PHILIPS

Lead Managment

Case studies

Your guide to CIED infection

A collection of case studies

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About the author

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Dr. Sohail is an Associate Professor of Medicine at Mayo Clinic and holds a joint appointment with the Divisions of Cardiovascular Diseases and Infectious Diseases. His research interest is in cardiovascular infections, including cardiovascular implantable electronic device infections, native and prosthetic valve infective endocarditis, ventricular assist device infections, vascular graft infections and percutaneous vascular closure device infections. He has published over 60 original peer-reviewed articles in major medical journals such as the Journal of the American College of Cardiology, Archives of Internal Medicine, Circulation, Arrhythmia and Electrophysiology, American Journal of Cardiology, Clinical Infectious Diseases, Pacing and Clinical Electrophysiology, Catheterization Cardiovascular Intervention, and Mayo Clinic Proceedings, among others. These papers address important clinical questions related to the epidemiology, risk factors, clinical presentation, diagnosis, management, complications, outcomes and cost associated with cardiovascular infections. In addition, he has authored 10 book chapters on endocarditis and device infections.

Being an expert in the field of cardiovascular infections, Dr. Sohail has been an invited speaker at the meetings of the Heart Rhythm Society, the American Heart Association, the Infectious Diseases Society of America, European Congress of Clinical Microbiology and Infectious Diseases, and the European Society of Cardiology, among others. In addition, he has been a Visiting Professor at the University of Naples in Italy.

He is currently a member of the Council of Clinical Cardiology, and the Council on Quality of Care and Outcomes Research for the American Heart Association. He is reviewer of numerous scientific journals, including The New England Journal of Medicine, Clinical Infectious Diseases, Journal of the American College of Cardiology and JAMA.

Frequently asked questions about cardiac device infection

Q: How do patients with CIED infection present?

A: CIED infections can present as:

- Pocket infections: redness, pain, swelling, drainage and/or erosion of overlying skin at the CIED generator pocket site
- Bacteremia with or without endocarditis or inflammatory changes at the CIED pocket site[1]

Q: What should be done for a patient with a CIED and positive blood culture results?

A: Patients with a CIED and positive blood cultures should undergo further evaluation by TEE for possible endocarditis or device lead infection. If TEE is suggestive of device infection, the patient should be referred to a cardiologist for device removal.[2]

Q: Can patients with CIED infection be treated with antibiotics alone?

A: No. All patients with an infected CIED require complete generator and lead removal. Antibiotic therapy is often not sufficient and is associated with a 4X higher rate of recurring infection.[3]

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Managing cardiac implantable electronic device (CIED) leads has never been more important. Patients with CIEDs are on a lifelong journey, and as physicians, we are here to help ensure that it is a healthy one. CIED patients are younger and living longer, requiring more upgrades and device replacements, potentially leading to higher infection rates.

The prevalence of infection increased 320% in a 10-year period,[5] far outpacing the rate of implants. More than six in 10 patients suffering from cardiac device infections are treated with antibiotics or not treated at all[1]. Nearly 50% of patients with CIED infections do not survive beyond three years.[6]

The presence of a system infection, pocket infection or endocarditis is a Class I indication to remove all hardware, including leads.

Symptoms can be subtle, and vigilance is the best protection to help ensure that infections are detected early and treated appropriately.

The following case studies are compiled to provide insight into how CIED infection patients may present and how these particular patients were treated.

Case 1

A 65-year-old male presents to the cardiology clinic complaining of redness and pain at pacemaker pocket site that was implanted last week. He has no fever, chills or other systemic symptoms. On exam, there is mild erythema of incision site at pacemaker generator pocket. No swelling of the pocket, spreading cellulitis or purulent drainage was noted. The rest of the physical examination is normal.

How will you manage this patient?

Should you obtain blood cultures?

Should the device be removed?

