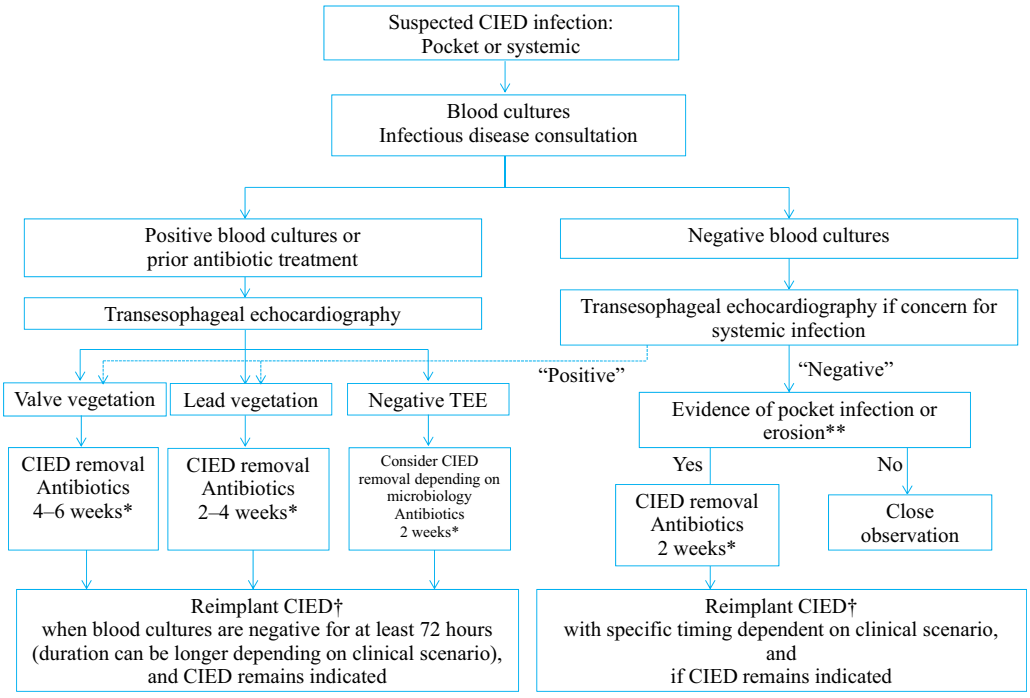

Figure 2 Management of suspected CIED infection. *Refer to text for specific recommendations depending on microbiology. Antimicrobial therapy should be at least 4–6 weeks for endocarditis (4 weeks for native valve, 6 weeks for prosthetic valve or staphylococcal valvular endocarditis). If lead vegetation is present in the absence of a valve vegetation, 4 weeks of antibiotics for *Staphylococcus aureus* and 2 weeks for other pathogens is recommended. †Usually the contralateral side; a subcutaneous ICD may also be considered. **2010 AHA CIED Infection Update distinguishes between pocket infection and erosion (Baddour et al. Circulation 2010;121:458–477).

- Situations in which CIED infection is not certain: impending exteriorization, isolated left heart valvular endocarditis in a patient with a CIED
- Superficial incisional infection: involves only skin and subcutaneous tissue of the incision, not the deep soft tissues (eg, fascia and/or muscle) of the incision

A general algorithm outlining the steps for diagnosis of CIED infection and management is shown in Figure 2.

8.1.1.2. Clinical Presentation

The device pocket can become infected at the time of implantation, at replacement, or during subsequent surgical manipulation of the pocket. A pocket infection, either as the primary source or secondary source disseminated from bloodstream infection, manifests with local inflammatory changes, which can include pocket erythema (41%), swelling (38%), pain and tenderness (28%), warmth (18%), drainage (38%), and device exposure (21%).[140]

Device cutaneous erosion can occur through fat necrosis and migration from the deep layers through the skin. Usually this occurs at a time remote from the CIED procedure, proceeding slowly through progressive migration and loss of tissue from outward pressure of the generator. In some cases, when the pocket is not closed appropriately due to loose sutures or large gaps between the sutures, the incision can become dehisced. Once the implanted device is exposed, it is considered to be infected, because it is in direct contact or communication with the skin and local bacterial pathogens.[141]

Initial signs of erythema, tenderness, and swelling after a CIED procedure can represent a superficial infection or a true pocket infection (Figure 3). Pocket infection can track along the intravascular portion of the lead to involve the intravascular and intracardiac portion of the CIED.[141] Therefore, patients might present with systemic symptoms, such as fever, chills, malaise, fatigue, or anorexia, similarly to those patients who present with primary bloodstream infection. However, some patients with CIED lead vegetations do not have systemic signs and symptoms. Although early CIED infection, defined as less than 6 months, was more likely to present with pocket infection, while late CIED infection was more attributable to bacteremia and/or endocarditis, the timing of the infection after CIED placement alone does not reliably suggest whether an infection is localized or systemic.[142]

Patients can present with primary bloodstream infection (bacteremia, lead infection, or endocarditis) with or without generator pocket involvement (Figure 4). In such circumstances, systemic symptoms are often prominent. The severity and onset of symptoms and physical signs are related to microbial and host factors. Staphylococcal species are responsible for 60%–80% of CIED infections.[117,123,143] *Staphylococcus aureus* is a notably virulent bacterium accounting for 25% of CIED infections, which often result in acute onset of fever and rigors. Coagulase-negative staphylococcus is the most common cause of device pocket-related infection but is less virulent and has fewer systemic symptoms.[144,145] Staphylococcal pathogens can be resistant

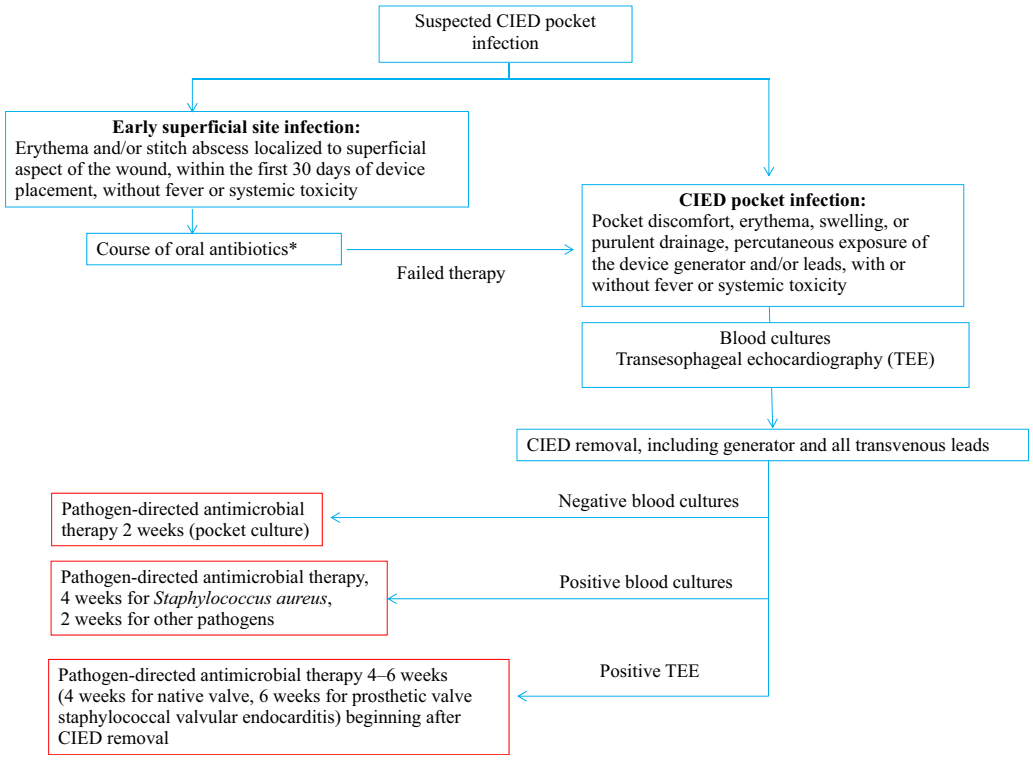

Figure 3 Management of suspected pocket infection. *See text for examples.

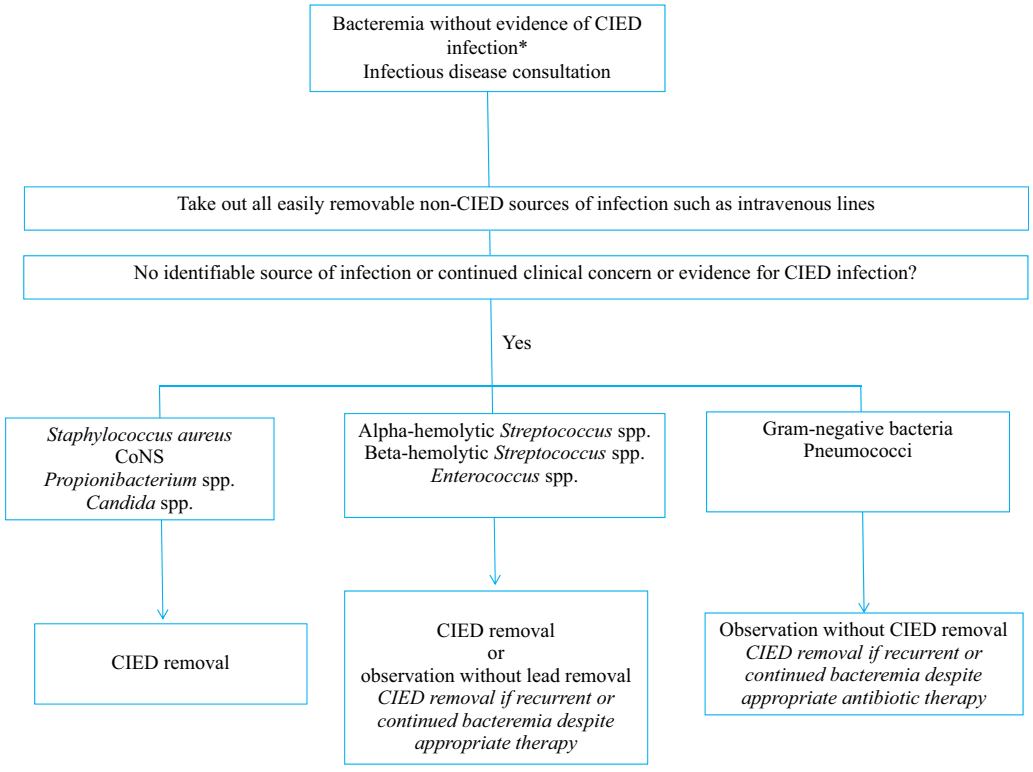

Figure 4 Management of bacteremia without evidence of CIED infection. *Important to distinguish between blood stream infection and contamination in bacteremia involving skin flora.

Table 3 Risk factors for cardiovascular implantable electronic device infection[154–166]

Patient-related factors	Procedure-related factors	Microbe-related factors
Age	Pocket reintervention (generator change, upgrade, lead or pocket revision)	Highly virulent microbes (eg, staphylococci)
Chronic kidney disease	Pocket hematoma	
Hemodialysis	Longer procedure duration	
Diabetes mellitus	Inexperienced operator	
Heart failure	ICD (compared with PM)	
Chronic obstructive pulmonary disease	Lack of use of prophylactic antibiotics	
Preprocedure fever		
Malignancy		
Skin disorder		
Immunosuppressive drug		
Prior CIED infection		
Anticoagulation		

CIED = cardiovascular implantable electronic device; ICD = implantable cardioverter defibrillator; PM = pacemaker.

to antimicrobial therapy and the host defense system because they form a protective biofilm.[145,146] A biofilm is defined as a device surface-associated community of one or more microbial species that are layered together by the product of polysaccharide intercellular adhesion, firmly attached to one another, and encased in an extracellular polymeric matrix that holds the biofilm together. Biofilm prevents the eradication of CIED infection by antibiotics alone without device system removal. Nonstaphylococcal CIED-related infections are prevalent and diverse, with a relatively low virulence and mortality rate.[147] Among 30 patients who presented with Gram-positive nonstaphylococcal bacteremia—most commonly the enterococcus species, viridans group streptococci, and *Streptococcus pneumoniae*—6 had confirmed CIED site infection. The remaining 24 patients underwent antibiotic therapy only, 2 of whom ultimately required CIED extraction for persistent bacteremia.[119] Less than 10% of CIED infections are caused by Gram-negative bacilli, such as *Klebsiella pneumoniae* and *Serratia marcescens*.[143] CIED fungal infection is uncommon, identified in only 2% of 189 documented CIED infections.[143] Gram-negative bacteremia uncommonly results in secondary seeding of the device. Empirical and broad antimicrobial coverage against Gram-positive and Gram-negative bacteria is recommended until the infecting pathogen is identified.[148]

The S-ICD involves no hardware exposure to the intravascular system, which is the unique innovative feature of this technology. Pocket infection and erosion rates were 1.7% and 1.2%, respectively.[149,150] Device pocket infection requiring surgical intervention is the most common infectious complication for S-ICD, and no systemic infection case has been identified from the EFFORTLESS registry.[150]

8.1.1.3. Blood and Device Pocket Culture

At least two sets of blood culture should be obtained before starting antimicrobial therapy in patients with suspected CIED infection. Microbial growth can be suppressed by antibiotics, which can mislead or mask the clinical diagnosis of device infection. Blood cultures should include both aerobic and anaerobic bacterial cultures. Patients with bloodstream infection might manifest systemic leukocytosis.

