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# Cardiac implantable electronic device infection: Does the device need to be extracted?

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## Abstract

**Background:** Cardiac implantable electronic devices (CIED) have become a common treatment modality in clinical practice. The increase in utilization of these devices has been associated with an increase in infection rates. Published guidelines define when a device is deemed infected (CDI); recommendations for the work-up of CDI and criteria for extraction. Few data exist as to adherence to these guidelines.

**Objective:** We wanted to o evaluate whether devices diagnosed as CDI fit guidelines, whether clinicians followed work-up recommendation of CDI, and whether CIED was extracted according to the guidelines criteria in our hospital.

**Methods:** A retrospective review was performed in our hospital between 2008 and 2017. Adult patients (pts) 18 years and older who had their device extracted (DE) with a diagnosis of CDI were included. A total of 95 pts were identified.

**Results:** We included 95 pts who were diagnosed as having CDI and who had their DE. Work-up of patients with a diagnosis of CDI was inconsistently followed. Blood cultures, Echocardiogram, lead cultures (LC), and device pocket cultures (PC) were done in 100%, 90.5%, 75.6%, and 49.3%, respectively. Thirty out of 90 pts. (33%) did not meet guidelines criteria for extraction.

**Conclusions:** In our institution, a one third of the pts diagnosed with CDI who had DE had no indication for DE per guidelines recommendations. Clinicians did not follow recommendations for work-up of CDI consistently. Low adherence was seen in obtaining LC and PC. CIED extraction guidelines should be followed to prevent unnecessary complications and cost.

KEYWORDS

Cardiac implantable electronic devices, Device extraction, Endocarditis, Guidelines, Infection

## 1 | INTRODUCTION

The last few decades saw a significant increase in the use of cardiac implantable electronic devices (CIED) such as pacemakers (PPM), automated implantable cardioverter defibrillator (AICD), and cardiac resynchronization devices. A US study reported an increase of 12% in the number of CIED implantations between 2004 and 2006.[1] The rate of cardiac device infection (CDI) is estimated to be 0.5% with primary implants, and ranges from 1% to 7% with secondary procedures.[2–4] Underlying factors associated with CDI include combination devices, longer procedure time,[5,6] implantation by inexperienced operators,[3,7,8] and advanced age.[9] Comorbid conditions associated with CDI include diabetes mellitus (DM),[10] renal insufficiency[10,11] and immunosuppression at the

time of implantation.[2,3] An increase in the incidence of CDI has been parallel to the increase in device implantation. Voigt et al[1] described an increase of 57% in CDI; this increase was attributed in part to the expanding indications for CIED use as well as the age of the population requiring CIED. Diagnosis and management of CDI are often complex and pose a difficult clinical dilemma to the clinicians involved. Extraction of the device, if indicated, could be associated with serious complications and significant expense.[12] The American Heart association (AHA) and the Heart Rhythm Society (HRS) have published guidelines for the management of CDI.[13,14] Data regarding adherence to device extraction guidelines are lacking.

The goal of this study was to evaluate whether clinicians followed guideline definition of CDI, whether they adhered to recommendations for the work-up of pts suspected of having CDI, and to evaluate whether there was an indication for device extraction according to the guidelines.

## 2 | METHODS

A retrospective analysis was performed in a 680-bed tertiary care teaching hospital from 2008 to 2017. Adult patients (pts) >18 years, diagnosed with CDI were included in the study. The patients were identified based on the current procedural terminology (CPT) code of CIED extraction. The study was approved by the Institutional review board at our institution.

The diagnosis of CDI was made if the clinician described either a clinical or documented microbiological feature compatible with guidelines definition of CDI: Patients were defined as having an isolated pocket infection if they had localized erythema, swelling, pain tenderness, warmth, or drainage over the pocket site with negative blood cultures or if a culture was positive from the pocket site with negative blood cultures and no vegetations on echocardiogram. CIED endocarditis was defined as bacteremia with lead or valvular vegetations. Bacteremia was defined as positive blood cultures with or without systemic infection signs and symptoms. Blood cultures were considered positive if they yielded at least one blood culture set positive for Streptococci, Enterococci, *S aureus*, yeast, any Gram-negative organism, or at least two blood culture sets obtained at 2 different times yielding coagulase-negative Staphylococcus (CoNS).

Work-up of patients suspected as having CDI as recommended by the guidelines[13,14] include: 2 sets of blood cultures to be drawn at the initial evaluation; Transesophageal echocardiogram (TEE) for pts who had positive blood cultures or those who had negative blood cultures but received antibiotics before blood cultures were drawn and for all pts with *Staphylococcus aureus* (*S aureus)* bacteremia; generator pocket tissue Gram stain and culture at the time of extraction; and culture of the lead tips after removal.

A patient was considered having an appropriate extraction if there was a pocket infection, infective endocarditis (bacteremia in the presence of vegetation on device lead or valve), and any unexplained *S aureus* bacteremia. A device was deemed inappropriately extracted if there was an alternative source of infection, or if the extraction did not meet criteria for extraction according to the guidelines.