Answer: Superficial incision site infection can be managed with antibiotic therapy alone and device removal is not indicated in these cases. There is no need to obtain blood cultures as the patient has no fever or other systemic symptoms. These infections are typically due to staphylococci. A five- to-seven-day course of an oral antibiotic (e.g., cephalexin or cefadroxil) is appropriate. Clindamycin can be an alternative in patients who are allergic to penicillins. For patients who are known to be colonized with MRSA or live in an area of high MRSA prevalence, Bactrim (TMP-SMX) should be prescribed for empiric coverage. Patient should be seen back in the clinic in two weeks to make sure that infection has resolved.[4]

Case 2

A 54-year-old female recipient of an implantable cardioverter-defibrillator six months ago. She presents with redness, swelling and drainage from the ICD pocket that started four weeks ago. She has no fever. She was initially seen by her primary care doctor, who prescribed a one-week course of Bactrim (TMP-SMX). Redness and swelling initially improved but recurred once antibiotic therapy was discontinued. On exam, there is redness, swelling at the pocket site and it is tender to palpation. The incision itself appears well healed. There are no stigmata of endocarditis on examination.

What should be the next step in management?

Should this patient undergo device removal?

Answer: This patient has ICD pocket infection. The most likely mechanism of infection in this case is device contamination with skin flora at the time of implantation. Coagulase-negative staphylococci (S. epidermidis) are the most common organisms in this setting. These organisms cause indolent infection and can present several months after device implantation or manipulation. All patients with device infection (whether limited to generator pocket or associated with bloodstream/lead infection) should undergo complete device removal to achieve cure. Partial removal of the device (generator only) is associated with high and unacceptable risk of relapse of infection. EP service should be consulted and extraction should be planned as soon as possible. If lead extraction is feasible in the next 24 hours, antibiotic therapy should be withheld until pocket tissue cultures can be obtained, and then the patient can be started on empiric antibiotic therapy with vancomycin. If blood cultures remain negative, a 10- to 14-day course of antibiotic therapy, guided by culture results, is recommended after device removal.[5-8]

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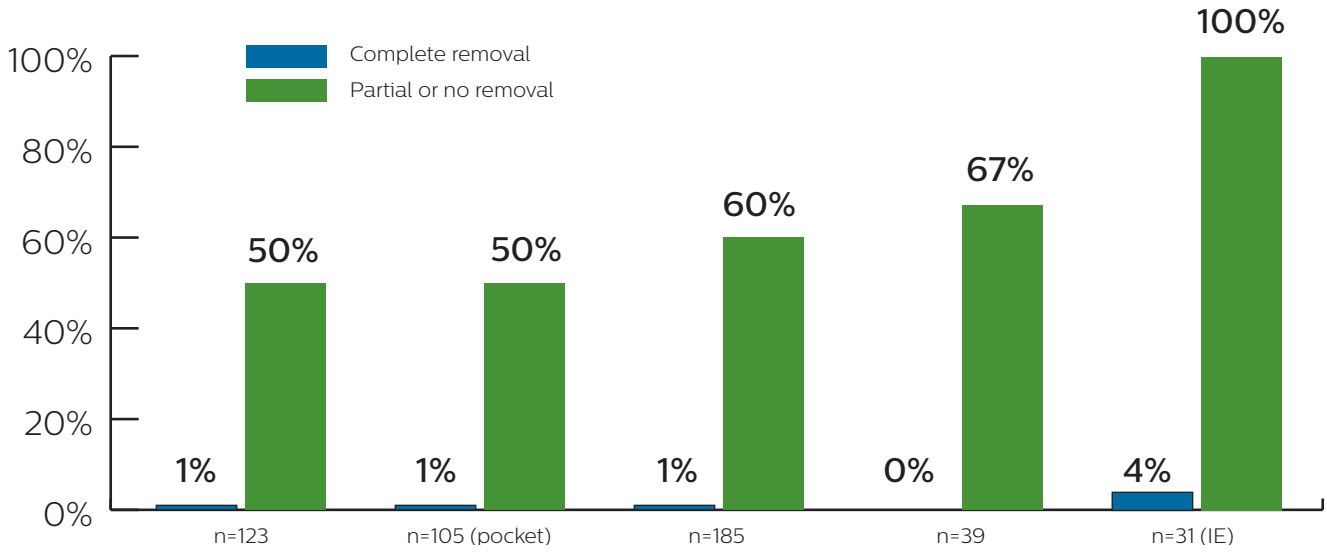
Relapse rates by CIED infection treatment [5-8]