Device pocket swabs for Gram stain/culture and tissue culture at the time of device removal are useful in identifying the causative organism and supporting a diagnosis of CIED infection. The sensitivity of tissue culture (69%) is higher than that of the swab culture (31%) of the pocket.[117] A connector culture provides a more than 90% positive yield.[151] If the Gram stain is negative, a tissue culture should be sent for mycobacteria and fungal stains. The entire lead or lead tip should also be sent for culture, although lead contamination might occur when leads are extracted through the generator pocket. Use of the vortexing-sonication technique increases culture sensitivity and enhances microbial detection.[152] When a CIED infection is suspected, performing percutaneous pocket aspiration should be carefully considered because the diagnostic yield is low and there is the potential risk of introducing microorganisms into the pocket, thereby causing infection.[153]

8.1.1.4. Imaging Diagnosis

TEE is a useful imaging modality in establishing the diagnosis of CIED-related endocarditis and/or lead infection. The sensitivity of TEE for endocarditis and perivalvular extension of infection is superior to that of TTE. Fowler et al reported that the sensitivity of TTE for detecting endocarditis was only 32%, and the specificity was 100% when compared with TEE. The addition of TEE resulted in one false-positive result (specificity 99%).[118] TEE is critically important for patients with *Staphylococcus aureus* bacteremia, because the rate of lead-associated endocarditis is substantial. TEE should be considered for all patients who have documented or suspected bloodstream infection or CIED pocket infection. Device pocket infection often demonstrates evidence of intravascular lead involvement in 88% of patients presenting with pocket infection and might not always be associated with systemic infection symptoms.[123] TEE is helpful in assessing unrecognized bloodstream infection. The benefits of TEE include confirmation of systemic involvement of CIED infection (endocarditis, vegetation on the valve or lead(s), valvular malfunction, perivalvular abscess), guidance of reimplantation timing strategy, antibiotic therapy duration, and extraction approach, such as in the presence or absence of patent foramen ovale, tricuspid valve

regurgitation or lead impingement, and the size and shape of lead vegetation(s).[119–121]

When the diagnosis of CIED pocket or lead infection is doubtful, ^{18}F-FDG PET/CT scanning might provide helpful evidence. One prospective study showed PET/CT had a high sensitivity of 87% and a specificity of 100% for device pocket infection but a low sensitivity of 31% and a specificity of 62% for endocarditis.[127] In another single-center, prospective, controlled study of 86 patients, patients with suspected generator pocket infection requiring CIED extraction had significantly higher ^{18}F-FDG activity (4.80 [3.18–7.05]) compared with those who did not have the infection (1.40 [0.88–1.73]) and compared with the controls (1.10 [0.98–1.40]).[128] These findings have been supported by other authors.[124,125] Furthermore, PET/CT imaging can disclose undiagnosed alternate sources of infection, such as occult spondylodiscitis.[124] The diagnostic performance of ^{99m}Tc-HMPAO-WBC scintigraphy had a sensitivity of 94% for both detection and localization of CIED-associated infection.[129]

8.1.2. Predictors for Cardiovascular Implantable Electronic Device Infection and Prognosis

Device-related infection is the result of the interaction between the device, the microbe, and the host (Table 3).[153]

8.1.2.1. Patient Risk Factors

Older age and concomitant comorbidities are associated with CIED infections. Approximately 70% of device recipients were 65 years of age or older, and more than 75% had one or more coexisting medical conditions in a community-based study.[154,155] Data from the community-based practice and NCDR have consistently shown that patients older than 60 years of age receive ICDs more often than young patients (70% vs 30%).[156] Increased implantation in older patients with increased comorbidities has set the stage for higher rates of CIED infection. In the REPLACE Registry, a higher Charlson comorbidity index predicted the risk of infection (2.79 vs 2.32 [95% CI 0.08–0.86]; P=.019).[157] A meta-analysis of 180,004 patients from 60 prospective and retrospective studies concluded that the significant host-related risk factors for infection included diabetes mellitus (odds ratio [OR] 2.08 [95% CI 1.62–2.67]), end-stage renal disease (OR 8.73 [95% CI 3.42–22.31]), chronic obstructive pulmonary disease (OR 2.95 [95% CI 1.78–4.90]), corticosteroid use (OR 3.44 [95% CI 1.62–7.32]), history of previous device infection (OR 7.84 [95% CI 1.94–31.60]), renal insufficiency (OR 3.02 [95% CI 1.38–6.64]), malignancy (OR 2.23 [95% CI 1.26–3.95]), heart failure (OR 1.65 [95% CI 1.14–2.39]), preprocedural fever (OR 4.27 [95% CI 1.13–16.12]), anticoagulant drug use (OR 1.59 [95% CI 1.01–2.48]), and skin disorders (OR 2.46 [95% CI 1.04–5.80]).[158] Other studies have reported similar findings.[14] Once CIED infection is diagnosed, women have a higher risk of death than men.[159,160]

Chronic renal disease is very common in patients with an existing CIED. Among a series of 503 patients who underwent lead exaction, predominantly for CIED infection, 54% had class III-V chronic renal disease.[161] In a study group of 1440 patients, Tompkins et al found the CIED infection rate to be 12.5% in patients with end-stage renal disease, which was significantly higher than the rate of 0.2% in patients without end-stage renal disease.[162] An analysis from the United States Renal Data System, which included 546,769 patients with end-stage renal disease, showed that 6.4% of this study cohort had CIEDs in place and 8.0% of those with CIEDs developed CIED infection. Notably, only 28.4% of infected CIEDs were removed. Patients with end-stage renal disease and infected CIEDs had a poor prognosis. Although the rate of device extraction was low, this strategy appears to be associated with a modest improvement in survival.[163]

8.1.2.2. Procedure-Related Factors

Apart from the host-related factors, the procedure itself and related complications are also strongly associated with the risk of CIED infection. Reopening the pocket, including generator change, CIED upgrade, and lead or pocket revision or manipulation, increases the opportunity of introducing bacteria into the pocket. In a meta-analysis, the following procedure-related factors were identified: postoperative hematoma (OR 8.46 [95% CI 4.01–17.86]), reintervention for lead dislodgement (OR 6.37 [95% CI 2.93–13.82]), device replacement/revision (OR 1.98 [95% CI 1.46–2.70]), temporary pacing (OR 2.31 [95% CI 1.36–3.92]), operator inexperience (defined as <100 prior CIED procedures) (OR 2.85 [95% CI 1.23–6.58]), and procedure duration (weighted mean difference 9.89 [95% CI 0.52–19.25]).[158] In the REPLACE Registry, all 1774 patients received preoperative intravenous (IV) antibiotics before the CIED generator change, and 68.7% received postoperative antibiotics. CIED infection developed in 22 patients (1.3%), and patients with infections were more likely to have had postoperative hematomas (5 of 22 [22.7%] vs 17 of 1722 [0.98%]; P=.002).[157]

8.1.2.3. Microbes

Prospective surveillance microbiology and genetic analysis have shown the surprising finding that positive bacterial DNA can be identified in 23% of device pockets, on 29.5% of device surfaces, and in both locations in 14%. Despite the common nature of pocket colonization, only a subset develop clinical infection.[160] *Staphylococcus aureus* and coagulase-negative staphylococcus are the most common and virulent causes of CIED infection within and beyond 1 year of CIED implant.[164,165] As compared with coagulase-negative staphylococcus, *Staphylococcus aureus* has a longer bacteremia duration of more than 3 days, longer hospital stay, and increased mortality (25% vs 9.5%).[144] Nonstaphylococcal CIED infection has relatively low virulence and has lower mortality than that of staphylococcus.[148]

8.2. Management Recommendations

COR	LOE	Recommendations	References
I	B-NR	**A complete course of antibiotics based on identification and in vitro susceptibility testing results after CIED removal is recommended for all patients with definite CIED system infection.**	1,140,153,166–168

A complete course of antibiotics is recommended to treat device pocket and/or bloodstream infection and/or valvular endocarditis.[1,140,153,166–168] After device and lead removal, antibiotics are more effective for eradicating the infection. Selection of the appropriate antimicrobial agent should be based on identification and in vitro susceptibility testing results. Patients with infections due to methicillin-susceptible staphylococcal strains can be administered cefazolin or nafcillin. Vancomycin should be administered to patients with infection due to methicillin-resistant staphylococci. Although there are no clinical trials that have tested the minimum duration of antibiotic therapy, in general, a 2-week antibiotic therapy after lead extraction is recommended for CIED pocket infection and 10 days for pocket erosion.[153] For patients with bloodstream infection without valvular involvement, a minimum 2-week course of antimicrobial therapy is recommended after extraction of the infected CIED. Antimicrobial therapy should be at least 4–6 weeks for complicated infection including endocarditis. The duration of antimicrobial therapy should be calculated from the day of completion of the lead extraction or negative blood cultures (whichever occurred last).

COR	LOE	Recommendations	References
I	B-NR	**Complete device and lead removal is recommended for all patients with definite CIED system infection.**	169–171

Early diagnosis of CIED infection and performing lead extraction within 3 days of diagnosis is associated with lower in-hospital mortality.[169] A multivariate analysis found a 7-fold increase in 30-day mortality if the CIED was not removed. Although CIED removal resulted in fatal complications, the mortality associated with a delay in removal was even higher.[170] Therefore, CIED-associated infections are the strongest indication for complete CIED system removal and should not be delayed, regardless of the timing of the start of antimicrobial therapy.[1,171]

COR	LOE	Recommendations	References
I	C-EO	**Complete removal of epicardial leads and patches is recommended for all patients with confirmed infected fluid (purulence) surrounding the intrathoracic portion of the lead.**	

Infection can occur in patients with surgical epicardial leads and/or patches that are connected to a pectoral or abdominal generator. Complete removal of infected portions of epicardial leads and patches is recommended to eradicate the infection after weighing the risk of surgery and mortality from infection.[172]

COR	LOE	Recommendations	References
I	B-NR	**Complete device and lead removal is recommended for all patients with valvular endocarditis without definite involvement of the lead(s) and/or device.**	153,169

Complete CIED removal should be performed when patients undergo valve replacement or repair for infective endocarditis, because the CIED could serve as a nidus for relapsing infection and subsequent seeding of the surgically treated heart valve.[153] A recent study has shown that complete CIED removal appears curative for patients with CIED infection in the presence of prosthetic heart valves and thus might prevent repeat valve surgery.[169]

COR	LOE	Recommendations	References
I	B-NR	**Complete device and lead removal is recommended for patients with persistent or recurrent bacteremia or fungemia, despite appropriate antibiotic therapy and no other identifiable source for relapse or continued infection.**	153,165

Persistent or relapsing bacteremia or fungemia after a course of appropriate antibiotic therapy when there is no other identified source for bacteremia or fungemia suggests CIED and lead infection. In this scenario, the retained intravascular leads are very likely to be the source of infection. Complete removal of hardware is recommended to eradicate the infection.[153,165]

COR	LOE	Recommendations	References
I	C-EO	**Careful consideration of the implications of other implanted devices and hardware is recommended when deciding on the appropriateness of CIED removal and for planning treatment strategy and goals.**	

Patients who have received a CIED might have other implanted devices and hardware. For example, left ventricular assist device (LVAD) recipients often have a CIED in place (up to 87%). In a large series of 247 LVAD patients, 2.8% had CIED infection. Patients with an LVAD and CIED infection should undergo CIED removal to eliminate a potential source of microbial seeding and infection. Chronic suppressive antibiotic therapy is warranted in concomitant LVAD infection.[173]

8.2.1. Antimicrobial Therapy

For patients who present with bacteremia, a broad empiric antimicrobial therapy to cover both Gram-positive and Gram-negative microbes is recommended until the causative organism is identified.[148,174] Ninety-seven percent or more of patients who present with either pocket infection or endocarditis can be cured after combined lead extraction and antibiotic therapy.[140,166–168]

A complete course of antibiotics is recommended to treat the device pocket and/or bloodstream infection and valvular endocarditis.[153,168] After the device and lead removal, antibiotics are more effective in eradicating the infection. Selection of the appropriate antimicrobial agent should be based on identification and in vitro susceptibility testing results. Given that staphylococci are the most common microbe and nearly half of these are methicillin resistant, vancomycin should be

administered initially as an empirical antibiotic coverage until the microbiological etiology is identified.[140] Patients with infections due to methicillin-susceptible staphylococcal strains can be administered cefazolin or nafcillin, with discontinuation of vancomycin. Vancomycin should be continued in patients with infection due to methicillin-resistant staphylococci. Although no clinical trials have tested the minimal duration of antibiotic therapy, in general, a 2-week antibiotic therapy after lead extraction is recommended for CIED pocket infection, and 10 days is recommended for pocket erosion.[153] For patients with bloodstream infection without valvular involvement, a minimum of 2 weeks of parenteral antimicrobial therapy is recommended after extraction of the infected CIED. The duration of antimicrobial therapy should be at least 4–6 weeks for complicated infection, including endocarditis, septic thrombophlebitis, osteomyelitis, and persistent bacteremia, despite device removal and appropriate initial antimicrobial therapy; the duration of antimicrobial therapy should be calculated from the day of lead extraction or negative blood cultures (whichever occurred last). In particular, patients with staphylococcal bacteremia need repeated blood cultures to document the clearance of infection.

Under certain circumstances, long-term antimicrobial suppressive therapy and local wound care strategies are used as a palliative therapy in selected patients with CIED infection who are excessively high-risk candidates for device removal.[175] These patients usually have a stable cardiovascular status, clinical improvement with initial antimicrobial therapy, and clearance of bloodstream infection. The choice of antimicrobial therapy and its dosing are empirical, given the limited available study results. The long-term outcome of this approach is unknown, and this approach is only considered when conventional management is contraindicated or is less favorable to an individual patient who has a high risk for CIED extraction, such as a high likelihood of requiring surgical extraction, inability to reimplant, loss of CRT, ongoing risk of reinfection due to other sources of infection that cannot be eradicated, or a life expectancy shorter than a year. Long-term antimicrobial suppression therapy is a palliative approach, which should be the last option compared with the recommended curative lead extraction approach.

