

Rising CIED infection rates¹

Study on increased CIED infection

A recent study from the Mayo Clinic found a significant increase in CIED infection rates in the past few decades. The study assessed 2,163 patients over a 28 year span.

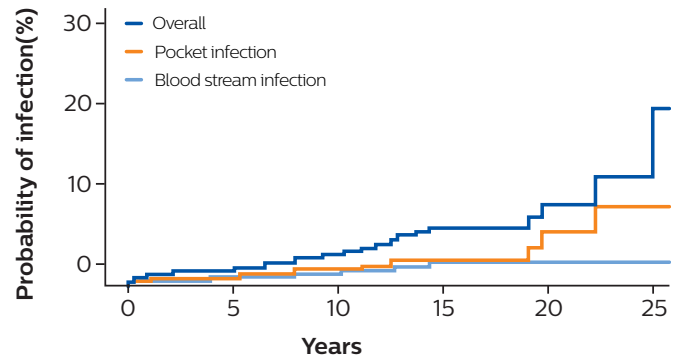
Results

Overall CIED infection rate was 6.2% at 15 years and 11.7% at 25 years of follow-up.

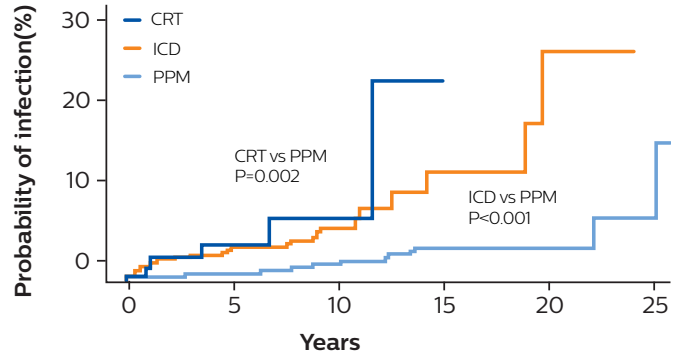
The infection rate was 24.1% after the third procedure (1/4 patients with 3+ pocket manipulations [i.e. implant, pocket manipulation 2, pocket manipulation 3] at risk of developing an infection).

After the third procedure, there was a significant difference among the PPM, ICD and CRT groups with 15-year infection rate being much higher in the ICD group than in the PPM group.

Cumulative probability of infection in CIED patients



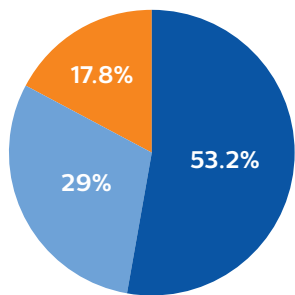
Number at risk	2,163	1,133	463	163	52	11
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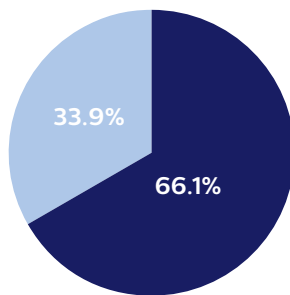
Number at risk	109	44	12	1	9	11
	373	221	93	28	43	
	1,681	868	358	134	43	11

“Our analysis revealed a 3-fold increase in infection rate in ICD and CRT recipients compared with PPM recipients.”¹

When infection occurred

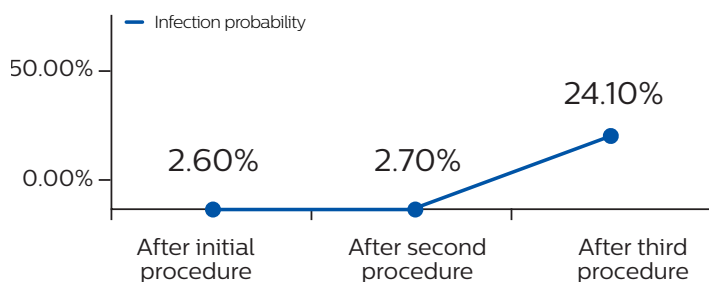


Infection type



- After initial implantation
- After second procedure
- After third or more procedures
- Bloodstream infections
- Pocket infections

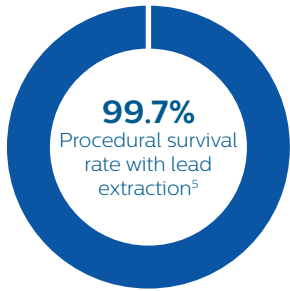
15-year cumulative probabilities of CIED infection



Expert guidelines mandate² (Class I indication):

1. Extractor consult for device patients with documented infection
2. Complete device removal for CIED infection

More than 60% of patients suffering from CIED infections are treated with antibiotics only or not treated at all, which leads to relapse and mortality.³



Timely, safe lead extraction can save lives and prepare patients for long-term health.

“Complete system removal, including the leads, is warranted in all patients with CIED infections in the absence of patient refusal or medical contraindications.”⁷

Immediate system removal is associated with a threefold decrease in one-year mortality vs. preliminary antibiotic treatment and delayed system removal.⁴

Lead extraction, when indicated, is a highly successful, potentially lifesaving procedure, with a clinical success rate of 97.7% and a procedural survival rate of 99.72%.⁵ With introduction of the Bridge occlusion balloon, SVC tear survival has increased from 56.4% to 88.2%.⁶

infection + device = removal

Abbreviations

CIED	Cardiovascular implantable electronic device
PPM	Permanent pacemaker
ICD	Implantable cardioverter defibrillator
CRT	Cardiac resynchronization therapy
SVC	Superior vena cava

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2. Kusumoto et al. 2017 HRS Expert Consensus Statement on Cardiovascular Implantable Electronic Device Lead Management and Extraction. Heart Rhythm, 2017.
3. Sohail, M Rizwan, et al. Incidence, Treatment Intensity, and Incremental Annual Expenditures for Patients Experiencing a Cardiac Implantable Electronic Device Infection: Evidence From a Large US Payer Database 1-Year Post Implantation. Circ Arrhythm Electrophysiol. 2016; 9(8).
4. de Bie, Mihály K., et al. "Cardiac device infections are associated with a significant mortality risk." Heart Rhythm 9.4 (2012): 494-498.
5. Wazni, O. et al. Lead Extraction in the Contemporary Setting: The LEXiCon Study: A Multicenter Observational Retrospective Study of Consecutive Laser Lead Extractions, J Am Coll Cardiol, 55:579-586.
6. Ryan Azarrafiy, BA; Darren C. Tsang, BS; Bruce L. Wilkoff, MD, FHRS; Roger G. Carrillo, MD, MBA, FHRS. The Endovascular Occlusion Balloon for Treatment of Superior Vena Cava Tears During Transvenous Lead Extraction: A Multi-Year Analysis and An Update to Best Practice Protocol. Circulation: Arrhythmia and Electrophysiology, August 2019.
7. Peacock Jr, James E., et al. "Attempted salvage of infected cardiovascular implantable electronic devices: Are there clinical factors that predict success?." Pacing and Clinical Electrophysiology 41.5 (2018): 524-531.