Case 3

A 72-year-old male with history of diabetes, coronary artery disease and heart failure is hospitalized with right lower extremity cellulitis. He underwent a CRT-D placement three years ago and the device has been functioning appropriately. On examination, he is febrile (39 ºC), diaphoretic and appears ill. Cardiac exam reveals a 2/6 systolic murmur at left upper sternal edge. CRT-D generator pocket site looks normal. There are no stigmata of endocarditis on examination. His lab workup shows leukocytosis (WBC 15,000), serum creatinine 1.4 mg/dL and normal liver function tests. CRP is elevated. Blood cultures reveal GPC, which is later identified as S. aureus by microbiology lab.

What is the next step in management of this patient?

Should this patient undergo TEE?

Is device removal indicated?

Answer: Patients with S. aureus bacteremia (SAB) are at high risk of hematogenous seeding of CIED leads or generator. Published data suggest that a third of the patients with SAB have underlying CIED infection even when CIED pocket looks normal[10]. All patients with SAB should undergo TEE to look for evidence of CIED lead infection or valvular vegetation. Patients with SAB and positive TEE for lead or valve infection, those with SAB lasting more than 72 hours, or those with relapse of SAB with conservative management (negative initial TEE) should undergo CIED removal.[13] Attempts at conservative management are associated with high mortality (>50%) and even higher rates of relapse (80% to 100%).[10]

Delay in device removal in these cases is also associated with higher mortality compared to urgent removal after hospital admission.[14]

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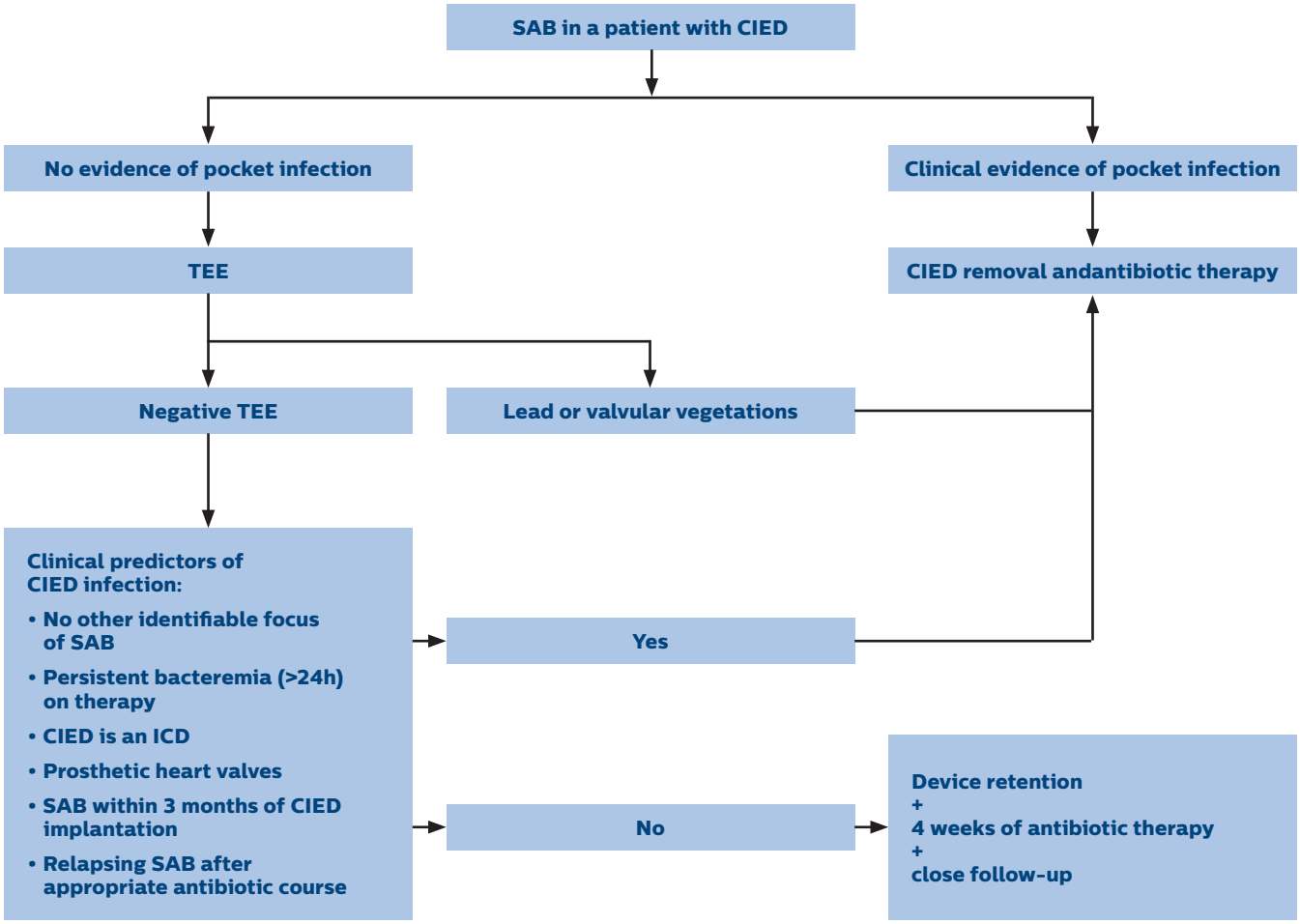
Management of adults with Staphylococcus bacteremia and cardiovascular implantable electronic device. [9*]