8.2.2. Cardiovascular Implantable Electronic Device Extraction

Early diagnosis of CIED infection, including pocket abscess, erosion, bacteremia, lead vegetation, and endocarditis, and performing lead extraction within 3 days of diagnosis are associated with lower in-hospital mortality.[169] In a large CIED infection cohort, the 30-day mortality rate was 5.5%, and 1-year mortality was 14.6%. A multivariate analysis indicated a 7-fold increase in 30-day mortality if the CIED was not removed. Although CIED removal resulted in fatal complications, the mortality associated with delayed removal was significantly higher.[170] Therefore, CIED-associated infections are the strongest indication for complete CIED system removal and should not be delayed, regardless of the timing of the start of antimicrobial therapy. Furthermore, infection relapse could occur due to retained hardware.[1,171]

Erosion of any part of the CIED indicates contamination of the entire system, and complete device removal should be performed. Complete CIED removal should be performed when patients undergo valve replacement or repair for infective endocarditis, because the CIED could serve as a nidus for relapsing infection and subsequent seeding of the surgically treated heart valve. A recent study showed that complete CIED removal appears curative for patients with CIED infection in the presence of prosthetic heart valves and can spare valve surgery.[167]

Infection can occur in patients with surgical epicardial leads and/or patches that are connected to a pectoral or abdominal generator. Complete removal of infected epicardial leads and patches is recommended to eradicate the infection after balancing the risk of surgery and mortality from infection.[172] However, in patients with epicardial leads and patches and a localized pocket infection, a separate incision away from the pocket where the epicardial leads or patches enter the thoracic cavity can be used to access and cut the lead(s). The proximal portion of the epicardial lead or patch can be removed from the infected pocket.

Up to 87% of LVAD recipients have a CIED. In a large series of 247 patients with an LVAD, 2.8% developed a CIED infection. Patients with LVADs and CIED infection should be considered for CIED removal. Chronic suppressive antibiotic therapy might be required for patients with concomitant LVAD infection.[173]

Generally, a single positive blood culture with no other clinical evidence of infection should not result in removal of the CIED system. However, *Staphylococcus aureus* should always be considered a pathogen, and evaluation for a likely source should be undertaken. Superficial or incisional infection without device involvement is not an indication for CIED removal. Superficial incisional infection involves only skin and the subcutaneous tissue of the incision, not penetrating to the deep soft tissues (eg, fascia and/or muscle) of the incision, and does not present late after a CIED intervention. Patients with superficial incisional infection or hematoma can present early after CIED intervention with signs of inflammation, such as pain, tenderness, erythema, and local warmth. The patient should be closely followed for progression to a deeper infection, which would require extraction. Seven to 10 days of oral antibiotic therapy with activity against staphylococci is reasonable.[153]

8.2.3. Post Lead Extraction Wound Care

After removal of infected leads and generator, a thorough debridement of the device pocket is necessary to remove

all infected and fibrotic tissue, including the entire capsule. The wound should be irrigated using sterile normal saline solution to remove small debris. There are several strategies that can be employed for postextraction wound management, including primary closure with or without the use of a drain, or staged closure using a drain or wound vacuum.

8.2.4. New Device Implantation

Reassessment of the need for a new CIED is imperative after removal of an infected CIED. Some patients might have had interval improvement in rhythm or cardiac function and no longer meet a guideline indication for permanent pacemaker, ICD, or CRT, or a patient might not wish to receive a new device. The optimal timing of device replacement is unknown. There are no prospective trial data on the timing of new device replacement and risk of relapsing infection. A new implantation can reasonably be postponed until blood cultures are negative for 72 hours, although implantation should be delayed if the patient has another undrained source of infection, such as a psoas abscess.[1,143,153] Replacement device implantation should be performed in an alternative location such as the contralateral side, the iliac vein, or using epicardial or subcutaneous implantation. Single-center studies have suggested that same-day implantation is feasible for patients with isolated pocket infections and is not associated with adverse outcomes.[1] Figure 2 shows an algorithm of diagnosis, management, and CIED reimplantation for suspected CIED infection.

For pacemaker-dependent patients, temporary pacing is required as a bridge to reimplanting a new permanent device. Epicardial pacing is an option but has been associated with higher mortality.[168] A commonly adopted alternative is temporary pacing using a screw-in pacing lead connected to an external re-used can, sometimes called "semi-permanent" pacing.[176,177] This approach allows patients to safely await implantation of a new device for the recommended 72 hours to 14 days, depending on clinical status. For ICD patients with a high risk of short-term, sudden cardiac death, the wearable defibrillator (LifeVest, ZOLL) is an option as a bridge to reimplantation.

8.3. Prevention

Performing an evaluation before implanting the device is important to ensure that patients do not have clinical signs of infection. The implantation should be postponed if signs of infection are present. Observational studies have consistently found that perioperative systemic antibiotics delivered 1 hour before the procedure significantly reduced the incidence of device infection compared with no antibiotics, with a relative risk reduction of 40%–95%.[158,178] In a double-blind, randomized, prophylactic antibiotics vs placebo study of 1000 patients who presented for primary device implantation or generator replacement, the safety committee interrupted the trial after 649 patients were enrolled due to a significant difference in favor of the antibiotic arm (infection rate, 0.63%) compared with the placebo group (3.28%; relative risk 0.19; $P=.016$).[179] In addition to surgical area sterilization and antiseptic preparation of the skin at the surgical site, systemic antibiotic use is a standard therapy and should be administered before the surgical incision is performed. A first-generation cephalosporin, such as cefazolin (within 1 hour before the incision) or vancomycin (within 2 hours before the incision), is commonly administered. Vancomycin or clindamycin are alternatives to a first-generation cephalosporin for patients who are allergic to cephalosporins. Using an antibiotic solution to irrigate the device pocket has not been shown to decrease device pocket infection when compared with saline irrigation.[180] Postoperative antibiotic therapy is not currently recommended, because there are no convincing data to support the administration of postoperative antibiotic therapy. Furthermore, there is a potential risk of adverse drug events and selection of drug-resistant organisms. To determine whether additional measures during or after device implantation would further reduce the risk of CIED infection, the Prevention of Arrhythmia Device Infection Trial (PADIT) has completed the enrollment of over 12,500 patients who underwent generator change, system upgrade, or new CRT CIED, and is now in the follow-up stage. The study is designed to assess (1) the effect of alternate or additional preoperative antibiotics, especially vancomycin; (2) the role of using intraoperative, wound pocket irrigation (with an antibiotic); and (3) the benefit of postoperative antibiotics.[181] In a randomized, single-center, single-operator study of 1008 patients, povidone iodine ointment, neomycin ointment, and antiseptic pads showed no benefit in preventing CIED infection when compared with placebo.[182] Another new technology using a nonabsorbable antibacterial envelope placed around the device generator has shown a significant reduction in CIED infection from 1.5% to 0.6% in a nonrandomized study when compared with historical controls.[183] The absorbable antibacterial envelope also appears to be associated with a lower incidence of CIED-related pocket infections in high-risk patients.[184] A randomized study is currently underway to provide further evidence for the clinical utility of antibacterial envelope use.[185]

The predominance of staphylococci as pathogens in CIED infection rather than oral flora suggests that antibiotic prophylaxis for dental procedures is of little or no value.[186] Antimicrobial prophylaxis is not recommended for dental or other invasive procedures not directly related to device manipulation to prevent CIED infection.

9. Indications for Lead Extraction (Noninfectious)

COR	LOE	Recommendations	References
		Chronic Pain	
IIa	C-EO	**Device and/or lead removal can be useful for patients with severe chronic pain at the device or lead insertion site or believed to be secondary to the device, which causes significant patient discomfort, is not manageable by medical or surgical techniques, and for which there is no acceptable alternative.**	

Chronic pain at the device site or lead insertion site is an infrequent indication for lead extraction.[187,188] The scope of this problem has not been well defined and is likely multifactorial, ranging from indolent infection to musculoskeletal conditions.[117,189–193] An individualized treatment plan is clearly necessary, but removal of the device and lead extraction are reasonable for patients with severe chronic pain in which alternative management strategies are not available or have failed.

		Thrombosis/Vascular Issues	
I	C-EO	**Lead removal is recommended for patients with clinically significant thromboembolic events attributable to thrombus on a lead or a lead fragment that cannot be treated by other means.**	

Clinically significant thromboembolic events related to transvenous leads occur infrequently, but have been reported and are of particular concern in patients with intracardiac shunts.[194–196]

I	C-EO	**Lead removal is recommended for patients with SVC stenosis or occlusion that prevents implantation of a necessary lead.**	

Lead-induced venous thrombosis can occur early or late after implantation of a transvenous pacemaker.[197] Thrombosis can cause an occlusion of the SVC, making placement of additional transvenous leads difficult. Under these circumstances, removal of an existing lead is recommended to gain access and allow for placement of the necessary lead.

I	C-EO	**Lead removal is recommended for patients with planned stent deployment in a vein already containing a transvenous lead, to avoid entrapment of the lead.**	

Percutaneous stent implantation has now become first-line treatment for pacemaker-induced SVC syndrome.[197,198] Existing leads should be removed prior to stent placement, thus preventing entrapment of these leads behind the stent.

I	C-EO	**Lead removal as part of a comprehensive plan for maintaining patency is recommended for patients with SVC stenosis or occlusion with limiting symptoms.**	

Although lead-related venous thrombosis occurs relatively commonly, the incidence of pacemaker-induced SVC syndrome has been reported to be less than 0.1%.[197,198] However, patients who do become symptomatic might have debilitating symptoms requiring treatment. Lead removal and subsequent stent placement have emerged as the most effective treatment and should be part of the overall treatment strategy.

IIa	C-LD	**Lead removal can be useful for patients with ipsilateral venous occlusion preventing access to the venous circulation for required placement of an additional lead.**	[199,200]

In the context of a device upgrade or requirement of an additional lead, venous access can become an issue due to venous occlusion of the desired venous access point. Management options include contralateral lead implantation with tunneling across the chest, extraction of a redundant lead, or subclavian venoplasty. An individualized approach should be taken based on operator and center expertise. Use of extraction as a first-line approach to device upgrades for patients with venous occlusion is well described and can be a useful strategy in experienced centers.[199,200]

		Other	
I	C-EO	**Lead removal is recommended for patients with life-threatening arrhythmias secondary to retained leads.**	

There are reports in the literature of refractory ventricular arrhythmias that occurred after an RV lead placement that resolved with extraction.[201]

IIa	C-EO	**Lead removal can be useful for patients with a CIED location that interferes with the treatment of a malignancy.**	

CIED relocation is recommended when the CIED is situated in the path of planned radiation beam therapy that would interfere with adequate tumor treatment.[202] There are limited clinical data on CIED relocation options but could include removal or tunneling of existing leads or the use of lead extenders. Radiation exposure to the device itself is, however, not a primary concern and should not prompt a CIED relocation.

(Continued)

(*Continued*)

		Other	
IIa	C-LD	**Lead removal can be useful for patients if a CIED implantation would require more than four leads on one side or more than five leads through the SVC.**	110,193, 200
Analysis of extraction registries has reported higher complication rates with extraction when there are large numbers of leads that need to be removed.[200] Studies have reported increased shoulder pain and other complications in patients with higher numbers of leads from the same shoulder.[110,193]			
IIa	C-EO	**Lead removal can be useful for patients with an abandoned lead that interferes with the operation of a CIED system.**	
Isolated case reports have described adverse lead-lead interactions that require removal of an abandoned lead.[54,203]			
IIb	C-LD	**Lead removal may be considered for patients with leads that due to their design or their failure pose a potential future threat to the patient if left in place.**	57,62,64, 132
Sprint Fidelis (Medtronic, Minneapolis, MN) and Riata (Abbott, Sylmar, CA) ICD leads and the Accufix Atrial J Leads (Telectronics) have all had recalls due to concern for early failure or potential for patient harm. There is evidence that extraction of these leads does not pose a higher risk to patients than that of other nonrecalled leads.[62,132] Nonetheless, there is a potential for adverse events, which should always be considered when deciding on an extraction plan.[64] Thus, when there is a safety alert for the lead, there should be an additional clinical indication for opening the pocket when the lead is still functional and does not therefore pose a manifest risk to the patient. This is supported by the experience with the Telectronics Accufix extraction.[57]			
IIb	C-EO	**Lead removal may be considered for patients to facilitate access to MRI.*** **Removal of leads to prevent their abandonment, removal of broken or abandoned leads, or removal of leads to allow implantation of an MRI conditional system*	
Recommendations for managing CIEDs in the MRI setting have been addressed in the 2017 HRS consensus document.[202] Substantial evidence has been accumulated to demonstrate that MRI can be safely performed in most magnetic resonance (MR) nonconditional CIED systems without abandoned or epicardial leads; however, discussions regarding the risks and benefits should be held prior to imaging due to the risks, particularly in the setting of pacemaker-dependent patients with an ICD or those with battery voltages near the elective replacement indicator.[204–208]			
IIb	C-EO	**Lead removal may be considered in the setting of normally functioning nonrecalled pacing or defibrillation leads for selected patients after a shared decision-making process.**	
There are rare clinical situations in which lead removal of a normally functioning lead may be considered after discussion with the patient. For example, lead survival of nonrecalled defibrillator leads in younger patients was 89% at 5 years, characterized by a progressively decreasing survival curve.[27] It is possible that removal and reimplantation of a new defibrillator lead might represent a strategy associated with less long-term risk when compared with generator change.			

Although the indication for lead extraction to clear a cardiac device-related infection is relatively uncontroversial (ie, there is a mortality benefit to removing an infected device), the decision-making process regarding lead extraction for noninfectious indications is frequently less straightforward. Not only are there no randomized data to guide treatment, but it is unclear in many cases whether the risk of extraction would outweigh the benefit of having the lead(s) removed. If the litmus test of whether to offer a medical treatment or procedure is to make a patient feel better or live longer, many of the noninfectious indications below are in a relatively gray zone. For each of the indications listed for noninfected lead extraction, there should be a clinical goal that balances the risk of removal, and reasonable alternatives should be considered (Table 2). The recommendations are also made with the understanding that extraction is performed in conformance with the standards in the 2009 HRS Extraction document and the current document.

9.1. Chronic Pain

Chronic pain at the device site or at the lead insertion site is an infrequent indication for lead extraction, and the scope of this problem has not been well defined. The incidence of chronic pain following a CIED implantation has not been fully established but generally represents about 1%–3% of lead extraction cases.[187,188]

Pain and tenderness at the device site represent a wide range of clinical scenarios, from an underlying infection to possible CIED allergies or musculoskeletal problems. The presentation of a device infection is often variable. It is conceivable that chronic pain at the device site might be a manifestation of an indolent, chronic infection by a slow-growing organism, but the direct relationship between subclinical device infections and chronic pain remains to be elucidated.

CIED contact dermatitis has been well established, with many case reports illustrating a wide spectrum of possible symptoms, ranging from pain and tenderness to dermatological manifestations.[190,191] The diagnosis of CIED contact

dermatitis is confirmed with positive skin patch testing of any of the components of the CIED system, together with an absence of proof of infection.

Implantable cardiac defibrillators have been associated with postoperative discomfort and pain.[192] Chronic shoulder pain and disability were described in 131 (54%) patients more than 3 years after ICD implantation.[193] The only predictor of shoulder pain was the number of implanted leads. Another possible cause for musculoskeletal pain at the device site and shoulder region is thoracic outlet syndrome, which can cause pain, numbness, and fatigue of the shoulder and arm due to compression of the brachial plexus and subclavian vessels.

Although these are possible etiologies for chronic pain at the device site and/or lead insertion site, it is important to keep in mind that this clinical scenario can be multifactorial, and a careful and individualized treatment plan is necessary. Removal of the device and lead extraction are reasonable for patients with severe chronic pain after discussion with the patient and when alternative management strategies are not available or have failed to resolve the problem.

9.2. Thrombosis/Vascular Issues

Venous thrombosis after pacemaker or ICD system implantation is a known, although often under-recognized, condition that can challenge system revision and device upgrades, contribute to the development and symptoms from SVC syndrome, and infrequently lead to thromboembolic complications.

In the context of a device upgrade or requirement of an additional lead, venous access could become an issue. Previously placed leads might have caused a venous obstruction, and an assessment of patency is recommended either through venous ultrasound or a chest CT prior to the procedure. A peripheral IV contrast injection can also be performed at the time of the procedure. Knowledge of venous patency prior to the procedure is preferable because this could impact the procedural strategy.

In case of an obstruction/occlusion, options include a contralateral lead implantation with tunneling across the chest, extraction of a redundant lead, and subclavian venoplasty. An individualized approach should be taken based on operator and center expertise. In the case of tunneling, a standard tunneling tool is used, set to cross the sternum subcutaneously. This procedure can be somewhat more difficult in a patient with a previous sternotomy but is essentially always achievable. Although this could be the most straightforward option at the time of the upgrade, there are some drawbacks to keep in mind. Leads are now added without removal of potentially unnecessary leads, with the result that future lead revisions are made more challenging, and venous access is further compromised.

Alternatively, a subclavian venoplasty can be considered. Percutaneous balloon venoplasty is typically applied by interventional radiology in many different clinical scenarios but is less well documented in cardiac device cases. The subclavian venoplasty approach was successful in 371 of 373 patients as reported by Worley et al in 2011.[209] Total angiographic occlusion was demonstrated in 65% of cases by peripheral venogram but in only 20% of cases by contrast injection at the site of obstruction, demonstrating the importance of additional contrast injections at the site of the occlusion to fully assess patency. The authors also reported successful crossing of a hydrophilic wire in 86% of cases, allowing for balloon dilatation of the partially occluded segment and subsequent lead placement. Similar success rates were reported in a smaller, single-center experience of subclavian venoplasty in upgrade cases.[210] The venoplasty approach preserves contralateral venous access and can be performed in an electrophysiology laboratory, provided there is operator and staff expertise and appropriate equipment available. As with the tunneling approach, venoplasty adds to overall lead burden by leaving redundant lead(s) behind and is not applicable in cases of a complete occlusion that cannot be crossed.

Use of lead extraction in cases of unsuccessful wire crossing and complete obstruction has been described, as well as a first-line approach to device upgrades in patients with venous occlusion.[199,200,209,211] Under these circumstances, an existing lead is extracted with specific extraction tools such as laser or a mechanical rotational tool, allowing for venous access through the sheath after the lead has been removed. Lead extraction to regain venous access of an occluded vein preserves the contralateral side for potential future use and minimizes overall lead burden.

SVC occlusion in the setting of well-developed collateral flow might preclude placement of additional, required leads in a patient with existing leads. Under these circumstances, an extraction of an existing lead is one approach to gain access to endocardial tissue. Patients can also present with symptoms related to the SVC obstruction, consistent with SVC syndrome. In a literature review, anticoagulation, thrombolysis, and venoplasty alone were all associated with high recurrence rates. Surgery and stenting were more successful: recurrence rates were 12% and 5% over a median follow-up of 16 (range 2–179) and 9.5 (range 2–60) months, respectively.[197,198] When a stenting strategy is deployed, it is important to keep in mind that all existing transvenous leads will need to be extracted prior to the stent placement to avoid entrapment of leads behind the stent.

CIED-related thromboembolic complications can also occur. Lead-related thrombus is commonly observed in patients with transvenous CIED leads; however, clinical pulmonary embolus appears to occur with a low incidence.[196] The risk clearly increases in patients with intracardiac shunts, as observed in a large retrospective study of patients with transvenous leads who had an increased risk of cardioembolic stroke/transient ischemic attack in the presence of a diagnosed patent foramen ovale.

9.3. Abandoned Leads

It is often possible to abandon a failed or no longer required lead and/or implant the needed leads through the same or

alternative implantation route. It is less common for a patient to exhibit symptoms or be at risk of death from the abandonment of noninfected leads. It is therefore harder to calculate the risk-to-benefit ratio of lead extraction in these patients. When this indication is considered, it is crucial to balance the risk of the intervention (including the lead extraction operator's experience) with the patient's situation.[57,62,68] Nonetheless, the presence of an abandoned lead is a common reason for extraction; as many as 38% of all leads extracted were removed for this reason, according to one registry.[27,212] Several other important observations favor earlier lead extraction instead of abandonment. Leads are more difficult to remove when left behind; when removed, the leads are associated with an increased risk of major complications, which progresses as the implantation duration increases. This situation could be of particular relevance in a pediatric population in which there is some evidence that the mortality rate could be lower, albeit with arguably higher stakes.[27,204] It is therefore difficult to anticipate how taking the risk now vs later is best assessed. These extraction risks increase as the interlead fibrosis thickens and covers more of the surface of the lead, especially when there are multiple leads.[68,213] Lead fragility is also proportional to implant duration and increases with the body's chemical and mechanical stresses, reducing the likelihood of complete lead removal.[212] The risks are further increased with even modest calcification of the fibrosis. Therefore, in a 20-year-old patient with complete heart block and two failed leads, implanting new leads without extracting the old ones, although feasible, is usually inadvisable. Alternatively, in a 90-year-old patient with one failed lead or an occluded vessel precluding the reuse of the ipsilateral subclavian vein, it might be more reasonable to consider that failure to remove the lead would never become a clinical issue for the patient. It is also important to consider how long the lead has been implanted, the fragility or tensile robustness of each particular lead, and the ease or difficulty of extracting the particular lead model. These issues are particularly important for lead management in children and young adults and highlight the importance of thoughtful input from pediatric cardiologists, pediatric electrophysiologists, and lead extraction specialists with patients and their families at the initial CIED implant or subsequently when lead management issues arise.

9.4. Magnetic Resonance Imaging

Recommendations for the management of CIEDs in the setting of MRI have been addressed in the 2017 HRS consensus document.[202] Currently, there are several FDA-approved MR-conditional CIED systems that are safe for use in the MRI environment when managed according to specific labeling requirements, including reprogramming.[214–217] The definition of "MR nonconditional" comprises all CIED systems that have not been FDA-labeled as "MR conditional." This also includes CIED systems with leads from differing manufacturers, whether or not the leads have been approved as part of another MR-conditional system, as well as CIED systems with abandoned or epicardial leads.[202] However, because MR-conditional technology is relatively new, there are substantially more MR-nonconditional systems in the population.[218] Not all patients with MR-nonconditional CIED systems have reasonable imaging alternatives. Substantial evidence has accumulated to demonstrate that MRI can be safely accomplished in most MR-nonconditional CIED systems without abandoned or epicardial leads, yet discussion regarding the risks and benefits should be held prior to imaging due to the risks, particularly in the setting of pacemaker-dependent patients or those with battery voltages near the elective replacement indicator.[204–207] The evidence base for the safety of MRI in CIED systems with abandoned, epicardial, or fractured leads or at field strengths of >1.5 tesla is far less robust.[103–107,219] Studies suggesting the feasibility of MRI with abandoned leads, epicardial leads, or fragments have been confined to single centers using rigorous imaging protocols. For the individual patient, shared decision making regarding the risks of MRI vs the risks of lead extraction in this setting is therefore paramount.[103–107,219]

9.5. Recalled Leads

As discussed in Section 6, Fidelis and Riata ICD leads and the Accufix Atrial J Leads (Telectronics) have all been recalled due to concern for early failure or potential for patient harm. Nonetheless, the potential for adverse events associated with extraction also exists.[64] There should therefore be an additional clinical indication for opening the pocket when there is a safety alert for the lead while the lead is still functional and therefore does not pose a manifest risk to the patient. This is supported by the experience with the Telectronics Accufix extraction, in which the mortality associated with extraction was higher than the risk of mortality from leaving the lead in place.[57]

9.6. Lead Perforation

Although lead perforation is usually a relatively acutely presenting complication of device placement, delayed perforation has been reported even years after implantation.[220] It is likely that many leads have some degree of microperforation, given imaging findings of this, but they are usually not clinically significant. Clearly, if a lead perforation causes pain, bleeding, or other complications, extraction will be an important component for the patient's overall management strategy.

9.7. Severe Tricuspid Regurgitation

RV pacing and defibrillator leads are known to frequently lead to some degree of tricuspid regurgitation (TR), but this condition is usually clinically silent. Tricuspid valve dysfunction can result when leaflets fail to coapt due to excess lead loops traversing the valve orifice, retraction of the septal leaflet by the lead, or lead impingement on the valve apparatus.[221] The severity of tricuspid regurgitation following lead implantation varies from study to study, with one study reporting an increase by >1 grade in 24.2%

of patients, whereas another reported an increase ≥2 grades in 18.3%.[222] Risk factors associated with lead-induced tricuspid valve dysfunction include older age, defibrillator leads, location of leads (posterior and septal leaflets), and leads passing between chordae.[222] A recent study found that significant TR associated with pacemaker leads was associated with increased mortality.[223]

Polewczyk et al reported 63% improvement in TR severity and 75% clinical improvement in patients referred for lead extraction due to symptomatic TR.[221] Conversely, Nazmul et al reported no improvement in the severity of symptomatic TR following percutaneous extraction of RV leads (with reimplantation of ventricular leads into the coronary sinus [CS]).[224] The authors reported that dilation of the tricuspid valve annulus persisted following lead removal and suggested the presence of preprocedural annular dilation might be helpful in predicting patients less likely to improve following percutaneous lead revision.[220] Consequently, these patients could benefit from an open extraction that permits tricuspid valve annuloplasty at the time of lead extraction. Thus, a combined evaluation and approach, in conjunction with cardiothoracic surgery, is optimal with either percutaneous extraction followed by open tricuspid surgery or, more commonly, open surgery with removal of all visible lead portions followed by percutaneous removal of the remnants.

The risk of traumatic tricuspid valve injury during lead extraction varies from 3.5% to 19%.[225–227] Features associated with the development of postextraction TR include advanced age, extraction of two or more leads, use of powered sheaths, female sex, and defibrillator leads.[225–227] Outcomes following traumatic tricuspid valve injury are less clear; one study indicated that 26% of patients developed new right heart failure symptoms, and 11% required surgical repair.[227]

9.8. Arrhythmias

Operators routinely assess for an increase in the degree of ventricular ectopy when implanting RV leads, with concern that frequent premature ventricular contractions might be predictive of that lead location being proarrhythmic. There are reports in the literature of refractory ventricular arrhythmias that occurred after an ICD lead placement, which resolved with extraction.[201]

9.9. Radiation Therapy

The primary clinical concern occurs when the CIED is situated in the path of the planned radiation beam and might interfere with adequate tumor treatment. Under these circumstances, a CIED relocation is recommended by the recent HRS consensus statement.[202] Options for CIED relocation include device placement on the contralateral side, with tunneling of existing leads using adapters/lead extenders, placement of the new device system on the contralateral side while abandoning the existing leads, and placement of a new device system on the contralateral side with extraction of the existing leads. There are potential risks and benefits with each approach. Clinical factors such as the patient's overall prognosis and ability to tolerate procedures clearly need to be taken into account, and a shared decision-making process between the patient and the treating physicians should take place.

There is little evidence to substantiate a practice of CIED relocation with potential lead extraction to minimize radiation exposure to the device.[202,228,229] A number of studies have documented tolerance of the CIED generator well above the commonly recommended 2 Gy threshold and have established that the strongest predictor of CIED malfunction is exposure to neutron-producing beam energies >10 MV, not cumulative doses to the device.[202,228,229] Enhanced CIED monitoring without invasive measures is appropriate under these circumstances and should again involve an informed discussion between the patient and the treating physicians.