CIED: Cardiovascular implantable electronic device; ICD: Implantable cardioverter-defibrillator; SAB: Staphylococcus aureus bacteremia; TEE: Transesophageal echocardiogram.



Duration of antibiotic therapy depends on TEE results. A two to four-week course is usually adequate for patients with negative TEE. Patients with S. aureus endocarditis should be managed with six weeks of intravenous antibiotic therapy guided by antimicrobial susceptibility testing. Infectious Diseases consultation should be obtained in all cases of SAB and has been shown to reduce mortality and improve outcomes.

*Treatment algorithm is provided courtesy of Dr. Sohail and is not intended to be medical advice. Individual patients should consult their physicians.

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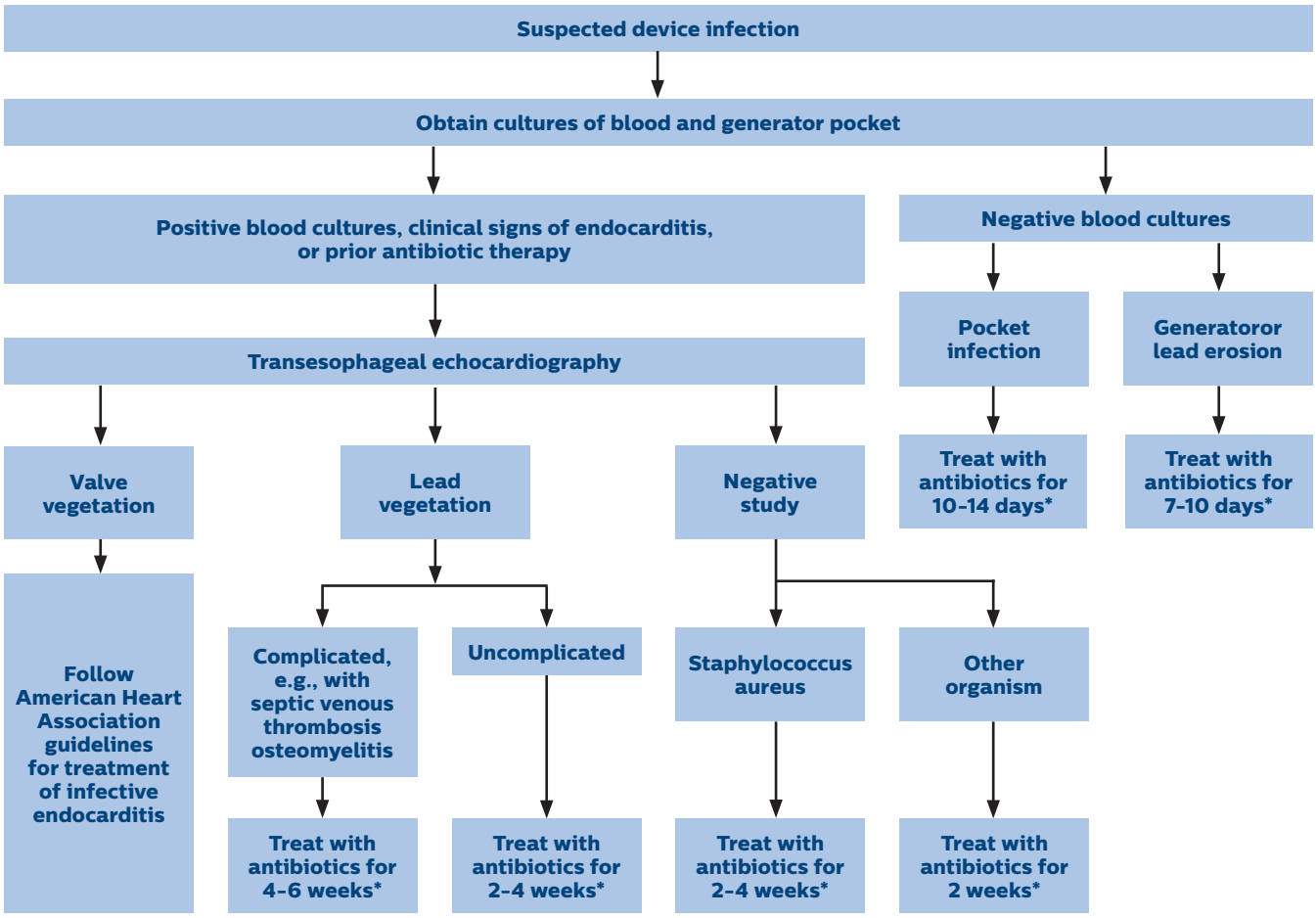
How to determine the duration of therapy for cardiovascular implantable electronic device infection[9**]



*Duration of antibiotics should be counted from the day of device explanation.

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Case 4

A 67-year-old female with diabetes, coronary artery disease and chronic renal insufficiency is hospitalized with fever, chills, rigors and left flank pain. She underwent a dual-chamber permanent pacemaker implantation two years ago. On examination, she is febrile and appears toxic. Abdominal exam is significant for left flank tenderness. Pacemaker pocket appears normal. Labs show leukocytosis (WBC 13,000) and elevated CRP. Urinalysis reveals pyuria, positive nitrite, leukocyte estrase and gram-negative rods. Blood cultures are reported to have grown Klebsiella oxytoca on day two of admission.

Should you perform a TEE to look for evidence of pacemaker lead infection?

Should this patient undergo device removal?