10. Periprocedural Management

10.1. Preprocedural Evaluation and Lead Management Strategy

The major risks associated with lead extractions can be attributed to the body's response to the foreign implanted material. Within a year, fibrosis encapsulates the leads and cardiac structures in direct contact with the lead. These sites of fibrosis can fuse, leading to dense adhesions between the endocardial structures and the lead that calcify over time. Sites of adhesion commonly occur at the site of venous entry, the SVC, and the electrode-myocardial interface.[230] Dense adhesions and calcified fibrotic lesions significantly affect the ease of extraction.[230,231] In addition to intravascular and intracardiac adhesions, lead-to-lead binding often occurs, further complicating the complexity of extraction. Lead dwell time and lead characteristics, including passive fixation and dual shocking coils, correlate with fibrous adherences.[230] Conversely, SVC and intracardiac adhesions are lower in leads with backfilled shocking coils and those treated with expanded polytetrafluoroethylene.[230] Interestingly, significant adhesions within the device pocket can be a marker for challenging extractions.[232]

An area that warrants consideration is the development of strategies to reduce the risk of difficult future extraction at the time of initial CIED implant or generator exchange. In addition to assuring appropriate indications for CIED implantation, methods for minimizing the need for future lead revisions and reduce the risk of future extraction include the following:

- Using implant techniques that minimize the risk for lead perforation and/or lead fracture
- Minimizing the risk of infection:
  - Proper administration of periprocedural antibiotics
  - Appropriate anticoagulation management[233]
  - Minimizing the use of temporary pacing[158]
  - Assessing the need for prophylactic capsulectomy, because this can increase the risk for pocket hematomas without decreasing pocket infections[234]

- Considering epicardial lead placement or subcutaneous defibrillators in patients at elevated risk for infection
- Ensuring proper postimplantation wound management
- Optimal lead selection:
  - Dual-coil defibrillator leads are more dangerous to extract and can have higher failure rates (due to more components) than single-coil ICD leads[235]
  - Coated and backfilled shocking coils have less tissue ingrowth than ICD shocking coils that allow tissue to grow under the coils[236]

Choosing the best lead management strategy warrants a thoughtful and patient-centered assessment of lead management options. Extraction should be offered when alternative lead management options appear less favorable to the patient's immediate and long-term risks. These alternatives include device reprogramming, lead abandonment, or, in the case of venous occlusion, venoplasty or contralateral lead placement.[209,210,237] The clinical factors associated with an increased risk of extraction are listed in Table 4. Several investigators have developed extraction risk models that consider factors such as lead dwell time, number of leads, patient age, and other comorbidities.[62,140,212,240–243,245–252] Age is often an important consideration for lead extraction. Higher risk of lead malfunction and longer exposure to potential complications from abandoned leads are often cited as a justification for lead extraction in younger patients.[26,27,253] Although lead extraction in elderly patients can be associated with higher overall risk of mortality, particularly in the presence of comorbidities, the procedural risk does not increase with age, and successful extraction can be performed when clinically appropriate.[62,250,251] Cumulative mortality rates following lead extraction range from 2.1%–3.3% at 30 days to 8.4%–10% at 1 year and 33%–46.8% at 10 years, with higher rates in patients with infected leads.[62,140,212,240,250–252]

Table 4 Factors associated with extraction procedure complications and longer-term mortality

Factor	Associated risk
Age	1.05-fold ↑ mortality[238]
Female sex	4.5-fold ↑ risk of major complications[239]
Low body mass index (<25 kg/m^2)	1.8-fold ↑ risk of 30-day mortality[62] ↑ no. of procedure-related complications[212]
History of cerebrovascular accident	2-fold ↑ risk of major complications[62]
Severe LV dysfunction	2-fold ↑ risk of major complications[62]
Advanced HF	1.3- to 8.5-fold ↑ risk of 30-day mortality[62] 3-fold ↑ 1-year mortality[240]
Renal dysfunction	ESRD: 4.8-fold ↑ risk of 30-day mortality[62] Cr ≥2.0: ↑ in-hospital mortality[210] and 2-fold ↑ risk of 1-year mortality[240]
Diabetes mellitus	↑ in-hospital mortality[212] 1.71-fold ↑ mortality[238]
Platelet count	Low platelet count: 1.7-fold ↑ risk of major complications[62]
Coagulopathy	Elevated INR: 2.7-fold ↑ risk of major complications and 1.3-fold ↑ risk of 30-day mortality[62] Anticoagulant use: 1.8-fold ↑ 1-year mortality[240]
Anemia	3.3-fold ↑ risk of 30-day mortality[62]
Number of leads extracted	3.5-fold ↑ risk of any complication[241] 1.6-fold ↑ long-term mortality[242]
Presence of dual-coil ICD	2.7-fold ↑ risk of 30-day mortality[62]
Extraction for infection	2.7- to 30-fold ↑ risk of 30-day mortality[62,241] 5- to 9.7-fold ↑ 1-year mortality[62,242] CRP >72 mg/L associated with ↑ 30-day mortality[243] 3.52-fold ↑ mortality[238]
Operator experience	2.6-fold ↑ no. of procedure-related complications[244]
Prior open heart surgery	↓ risk of major complications[241]

Cr = creatinine; CRP = C-reactive protein; ESRD = end-stage renal disease; HF = heart failure; ICD = implantable cardioverter defibrillator; INR = international normalized ratio; LV = left ventricular.

10.2. Management of Patients Undergoing Lead Extraction

Management can be divided into three phases (preparatory, procedure, and postprocedure phases), each containing distinct components aimed at minimizing the risk of procedure-related complications and facilitating the diagnosis and management of complications when they occur. As with any invasive procedure, complications will occur, and it is paramount that the extraction team is prepared to handle catastrophic complications to prevent unnecessary deaths.

10.2.1. Preparatory Phase

The purpose of the preparatory phase is to confirm appropriate indications for lead extraction, assess procedure complexity, define extraction approach and goals, and optimize the patient's clinical status in preparation for the procedure. The following key components should be addressed during this phase:

- Perform a comprehensive history and physical exam:
  - Perform anticoagulation management
  - Optimize hemodynamics
- Confirm the appropriate indications for extraction
- Perform the CIED interrogation:
  - Indicate lead model numbers, noting any lead that requires special consideration
  - Confirm lead implant dates
  - Identify prior abandoned leads and implant dates
  - Assess pacemaker dependency
  - Turn off rate-adaptive programming
- Obtain the preprocedural imaging when clinically appropriate. Options include the following:
  - Chest radiography (both posteroanterior and lateral) to assess lead position, identify the presence of abandoned leads, and confirm lead type

- Echocardiogram to assess LV function, identify intracardiac masses/vegetations, evaluate valve function and whether a patent foramen ovale is present, and identify intracardiac lead course and presence of pleural or pericardial effusions
- Cardiac CT to assess extravascular or extracardiac lead positioning and potentially identify sites of venous adhesions
- Fluoroscopy to identify sites of venous occlusion or stenosis and assess regions of lead mobility and adherence

- Define the extraction approach and procedure goals:
  - Percutaneous vs open extraction
  - Hybrid approach to the extraction
  - Goal of single vs multiple lead removal or complete system removal
  - Minimizing damage to nontargeted leads
- Determine the postextraction plan:
  - Indications for CIED reimplantation
  - Timing of CIED reimplantation
- Obtain the patient's informed consent

A comprehensive history and physical examination are necessary when assessing patients referred for lead extraction, including a review of the patient's comorbidities, medications, allergies, cardiac device history, indications, and implant dates. The physical exam should identify signs of decompensated heart failure and sequelae of CIED-related endocarditis; assess chest wall venous collaterals, which are suggestive of venous occlusion or high-grade stenosis; examine the device pocket for signs of infection (eg, fluctuance, cellulitis, draining sinuses, skin dimpling); and determine device location (eg, subpectoral, submammary). The cardiac device needs to be interrogated to obtain lead information, confirm malfunctioning leads, and assess pacemaker dependency. Patients who are not pacemaker-dependent should have their device reprogrammed to backup pacing modes (VVI 40 bpm) prior to the procedure to confirm lack of dependency. Information regarding abandoned leads can be obtained by reviewing prior operative reports, contacting device manufacturers, or performing chest radiography. Hemodynamic status should be optimized prior to the extraction procedure.

10.2.2. Anticoagulation

Patients who are implanted with cardiac devices are frequently undergoing oral anticoagulation or dual antiplatelet therapy. Continuation of anticoagulation and avoidance of heparin bridging when implanting the cardiac device are relatively recent changes in practice.[254–256] The decision to withhold antiplatelet or anticoagulation therapy when implanting the CIED is a matter of weighing the risks of exposing patients to thromboembolic events during unprotected periods vs periprocedural bleeding complications.[254–256] Unlike CIED implantation, potentially life-threatening hemorrhagic events are a common complication of lead extraction procedures. Anticoagulation management should therefore be considered separately from cardiac device implantation. Observational studies have shown an approximately 3-fold increased risk of major complications and 1.3- to 1.8-fold increased risk of death in patients with an elevated international normalized ratio (INR; >1.2) at the time of lead extraction, although a preliminary study described a patient cohort in whom extraction was performed with a therapeutic INR.[62,257] Anticoagulation therapy is usually conducted in the perioperative phase, but periprocedural anticoagulation strategies should be considered on a case-by-case basis, after assessing the thromboembolic risk during unprotected periods.[255,256]

10.2.3. Preprocedural Imaging

Preprocedural imaging is important to confirm the number and location of indwelling leads. This information can be easily obtained from a chest radiography or fluoroscopy. However, advanced imaging modalities can provide the same information and potentially identify extravascular or extracardiac lead positioning. Electrocardiogram (ECG)-gated cardiac CT is commonly used to identify ventricular lead perforation and appears more accurate, with greater interobserver agreement, than chest radiography for the diagnosis of lead perforation.[258,259] The use of ECG-gated multidetector CT altered the approach to lead extraction in 3% of cases at one institution and was useful in predicting challenging extractions based on the presence of venous adhesions in 43% of cases at one center.[231] Lead artifacts, however, remain an impediment to the diagnostic accuracy of determining intravascular lead positioning.

Fluoroscopy with venography can also be helpful in the preparatory phase, identifying regions of venous stenosis or occlusion and adhesion sites. The incidence of venous stenosis following initial device implantation can be as high as 61%, with complete occlusion at the venous entry site in one-fourth of patients.[88] The brachiocephalic vein and the SVC are common sites of stenosis. Venous occlusion increases the complexity of extraction, as demonstrated by the greater use of advanced tools, longer procedures, and fluoroscopy times.[260]

Transthoracic echocardiography can provide useful information regarding LV function, presence of intracardiac masses or vegetations, valvular disorders (including TR severity), intracardiac lead course (including anomalies such as inadvertent LV lead positioning), intracardiac adhesions or lead perforation, and preexisting pleural or pericardial effusions. Using transthoracic color Doppler echocardiography, Yakish et al demonstrated that turbulent flow in the SVC was more common in patients with lead dwell times of 2 years or more. Turbulent flow correlated with significant fibrosis in the SVC in a subset of patients who underwent transvenous lead extraction and correlated with more complex extractions.[261]

10.2.4. Extraction Approach: Open Versus Percutaneous Extraction

The percutaneous approach to lead extractions is generally preferred over open extractions because it is inherently less

invasive and significantly reduces patient morbidity.[1,178] Conversely, open extractions are generally favored in high-risk extractions to avoid potentially life-threatening complications that can be encountered during percutaneous extractions.[1] The challenge then becomes predicting which extractions are sufficiently high-risk to justify the inherent morbidities associated with open-heart surgery. In general, open extractions are considered when the patient has failed a prior extraction procedure, has another reason for cardiac surgery, or when cardiac imaging identifies large lead masses (vegetation or thrombus >2.5 cm).[1]

Case reports that discuss different ways of "debulking" lead-associated vegetations identified by preprocedural imaging prior to proceeding with lead extraction might offer options for patients with large vegetations that are deemed too high-risk for either transvenous or open extraction. Patel et al described three cases in which AngioVac was used to debulk lead vegetations.[262] This resulted in clinical improvement (including weaning of vasopressors) and permitted lead extraction to be safely performed 2–7 days later without complications. Thrombolytics have also been used to reduce vegetation size in patients with CIED-associated infective endocarditis.[263]

Once the optimal extraction approach has been defined, the next important step is to define the procedure goal. The procedure goal for CIED-related infection (including isolated pocket, bacteremia, or CIED-endocarditis) should be complete system removal.[1] The procedure goal for lead malfunction differs on a case-by-case basis and should be determined in the preprocedure phase.

10.2.5. Cardiac Device Reimplantation

Reassessment of appropriate indications for CIED reimplantation is imperative and should be part of the preparatory phase. Over time, clinical indications are updated, the patient's clinical status can change, such that device therapy is no longer necessary, or the patient's wishes can change, particularly regarding ICD therapy. In observational studies, over one-third of patients did not have devices reimplanted after undergoing system extraction for CIED infection.[140,143]

10.2.6. Informed Consent

The final step in the preparatory phase is informed consent, which ideally takes place with the patient in the presence of family members or other social support. A review of this discussion, 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.

10.3. Procedure Phase

10.3.1. Patient Preparation

Routine preoperative blood work, including complete blood counts and metabolic and coagulation panels, should be obtained prior to the procedure. The type and cross for 2–4 units of packed red blood cells should be obtained prior to the procedure, especially for those patients with a higher complication risk during extraction, and the blood products should be readily available in the procedure room. External patches that permit transcutaneous pacing and defibrillation should be placed on the patient outside of the sterile working field. Device reprogramming to inactivate tachytherapies and/or enable asynchronous pacing, when appropriate, can be performed once the patient is connected to a cardiac monitor. Patients should be sterilely prepped 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 blood pressure monitoring and pulse oximetry to monitor oxygenation. Given that most complications involve vascular tears of the upper extremities, IV access to permit rapid infusion of fluid, vasopressors, and blood products should be placed in the femoral veins. Some centers routinely place sheaths in the common femoral artery and vein to serve as access sites for rapid placement of perfusion cannulas if cardiopulmonary bypass is necessary. Most centers perform lead extractions under general anesthesia to minimize patient discomfort and facilitate the use of intraprocedural TEE, which also eliminates the need for urgent intubation should complications occur and allows the anesthesia team to focus on resuscitation rather than intubation.

For transient rate support during the extraction, isoproterenol may be considered, but temporary transvenous pacing is usually employed if longer periods of rate support are required. Temporary pacing using the femoral approach is generally preferred when a superior extraction approach is planned to minimize interaction between the temporary pacing catheter and extraction tools. Temporary pacing might be required at the beginning of the operation for patients who are not pacemaker-dependent, particularly those with baseline left bundle branch block. If longer periods of continued temporary pacing are required after the lead extraction procedure, the femoral venous temporary pacing catheters can be exchanged for externalized temporary pacemakers using active fixation leads placed typically via the superior veins. Alternatively, if clinically appropriate, a permanent pacing system can be immediately implanted after the extraction is complete.

10.3.2. Intraprocedural Imaging

Both TEE and intracardiac echocardiography (ICE) have been used intraprocedurally to assist with lead localization and characterization of masses and to provide clinically relevant information during periods of hemodynamic instability. ICE can be particularly helpful for imaging right-sided cardiac structures, because the catheter can be advanced to the chamber of interest. Conversely, visualization of right-sided structures using TEE can be somewhat challenging given their relative anterior position.

The safety and efficacy of preprocedural and intraprocedural ICE was first described by Bongiorni et al. Preprocedural axial images were obtained from the lead venous entry site to the RA and used to distinguish between free-

floating and adherent leads.[264] Fibrotic adhesions were visualized in the subclavian vein (80%), innominate vein (68%), RV (68%), and SVC (56%). Additionally, SVC and subclavian vein occlusion were identified by the inability to pass the ICE catheter in two patients. This imaging modality might be preferred by centers that routinely use ICE for other procedures.

A number of observational studies have reported the efficacy of TEE in identifying or excluding cardiovascular causes of hemodynamic instability during lead extraction.[265–267] Single-center observational studies indicate that TEE identified critical findings that prompted surgical intervention in 6%–40% of cases, prevented premature procedure termination in approximately 10%, and excluded cardiovascular causes of hypotension in approximately 50%.[265–267] TEE was placed at the beginning of the extraction procedure or as a rescue diagnostic procedure for managing refractory hypotension. Three-dimensional TEE is an emerging technology that can be useful for identifying adhesion sites.

Both modalities are helpful for characterizing lead vegetations, monitoring tricuspid valve function, and documenting pericardial effusions before and during lead extraction.[265,268] Narducci et al compared the diagnostic yield of ICE vs TEE in detecting vegetations in patients undergoing extraction for CIED-related infections. ICE was more sensitive than TEE at detecting vegetations in patients with definite (100% vs 73%) or probable (27% vs 12%) infective endocarditis using the modified Duke criteria, with an overall positive predictive value of 65.6% and negative predictive value of 100%.[268]

Intraprocedural imaging provides clinically relevant information that can enhance the safety of lead extraction, and its use during extractions is strongly recommended. The preferred imaging modality should be center specific, based on the operator's familiarity and comfort with image interpretation.

10.3.3. Extraction Tools

Extractions can be successfully completed using a variety of approaches and tools, including simple manual traction, locking stylets, telescoping sheaths, femoral snares, mechanical cutters, and laser sheaths. At a minimum, extractors should have a working knowledge of these tools and the situations in which the tools are particularly helpful. Lead extraction is usually performed via a superior approach at the lead insertion site. Simple traction with either a standard or locking stylet is usually attempted first. This approach is generally successful in removing leads that move freely within the vein but remain attached at the tip to the myocardium, which can be observed with infected leads or those with a short lead dwell time. Use of a locking stylet that allows application of traction force more distally within the lead is crucial for determining the ease of extraction, whether using either simple traction or specialized sheaths.

A number of single-center retrospective studies have reported their experience using various extraction tools designed to disrupt fibrous adhesions (Appendix 7). Optimal tool selection varies based on the lead-tissue interface, fibrotic lesion characteristics, lead characteristics, lead dwell time, and operator experience. Telescoping sheaths and femoral snares can effectively disrupt fibrous adhesions but tend to fail when confronted with dense fibrotic or heavily calcified lesions. Laser sheaths can handle fibrous lesions efficiently but can be less effective when confronted with heavily calcified lesions.[269] Mechanical cutters, on the other hand, can be more efficient at traversing densely calcified fibrotic lesions. Suffice it to say, no one tool is adept at negotiating all types of fibrous adhesions encountered during lead extractions. Switching between extraction tools and approaches might be necessary.

Not uncommonly, the operator must change the approach to salvage extractions. For example, Starck et al noted that adding femoral snaring to the superior approach increased complete success by 10% and clinical success by 13%.[270] Similarly, de Bie et al reported that clinical success increased from 84.8% with manual traction alone to 93.5% when combined with femoral snaring.[271] The femoral approach can also be helpful in snaring lead fragments and in older (OR 1.16 per year) or passive-fixation leads (OR 2.52), which are prone to fracture.[271,272]

Some centers prefer a strictly femoral approach. Bracke et al reported their experience using the Needle's Eye snare (Cook Medical) as the primary tool for pacing lead extraction.[272] Complete procedural success was reported in 94.4% of cases, with a mean pacing lead dwell time of 9.2 $\pm$ 5.8 years. Complete success using the snare was affected by lead location (CS 100%; RA 99.3%; and RV 90.1%). Failure and partial failures occurred in 1.8% and 3.8% of cases. The clear majority of these leads were RV leads with lead dwell times exceeding 10 years. Two (0.9%) RA perforations occurred that required surgical intervention. There were no procedure-related deaths. In a registry study of 3510 consecutive patients undergoing lead explantation, a femoral approach either as a primary strategy (9.09%) or secondary strategy (3.46%) was associated with a higher complication rate when compared with other approaches (1.43%).[273] In contrast to extracting via the implant vein, a strictly femoral approach does not maintain superior venous access.

A modified mechanical dilatation technique using multiple venous entry sites was described by Bongiorni et al.[264] This approach begins at the venous entry site with the introduction of telescoping countertraction sheaths, followed by transfemoral retraction of the lead to allow for snaring from an internal transjugular approach if the physician is unable to extract the lead fully from the venous entry site. The overall complete success rate at the author's center was 98.4% (manual traction 14.3%), with a 0.9% partial success rate and a 0.6% failed extraction rate. Major complications occurred in 0.7% of cases, all due to tamponade, and three (0.3%) cases resulted in death.

10.3.4. Extraction of Coronary Sinus Leads

Unlike atrial or ventricular leads, CS leads can often be removed with manual traction.[274] Fibrous adhesions are less common in the CS, perhaps due to smaller lead diameters and lack of direct (active or passive) fixation mechanisms.[275] However, as with other leads, longer dwell times and the larger lead diameters increase the need for mechanical or powered sheaths.[276] Complete and clinical success are similar to other leads, averaging 98%–99% (range 91%–100%).[274,276,277] The rate of major complications is low, ranging from 0% to 3.9%, excluding complications associated with the active fixation Medtronic StarFix lead.[274,276,277]

As with all extractions, CS lead reimplantation should be evaluated to ensure that appropriate indications exist. Whether to replace a CS lead in nonresponders to CRT is controversial and beyond the scope of this document. However, reimplantation can prove challenging due to thrombosis or occlusion of the main body of the CS or its tributaries as a result of direct vascular injury during the extraction.[276,277] Retaining access to the main body of the CS with a guide wire delivered through the working sheath's lumen is one way to retain access in noninfectious cases, when the plan includes reimplantation following extraction. Balloon occlusive venography can also be helpful to visualize the status of the branch through which extraction was performed and identify alternative targets.

10.3.5. Leads That Require Special Consideration

10.3.5.1. Medtronic StarFix (Model 4195)

Extractors should be mindful of the unique challenges posed during extraction of the Medtronic StarFix model 4195.[271–277] This is the only active-fixation CS lead that is currently available and is among the most difficult leads to extract. Inexperienced operators should probably avoid extracting this lead unless performed in consultation with an experienced extractor. At a minimum, extractors should have a working knowledge of the various techniques that have been used to facilitate extraction of this lead. Importantly, implanting physicians should have a compelling reason to implant this lead, particularly with the advent of quadripolar leads.

Successful removal of StarFix leads varies by study, ranging from as low as 50% to 100%.[238,278–280] Given that significant tissue ingrowth occurs around the fixation lobes, successful extraction is more likely with shorter implant times.[277,279] Major complications, including CS tears and pericardial tamponade, have been reported in 15%–17% of cases.[279,280]

10.3.5.2. Small-Diameter Pacing Leads

The SelectSecure lumenless pacing lead (model 3830, Medtronic, Minneapolis, MN) is a 4.1F diameter, nonretractable active-fixation lead that is delivered through a catheter. The lead's small diameter is particularly attractive for use in children who need pacing leads. The lead does not permit placement of locking stylets but can be successfully extracted with simple traction while simultaneously employing counterclockwise rotation on the lead.[281] Manual traction alone successfully removed 40.9% of SelectSecure leads with a mean lead implant duration of 4.1 ± 2.6 years. The remaining leads were removed using polypropylene countertraction sheaths (31.8%) and the Evolution mechanical sheath (27.3%).[282] Care should be taken when using powered sheaths with this lead, because establishing a rail can be challenging due to the differences in size between the sheath and lead. Small-diameter leads using a coaxial design (eg, Boston Scientific FINELINE 4469-4474) also require special care when extracting and are probably more difficult to completely extract. In some cases, using a combined femoral and superior approach will minimize the tension required to remove the lead.

10.3.5.3. Abbott Riata ICD Leads (Riata 1500 and Riata ST 7000 Series)

Extractors should be aware of the differences in lead design between Riata and conventional ICD leads and understand how these differences affect lead extraction. The 1500-series Riata leads are larger in diameter (8Fr) and lack backfilled shocking coils. As a result, these leads are susceptible to significant tissue ingrowth. The 7000-series Riata leads are smaller in diameter (7Fr) and contain backfilled shocking coils. Both leads are susceptible to the inside-out insulation defect that results in conductor cable externalization. Cable externalization rates are higher for the 1500 series than for the 7000 series (31.4% vs 6.3%, respectively; $P<.001$) Riata leads and increase over time (0% at <3 years; 13% at 3–5 years; 26% at >5 years).[70,283] By design, the externalized conductor cables are welded to the distal rather than the proximal edge of the shocking coil, which increases the likelihood of "snowplowing" during extraction.

During the extraction procedure, the operator should maintain equal traction on the defibrillator lead body and the externalized cables while advancing the working sheath to avoid dragging and prolapsing the cables proximal to the extraction sheath. Reduction of externalized conductor cables should be attempted before advancing the working sheath, otherwise it might be impossible to advance the sheath over the externalized cables. Use of a larger sheath to accommodate externalized cables could be beneficial. Extractors should also be aware of the potential for thrombus formation on externalized cables and consider preprocedural or intraprocedural imaging prior to lead extraction.[284]

10.3.6. Special Considerations

10.3.6.1. Management of Isolated Pocket Infections in Patients Who Refuse Lead Extraction

Centers have reported various approaches to managing isolated pocket infection in patients who refuse lead extraction.[285–287] Lopez et al described the use of a closed irrigation system that consisted of pulse irrigation and suction, using a solution of vancomycin and gentamycin for 72 hours following pocket debridement and washout in five patients with isolated pocket infection. Patients remained

free of infection during a mean follow-up of 19 months.[285] Puri et al described a similar closed irrigation system using povidone-iodine solution infused 4 times daily for 1 week, in addition to a 2-week course of oral antibiotics.[286] The authors reported no recurrent infection over a 2-year follow-up period. Poller et al used an alternative approach to manage isolated pocket infections in five people who refused lead extraction.[287] In these cases, the generator was removed and the leads were cut, allowing them to retract into the vascular space. A vacuum-assisted wound closure dressing was placed to promote wound closure, and devices were implanted on the contralateral side when appropriate. One patient in this study developed recurrent pocket infection at 69 days.

10.3.6.2. Leads Inadvertently Placed in the Left Ventricle

Inadvertent placement of leads into the left ventricle is a rare complication of device implantation that presents unique management challenges. Thromboembolism resulting in stroke is a potential complication, as is mitral valve dysfunction due to lead impingement or adhesion. Preprocedural and intraoperative TEE should be performed to evaluate the presence of thrombus and adherence to the mitral valve. In the absence of thrombus or adherence, the lead may be removed with simple manual traction. Open extraction is otherwise preferred, particularly in the presence of thrombi or mitral valve dysfunction.

10.3.6.3. Management of Retained Lead Fragments

Another area with emerging data is the consequence of retained fragments following a partial or failed extraction. A direct correlation between longer lead implant duration and retained lead fragments was observed by Rusanov et al.[172] One-third of patients with failed or partial extraction, initially referred for transvenous lead extraction due to infection, subsequently required an open extraction for endocarditis involving the retained lead fragment.[288] Gomes et al reported similar findings, noting an increased incidence of recurrent infection following initial extraction for infection in patients with retained fragments vs complete removal (13.5% vs 3%, $P=.001$).[289] Calvagna et al reported their experience retrieving retained fragments using femoral snaring, citing a 93% success rate with no major complications.[290] Therefore, the goal of extraction for patients with CIED-related infections should be complete system removal.[291]

10.3.6.4. Ghosts

Not infrequently, small residual fibrinous strands or masses remain within the RA or SVC following lead extraction. These so-called ghosts have an incidence ranging from 8% to 14% and are most commonly observed in patients with infectious indications for extraction.[291,292] Ghosts were more common in patients with CIED-related endocarditis (OR 7.63; $P=.001$) or positive blood cultures (OR 2.98; $P=.048$), and patients with ghosts had a higher mortality than those without ghosts (HR 3.47; $P=.002$).[292] The approach for these residual masses is unclear. Given the potential association between ghosts and adverse outcomes, their presence should probably be noted on postextraction imaging and might warrant closer postextraction follow-up. No specific therapy is indicated for patients with this finding.