Answer: This patient has pyelonephritis and bloodstream infection due to Klebsiella oxytoca. Secondary hematogenous seeding of CIED leads or pocket from a distant primary source of infection is extremely rare in patients with gram-negative bacteremia. Therefore, routine TEE is NOT recommended in patients who present with gram-negative bloodstream infection and have normal looking CIED pocket. CIED infection may be a consideration if there is clinical evidence of pocket infection or gram-negative bacteremia relapses after appropriate treatment of primary source.[15]

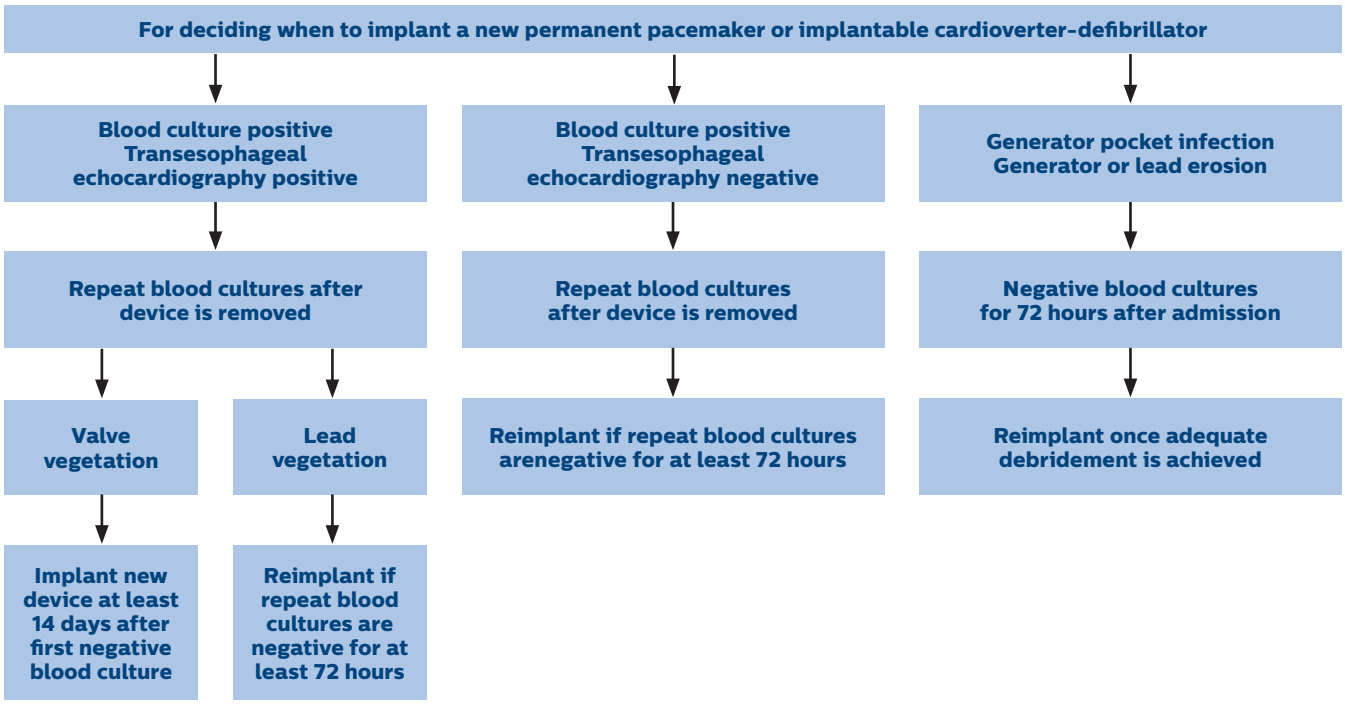
Case 5

A 75-year-old male is admitted to hospital with pacemaker pocket infection and bacteremia due to Staphylococcus aureus. TEE is negative for endocarditis or CIED lead infection. Patient underwent complete device removal on day three of admission. Repeat blood cultures after device removal are negative.

When can this patient undergo device reimplantation?

Answer: The first question to ask is whether patient needs a replacement device. Based on published data, a third of patients may no longer have an indication for ongoing CIED therapy after removal of infected device. If a new device is deemed necessary by EP, it can be implanted after repeat blood cultures post-infected-device removal are negative for 72 hours[13]. For patients who have positive TEE for endocarditis, a two-week delay between removal of infected device and placement of a new CIED is recommended.

Guidelines for reimplantation of new device in patients with pacemaker or ICD infection[9*]



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