10.3.7. Management of Complications

Prompt recognition and management of life-threatening complications is paramount in preventing catastrophic outcomes. To ensure optimal quality assurance, extraction programs should document all intraprocedural and postprocedural complications encountered during lead extractions. A review of the complications provides an opportunity for the extraction team to learn from the adverse events and identify ways to improve the safety and efficacy of extraction procedures.

Complications should be differentiated by severity into major and minor. Major complications are those that pose an immediate threat to life or that result in death. Minor complications are undesired adverse events that require medical intervention, including minor procedural interventions, but do not significantly affect the patient's function.

Some complications can be attributed to suboptimal implant techniques. One assumption of lead extraction is that the lead courses within the venous system, from the venous entry site to the cardiac attachment point. Unfortunately, this is not always the case. Identifying extravascular leads remains a diagnostic challenge. Extractors should have a high clinical suspicion for arteriovenous fistulas or leads inadvertently traversing the artery before entering the vein.[244] A breakdown of procedure-related complications and incidences reported in the literature is provided in Table 5.

Table 5 Extraction procedure-related complications

	Incidence, %
Major[62,210,245,246,274,282]	0.19%–1.80%
Death[62,210,245,246,282]	0.19%–1.20%
Cardiac avulsion[62,210,282]	0.19%–0.96%
Vascular laceration[62,210,245,246]	0.16%–0.41%
Respiratory arrest[62]	0.20%
Cerebrovascular accident[62,210]	0.07%–0.08%
Pericardial effusion requiring intervention[62,274]	0.23%–0.59%
Hemothorax requiring intervention[62,210]	0.07%–0.20%
Cardiac arrest[62]	0.07%
Thromboembolism requiring intervention[210]	0.07%
Flail tricuspid valve leaflet requiring intervention[62]	0.03%
Massive pulmonary embolism[304]	0.08%
Minor[62,210,245,246,282]	0.60%–6.20%
Pericardial effusion without intervention	0.07%–0.16%
Hematoma requiring evacuation[62,210,282]	0.90%–1.60%
Venous thrombosis requiring medical intervention[62,210]	0.10%–0.21%
Vascular repair at venous entry site[62,210,245]	0.07%–0.13%
Migrated lead fragment without sequelae[62]	0.20%
Bleeding requiring blood transfusion[62,245,282]	0.08%–1.00%
AV fistula requiring intervention[62]	0.16%
Coronary sinus dissection[62]	0.13%
Pneumothorax requiring chest tube[282]	1.10%
Worsening tricuspid valve function[282]	0.32%–0.59%
Pulmonary embolism[245]	0.24%–0.59%

10.3.8. Vascular Tears

Vascular tears involving the subclavian and innominate veins can result in ipsilateral hemothorax but can be difficult to identify or accurately localize. Awareness of the position of the working sheath and imaging with TEE or fluoroscopy can be helpful in identifying potential sites of injury. More importantly, about two-thirds of life-threatening vascular tears occur in the SVC, half of which are below and half of which are above the pericardial reflection.[293] This results in pericardial effusion and tamponade when below the pericardial reflection and in hemothorax and rapid demise when above the pericardial reflection unless the bleeding is immediately controlled. Deployment of an occlusive compliant balloon can control the severity of bleeding while the chest is opened and definitive repair is pursued. Although venography, coated stent implantation, and pericardiocentesis have been successfully employed, the time lost in avoiding opening the chest often results in avoidable mortality in many patients. Positioning an introducer sheath and a stiff guide wire that extends from the femoral vein to the right internal jugular or subclavian vein at the beginning of the extraction procedure allows for rapid deployment of an occlusive balloon to minimize bleeding as the patient is rapidly prepared for definitive repair. Initial studies have suggested that the occlusive balloon is safe and associated with improved survival in the setting of vascular tears of the SVC.[294,295]

Temporary measures to minimize blood loss can be critical to survival while awaiting definitive repair. It is critical that the surgical team responds immediately and provides backup in the surgical management of transvenous lead complications. In patients with a prior sternotomy, a right-sided thoracotomy and double-lumen endotracheal tube might be required for surgical access to a lateral tear above the pericardial reflection, emphasizing the importance of preprocedural planning involving the entire extraction team. Unfortunately, few studies have reviewed the surgical management of extraction-related complications.

10.4. Postprocedure Phase

The main goal of the postextraction phase is to monitor for postprocedure complications and ensure close follow-up for the prompt management of late complications. Physical examinations, including listening for arteriovenous fistula bruits over the subclavian areas, are important for all patients. Following extraction, most centers will obtain chest radiography and transthoracic echocardiograms within 24 hours of the procedure. The purpose of chest radiography is to rule out occult hemothorax or pneumothorax and document lead positions following implantation of either a temporary or permanent pacemaker. The echocardiogram is useful for screening unrecognized adverse events such as tricuspid valve injury, detecting the presence or stability of pericardial effusion, and documenting any remaining intracardiac masses (either retained fragments or so-called ghosts). For patients who undergo extraction for CIED-related infection, the postprocedure phase focuses on wound care management, appropriate selection and duration of antibiotics, and determining the appropriate timing for device reimplantation.

11. Facilities, Equipment, and Training

Given the potential for life-threatening complications, lead extractions should only be performed in centers with an environment fully supportive of a lead extraction program, which includes a collaborative lead extraction team, appropriate facilities, and all necessary equipment and facilities to perform extractions and manage complications.

A 2010 study specifically evaluated whether extractions can be performed safely in the electrophysiology laboratory with surgical backup.[296] The investigators reported similar success rates (93.1% vs 91.4%, $P=.227$), overall complication rates (2.2% vs 2.8%, $P=.431$), major complication rates (1.0% vs 2.1%, $P=.794$), and procedure-related mortality rates (0.12% vs 0.18%) when comparing procedures in the electrophysiology laboratory vs the operating room. Regardless of whether the extraction is performed in the electrophysiology laboratory or the operating room, the most important condition is that the location provides all necessary equipment to safely perform lead extractions and manage complications. It is essential that a cardiac surgeon and surgical team are immediately available, with access to equipment to perform emergent sternotomy or thoracotomy within 5 to 10 minutes. The primary focus of a lead extraction program should be to maximize procedure safety and efficacy. Recommendations for facilities and training have not changed from the requirements outlined in the 2009 HRS Extraction document.[1]

11.1. Personnel

The importance of a collaborative, multidisciplinary team cannot be overstated. For programs in which the primary operator is not a surgeon, the involvement of a cardiothoracic surgeon and surgical staff familiar with the management of lead extraction complications is critical to ensure safe outcomes.[1] Some centers have also included interventional radiologists and/or vascular surgeons as members of the multidisciplinary team to assist with percutaneous management of vascular tears. For centers that perform extraction in children and young adults, close collaboration between pediatric cardiologists, pediatric electrophysiologists, and lead extraction specialists is essential.

11.2. Operator Training and Maintenance of Skills

Appropriate training of all staff involved in the extraction team is required to maximize procedural safety and efficacy. Physicians performing extractions should be properly trained in all aspects of extraction techniques (superior and femoral approaches) and in recognizing and managing complications.

In general, procedure success and complication rates are influenced by extractor experience and overall center

volume.[297,298] Recommendations for training have not changed from those outlined in the 2009 HRS Extraction document.[1] That document recommended that physicians undergoing training in lead extractions should extract a minimum of 40 leads as the primary operator under the direct supervision of a qualified physician and a minimum of 20 leads should be extracted annually to maintain competency and were also adopted by a subsequent EHRA position paper.[299] More recently, the *2015 ACC/AHA/HRS Advanced Training Statement on Clinical Cardiac Electrophysiology (a Revision of the ACC/AHA 2006 Update of the Clinical Competence Statement on Invasive Electrophysiology Studies, Catheter Ablation, and Cardioversion)* noted that the minimal procedural volume to achieve and demonstrate clinical competence is 30 lead extractions.[300]

11.3. Simulators

Maytin et al evaluated the effect of virtual-reality lead-extraction simulations on electrophysiology fellows undergoing training for lead extractions.[301] In this study, eight fellows were randomized to simulator or conventional training and then compared based on procedural competency. All fellows underwent 4 hours of didactic training. The fellows randomized to the simulator group underwent 4 additional hours of simulator training. The fellows then participated in 5 months of clinical training in transvenous lead extraction, after which both groups underwent simulator case-based testing. All four fellows randomized to the conventional group experienced a simulator complication (two SVC tears, three RV avulsions), whereas only one complication (SVC tear) occurred in the simulator group (P=.02). Lead removal time was significantly longer in the conventionally trained group (12.5 ± 4.5 vs 5.5 ± 1.3, P=.02), and a trend toward excess pushing vs pulling forces was observed in the conventional group (push-pull: 1.3 ± 3.6 vs -1.0 ± 1.7, P=.31).[301]

When extractors who had performed over 40 lead extractions were asked to apply simple manual traction to a phantom torso, a significant range of applied forces emerged (3.0 N–24.7 N; median 10.9 N).[302] The investigators also found that the forces applied at the proximal end of the lead were 10% higher than those measured at the tip. These studies suggest that simulator training can provide valuable feedback to physicians and can represent important tools for maintaining competency and training physicians who are new to lead extractions.

11.4. Surgeon Training

The training of cardiothoracic surgeons who support percutaneous lead extractions has received little focus. Surgeons play a vital role in managing major complications that occur during lead extractions that directly affect patient outcomes. It is therefore imperative that surgeons engage in continuing educational activities that focus on the surgical management of lead complications and remain abreast of significant developments within the field of lead extraction.

12. Outcomes and Follow-up

COR	LOE	Recommendation	References
I	C-EO	**Extraction programs and operator-specific information on volume, clinical success rates, and complication rates for lead removal and extraction should be available and discussed with the patient prior to any lead removal procedure.**	

Data collection is a critical component for all lead extraction programs and complete transparency of the data and analyses should be available to the patient and all other stakeholders.

Outcomes following lead management interventions, which include not only lead extraction but also interventions such as venoplasty, pocket debridement, and lead abandonment, can be divided into two phases: procedure and postprocedure outcomes. By definition, outcomes consider both the perceived success of the procedure and procedure-related complications identified over a predefined period. Accordingly, lead intervention procedure outcomes are defined by the extraction procedure success and, where applicable, complications that occur during the extraction procedure and the inpatient hospitalization period. Postprocedure complications can be divided into two phases: early complications that occur within the first 30 days and late complications that occur within the first year. With regard to lead management interventions, the primary postprocedure complication of significance is infection, which presents well beyond 30 days in 43%–75% of patients.[143,240] To adequately capture these events, postprocedure outcomes should include infections that occur during each of the time periods: 30 days, 1–6 months and >6 months.

Complications that can trigger medical attention following discharge include upper extremity swelling due to venous thrombosis; recurrent infection, particularly in patients who underwent incomplete extraction for CIED infection; new pocket or systemic infection; lead perforation; lead dislodgement; heart failure; symptoms associated with tricuspid valve injury; pneumonia; and complications from thromboemboli, including pulmonary embolism. Prompt recognition and management of these complications is the responsibility of the providers who care for patients after CIED implant or after extraction. Thus, proper communication between the provider performing the CIED lead management procedure and the provider who assumes the longitudinal care of the patient is paramount when the two are distinct, exchanging any pertinent information about the procedure and hospital course.

There are three aspects to consider when defining the procedural success of lead extraction. The first addresses whether the initial clinical goals of the procedure were achieved; the second considers whether a retained fragment was left behind; and the third requires that there were no procedure-related permanent or disabling complications or death. Complete procedural success indicates that all targeted leads and all lead material were successfully removed from the vascular

space and is defined for the entire procedure, with no permanent, disabling complications or procedure-related death. Clinical success is defined as removal of all targeted leads with retention of no more than a small portion of lead material (<4 cm) that does not negatively impact the outcome goals of the procedure.[303] Conversely, procedure failure is defined as an inability to achieve either complete procedural or clinical success or the development of any permanently disabling complications or procedure-related death.

Lead extraction program-specific success and failure metrics should be prospectively collected and communicated to patients during the decision and consent process prior to each potential lead extraction procedure. Information discussed with patients during the shared decision-making process should at least include (1) the annual lead extraction volume at that center, (2) the lead extraction clinical success rate, and (3) major procedure-related complication/death rates during hospitalization. Writing committee members firmly believe this information should be made publicly available and should be communicated to patients during the shared decision-making and informed consent process to ensure complete transparency. Additional information is likely to be valuable to the patient, including (1) personal lead extraction volume and personal number of leads removed during lead extraction procedures (yearly and lifetime), clinical success rate, and complication rate; (2) volume broken down between ICD and pacing leads; and (3) extraction indications (eg, infection, lead malfunction, and superfluous leads). More complete data collection is desirable and useful to promote quality outcomes and identify opportunities for process improvement but is not required.

13. Data Management

It is the opinion of the writing committee that centers performing lead extraction procedures maintain or participate in a multicenter data capture system that includes the ability to calculate site-specific metrics for procedure success, failure, and complications for all lead removal procedures. Procedure success and complications should be categorized according to the definitions outlined earlier to ensure standardization of data. Periodic review of complications often highlights opportunities for procedure and system improvements and demonstrates a commitment to quality improvement. Center-specific databases should include patient demographic information, operator information, indications for extraction (eg, infection, lead malfunction, and superfluous leads), type of lead removed (ICD vs pacing), lead extraction clinical success rates, procedure success rates (complete and clinical), major and minor complications, and deaths that occur during the procedure or within the early or late postprocedure phases.

14. Registries, International Collaboration, and the Future

Registries will be critical to our further understanding of how best to manage leads in the setting of infection, lead failure, and changing clinical conditions. The AHA, ACC, STS, HRS, ESC, and EHRA have all embraced clinical registries as a way of capturing "real-world" clinical practices. The European Society of Cardiology-sponsored European Lead Extraction ConTRolled Registry (ELECTRa) is already yielding important results that can serve as benchmarks for clinical success rates, complication rates, and mortality using the definitions from the 2009 HRS Extraction document (www.escardio.org/Sub-specialty-communities/European-Heart-Rhythm-Association-(EHRA)/partner-organisations-networks/ELECTRa-Registry).[1,273] The Extract Registry and Study Group currently has six centers in the United States and one in Australia and is actively recruiting additional centers (http://www.extractstudygroup.org). A more widespread use of registries offers the opportunity to monitor trends in lead extraction procedures, compare extraction techniques, define characteristics of leads undergoing extraction, assess procedure success and complication rates, and provide a venue to conduct observational research.

Beyond extraction-specific registries, larger device-based registries will be able to provide information on lead management strategies in general. Information from the NCDR and the National Inpatient Sample has already contributed to our understanding of clinical outcomes with lead abandonment and extraction in patients with ICDs.[69,304] The use of a medical device surveillance tool with the NCDR could be useful for early real-time identification of failure-prone ICD leads.[305]

Interactions on technique and methodology can now be shared worldwide via the Internet. Although discussions at this point are informal, this type of information could be systematically collected and evaluated to help identify best practices, taking individual clinical situations into account. Although new technologies will be able to obviate the requirement for transvenous and epicardial leads for future CIEDs, lead management issues will likely remain important for the next decade of clinical medicine. New technologies have reduced the periprocedural risks of lead extraction, but all extraction programs require a multidisciplinary approach with the commitment of significant resources.

In Memoriam

This document is dedicated to Marc A. Rozner, PhD, MD, CCDS (1952–2016), and the entire writing committee wishes to honor his integrity and commitment to science and patient care.

Appendix

Supplementary Data

Supplementary data (Appendices 3–7) associated with this article can be found in the online version at https://doi.org/10.1016/j.hrthm.2017.09.001.

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Appendix 1 Author disclosure table

Writing group member	Institution	Consultant/Advisory board/Honoraria	Speakers' bureau	Research grant	Fellowship support	Stock options/ Partner	Board Mbs/Other
Fred M. Kusumoto, MD, FHRS, FACC (Chair)	Mayo Clinic, Jacksonville, Florida	None	None	None	None	None	None
Mark H. Schoenfeld, MD, FHRS, FACC, FAHA, CCDS (Vice-Chair)	Yale University School of Medicine, New Haven, Connecticut	1: United HealthCare Services	None	None	None	None	None
Bruce L. Wilkoff, MD, FHRS, CCDS (Vice-Chair)	Cleveland Clinic Lerner College of Medicine of Case Western Reserve University, Cleveland, Ohio	2: Abbott; 2: Medtronic; 2: Spectranetics	None	None	None	3: Medtronic	None
Charles I. Berul, MD, FHRS	Children's National Medical Center, Washington, District of Columbia	1: Medtronic; 2: American Heart Association	None	2: Medtronic	None	None	1: Up to Date
Ulrika M. Birgersdotter-Green, MD, FHRS	UC San Diego Health, La Jolla, California	1: BIOTRONIK; 2: Abbott; 2: Medtronic	1: Medtronic; 2: Abbott	2: Boston Scientific	None	None	None
Roger Carrillo, MD, MBA, FHRS	University of Miami, Coral Gables, Florida	1: Sensormatic; 1: Sorin Group; 1: Medtronic; 1: Boston Scientific; 4: Spectranetics	None	4: Abbott	None	None	None
Yong-Mei Cha, MD	Department of Cardiovascular Diseases, Mayo Clinic School of Medicine, Rochester, Minnesota	None	None	None	None	None	None
Jude Clancy, MD	Yale University School of Medicine, New Haven, Connecticut	1: Spectranetics	1: Abbott; 1: Boston Scientific; 2: Spectranetics	None	None	None	None
Jean-Claude Deharo, MD, FESC	CHU La Timone, Service de Cardiologie, Marseille, France, and AMU, UMR MD2, Faculté de Médecine Nord, Marseille, France	1: Livanova; 1: Abbott; 1: BIOTRONIK; 1: Boston Scientific; 1: Medtronic	None	None	None	None	None
Kenneth A. Ellenbogen, MD, FHRS	Virginia Commonwealth University Medical Center, Richmond, Virginia	1: Capricor; 1: Heart Rhythm Society; 1: American Heart Association; 2: Boston Scientific; 3: Merit Medical	1: Abbott; 1: AtriCure; 1: BIOTRONIK; 1: ZOLL Medical Corporation; 2: Biosense Webster; 2: Boston Scientific; 2: Medtronic	2: Daiichi-Sankyo; 2: National Institutes of Health; 3: Biosense Webster; 3: Medtronic; 3: Baim Institute for Clinical Research; 4: Boston Scientific	None	None	1: Elsevier; 1: Wiley-Blackwell
Derek Exner, MD, MPH, FHRS	University of Calgary, Calgary, Canada	1: Abbott; 1: GE Healthcare; 1: Medtronic	None	5: Abbott; 5: GE Healthcare; 5: Medtronic	5: Medtronic	3: HelpWare; 5: Analytics 4 Life	0: Analytics 4 Life; 0: GE Healthcare; 0: HelpWare
Ayman A. Hussein, MD, FACC	Cleveland Clinic, Cleveland, Ohio	None	None	None	None	None	None
Charles Kennergren, MD, PhD, FETCS, FHRS	Sahlgrenska University Hospital, Gothenburg, Sweden	1: BIOTRONIK; 2: Medtronic; 3: Boston Scientific; 3: Spectranetics	None	None	None	None	None
Andrew Krahn, MD, FRCPC, FHRS	The University of British Columbia, Vancouver, Canada	0: Boston Scientific; 0: Medtronic	None	1: Boston Scientific; 2: Medtronic	None	None	0: Canadian Cardiovascular Society

(*Continued*)

Appendix 1 (*Continued*)

Writing group member	Institution	Consultant/Advisory board/Honoraria	Speakers' bureau	Research grant	Fellowship support	Stock options/ Partner	Board Mbs/Other
Richard Lee, MD, MBA	Saint Louis University, St. Louis, Missouri	None	None	None	None	None	None
Charles J. Love, MD, CCDS, FHRS, FACC, FAHA	Johns Hopkins Hospital, Baltimore, Maryland	1: Abbott; 1: ConvaTec; 2: Medtronic; 2: Spectranetics	None	None	None	None	None
Ruth A. Madden, MPH, RN	Cleveland Clinic, Cleveland, Ohio	1: Medtronic	None	None	None	None	None
Hector Alfredo Mazzetti, MD	Hospital Fernandez, Buenos Aires, Argentina	None	None	None	None	None	None
JoEllyn Carol Moore, MD, FACC	Minneapolis Heart Institute, Abbott Northwestern Hospital, Part of Allina Health, Minneapolis, Minnesota	None	None	None	None	None	None
Jeffrey Parsonnet, MD	Dartmouth-Hitchcock Medical Center, Lebanon, New Hampshire	None	None	5: Procter & Gamble	None	None	None
Kristen K. Patton, MD	University of Washington, Seattle, Washington	1: American Board of Internal Medicine; 1: FDA Circulatory System Devices Panel	None	None	None	None	0: American Heart Association
Marc A. Rozner, PhD, MD, CCDS[†]	The University of Texas MD Anderson Cancer Center, Houston, Texas	None	None	None	None	None	None
Kimberly A. Selzman, MD, MPH, FHRS, FACC	George E. Wahlen Department of Veterans Affairs Medical Center, Salt Lake City, Utah	None	None	None	None	None	None
Morio Shoda, MD, PhD	Tokyo Women's Medical University, Shinjuku, Japan	1: Abbott; 1: Boston Scientific; 1: Cook Medical	None	None	None	None	None
Komandoor Srivathsan, MD	Mayo Clinic, Phoenix, Arizona	0: Abbott	None	None	None	None	None
Neil F. Strathmore, MBBS, FHRS	Royal Melbourne Hospital, Parkville, Victoria, Australia	None	None	None	None	None	None
Charles D. Swerdlow, MD, FHRS	Cedars-Sinai Medical Center, Los Angeles, California	1: Boston Scientific; 1: Medtronic	None	None	None	None	1: Medtronic
Christine Tompkins, MD	University of Colorado School of Medicine, Aurora, Colorado	1: Medtronic; 1: Spectranetics	None	None	None	None	None
Oussama Wazni, MD, MBA	Cleveland Clinic, Cleveland, Ohio	None	None	None	None	None	None

Number value: 0 = $0; 1 = ≤ $10,000; 2 = > $10,000 to ≤ $25,000; 3 = > $25,000 to ≤ $50,000; 4 = > $50,000 to ≤ $100,000; 5 = > $100,000.

[†]Deceased.

Appendix 2 Reviewer disclosure table

Peer reviewer	Institution	Consultant/Advisory board/Honoraria	Speakers' bureau	Research grant	Fellowship support	Stock options/ Partner	Board Mbs/ Other
Adrian M. Baranchuk, MD, FACC, FRCPC, FCCS	Queen's University, Kingston, Ontario, Canada	0: Bayer HealthCare; 0: Boehringer Ingelheim; 0: Medtronic	None	1: Bayer HealthCare; 5: Medtronic	None	None	None
Carina Blomström-Lundqvist, MD, PhD	Uppsala University, Uppsala, Sweden	1: Bayer Schering Pharma; 1: Biosense Webster; 1: Boston Scientific; 1: Bristol-Myers Squibb; 1: Medtronic; 1: Merck Sharp & Dohme; 1: Pfizer; 1: Sanofi	None	1: Cardiome Pharma Corp./Astellas; 1: Medtronic	None	None	None
Frank A. Fish, MD	Vanderbilt Heart and Vascular Institute, Nashville, Tennessee	None	1: Abbott	None	None	None	None
James M. Horton, MD	Carolinas Medical Center, Charlotte, North Carolina	None	None	None	None	None	None
Roberto Keegan, MD	Hospital Privado del Sur, Bahía Blanca, Argentina	1: Abbott	None	None	None	None	None
Miguel A. Leal, MD, FACC, FHRS	University of Wisconsin, Madison, Wisconsin	None	None	None	None	None	None
Nigel Lever, MBChB, FRACP	Green Lane Cardiovascular Service, Auckland City Hospital; University of Auckland, Auckland, New Zealand	None	None	None	None	None	None
Aman Mahajan, MD, PhD, MBA	UCLA Perioperative Services, UCLA Cardiac Arrhythmia Center and UCLA Neurocardiology Research Center, UCLA Health, Los Angeles, California	None	None	None	None	None	None
Marc R. Moon, MD	Washington University, St. Louis, Missouri	None	None	None	None	None	None
Siva K. Mulpuru, BS, MB, MBBS, MD, FHRS, CCDS	Mayo Clinic, Tucson, Arizona	None	None	2: National Institutes of Health	None	None	None

Number value: 0 = $0; 1 = $\leq$ $10,000; 2 = $>$ $10,000 to $\leq$ $25,000; 3 = $>$ $25,000 to $\leq$ $50,000; 4 = $>$ $50,000 to $\leq$ $100,000; 5 = $>$ $100,000.

Update

Heart Rhythm
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DOI: https://doi.org/10.1016/j.hrthm.2021.06.1174

Reply to the Editor—From AFFIRM to EAST—Better rhythm control and general AF management explain differences in outcomes

The EAST-AFNET 4 trial showed clinical benefit of systematic, early initiation of rhythm control therapy in patients with AF, with 21% fewer cardiovascular events compared to rhythm control given only to symptomatic patients.[1] Patients with recently diagnosed AF randomized to rhythm control in the AFFIRM trial did not experience such benefits.[2]

Improvements in the management of patients with AF can explain this difference. (1) Anticoagulation was routinely withheld after "successful" rhythm restoration in the days of AFFIRM, whereas >90% of the patients randomized in EAST-AFNET 4 were receiving continued anticoagulation, without intergroup differences. (2) We have developed methods to safely use antiarrhythmic drugs in patients with AF.[3] This results in low adverse event rates, as seen in the Catheter Ablation Versus Anti-arrhythmic Drug Therapy for Atrial Fibrillation (CABANA)[4] and EAST-AFNET 4[1] safety outcomes. This knowledge was not available at the time of AFFIRM.[5] (3) Catheter ablation is now routinely available and used, especially in patients with recurrent AF on rhythm control. These improvements probably explain the clinical benefit of systematic, early rhythm control in patients in EAST-AFNET 4[1] in contrast to the early AF patients in AFFIRM.[2]

In his letter, Dr Wang also calls for subanalyses of the EAST-AFNET 4 trial. These are ongoing, and we hope to report the first results later this year. Finally, all patients enrolled in EAST-AFNET 4 had AF documented by ECG. The option of screening for AF was not often used.

Paulus Kirchhof, MD (p.kirchhof@uke.de)

University Heart and Vascular Center UKE Hamburg, Hamburg, Germany

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ERRATUM

In the article "2017 HRS expert consensus statement on cardiovascular implantable electronic device lead management and extraction," by Fred M. Kusumoto, Mark H. Schoenfeld, and Bruce L. Wilkoff, et al., published in the December 2017 issue of Heart Rhythm (Volume 14, Issue 12, ppE503-E551, doi: https://doi.org/10.1016/j.hrthm.2017.09.001), in Table 4, there is an incorrect reference cited in row 13 regarding the "Presence of dual-coil ICD." The reference cited for associated risk "2.7-fold ↑ risk of 30-day mortality" should be 102, not 62. The error is regretted.