**TABLE 1** Patient characteristics, N = 95

| Patient characteristics | Number of patients, N = 95 |
|---|---|
| Mean age | 63 (range 23-90) |
| Gender | |
| Male | 67 (70%) |
| Female | 28 (30%) |
| Race | |
| Caucasian | 32 (34%) |
| African American | 32 (34%) |
| Hispanics | 5 (5%) |
| Asians | 3 (3%) |
| Devices | |
| AICD | 75 (79%) |
| PPM | 20 (21%) |
| Comorbidity | |
| Congestive heart failure | 57 (60%) |
| HTN | 52 (55%) |
| DM | 32 (34%) |
| Coronary artery disease | 23 (24%) |
| End stage renal disease | 13 (14%) |
| Chronic kidney disease | 4 (4%) |
| Malignancy | 2 (2%) |
| Renal transplant on immunosuppressive medications | 1 (1%) |
| Average duration of device prior to removal | |
| Extraction less than 6 mo from insertion | 3.6 mo (N = 3) (Range 1-6 mo) |
| Pts with extraction >6 mo from insertion | 4.73 y (N = 37) (Range 1-23 y) |

Data were collected on demographics, type of device, duration of the device, blood culture results, pocket culture results, device/lead culture results, and echocardiogram findings, mode of extraction, complications associated with device extraction, and outcome at 12 months postextraction.

## 3 | RESULTS

Ninety-five pts who underwent CIED extraction for CDI were included in the study. Sixty-seven (70%) were men. Mean age was 63 (range 23-90) years, 32 were Caucasian, 32 African American, 5 Hispanics, and 3 Asians.

Comorbid medical conditions included: DM in 32, end-stage renal disease (ESRD) in 13, and renal transplant on immunosuppressive medications in 1 pt. (Table 1). Devices included AICD in 75/95 (79%) and PPM in 20/95(21%).

TEE was done in 86/95 (90.5%); Transthoracic echocardiogram (TTE) was done in 49/95 pts (51.6%). Blood cultures were sent in all 95 (100%) of the pts. Lead cultures were done in 47/95 (49.4%) and yielded an organism in 33/47 (70.2%), the same organism was recovered from blood and lead cultures in 12/33 (36.3%) of the pts, *S aureus* in 8/12 (67%), *Staphylococcus epidermidis* in 2/12 (16.6%), and Pseudomonas in 2/12 (16.6%).

Data on original device placement were available for 40/95(42.1%); extraction took place 6 months after implantation in 37/40 (92.5%) of the pts and in less than 6 months in 3 pts. Overall a total of 4 pts died, 3 of them 6 months after the extraction. One patient who did not meet criteria for extraction died of cardiac arrest during the extraction procedure. All the patients had complete removal of the leads. Data on recurrent bacteremia after extraction were available for 53/95 (55.8%) pts, 5/53 (9.4%) had recurrent bacteremia.

Criteria for CIED extraction were met in 65/95 (69%); of these 55 (84%) had AICD and 10 had PPM. Pocket infection was documented in chart by physicians in 24 pts; however, only 22 of them had pocket site cultures sent and 21 had positive cultures. Isolated pocket infection without bacteremia or vegetations was seen in 10 pts. Six pts had lead vegetations with positive pocket cultures but without associated bacteremia, 3 had pocket infection with bacteremia and vegetations (IE), and 2 had pocket infections with bacteremia. Bacteremia was noted in 49/65 (75%) pts and IE was diagnosed in 38/65 (58.4%) pts. Lead vegetations was detected in 26/38 (68%) and valve vegetation alone was seen in 2 pts. In 10 pts there were both valve and lead vegetations (Table 2). Postextraction lead cultures were sent in 29/65 (45%) pts and 22 were positive. Organisms isolated from lead after extraction are outlined in Table 3.

Laser extraction was done in 53/65(81%) and open extraction was done in 12/65(18.4%). Three pts died postextraction as a result of sepsis with persistent bacteremia despite removal of the CIED, 1 died caused by brain abscess and hemorrhage, and 1 as a result of worsening of heart failure.

Criteria for device extraction were not met in 30/95 (31.5%) patients, of these 20 had AICD and 10 had PPM. Blood cultures were sent on all 30 patients. Echocardiogram was done in 26/30 (86.6%) pts (TEE 20, TTE 6). Lead cultures were done in 18/30 (60%) and organisms isolated are outlined in Table 4. Pocket infection was the reason stated for extraction in 17/30 (56.6%), although no localized signs of pocket infection were documented. Nine pts had pocket cultures sent and were all negative, and in the other 8 pts pocket cultures were not done. Two pts were transferred from another hospital without any information regarding possible site of infection and without any culture results. In 1 pt., blood cultures yielded gram (+) cocci which could not be further identified, the patient did not have an echocardiogram or did he have any description of pocket site infection, and had no pocket site cultures done. In 9 pts the presence of lead vegetations was the stated reason for extraction; in these cases not a single positive culture from any site was recorded in any patient, extraction was done without any clear stated reason (Table 5).

One patient had ventricular fibrillation with arrest during the extraction procedure and expired.

**TABLE 2** Diagnoses in patients who met the criteria for extraction N = 65

| | |
|---|---|
| Isolated Pocket | 10 |
| Pocket infection with vegetations on echocardiogram | 6 |
| Bacteremia | 49 |
| Bacteremia with vegetations on echo (Infective endocarditis) | 38 |
| Isolated *Staphylococcus aureus* bacteremia | 9 |
| Bacteremia with pocket infection | 2 |

## 4 | DISCUSSION

The last decade has seen an increase in CIED utilization and expansion in the indications for CIED to older populations with comorbidities,[15] the result of which has been an increase in the rate of CDI.[16] Some studies have shown that the increase in infection rate is rising faster than the rate of CIED implantation.[1]

Management of CDI is complex and occasionally requires extraction of the device.[17] The American Heart Association (AHA) and the HRS[13,14] published guidelines to assist clinicians in the management of CDI.[13,14] The guidelines propose a framework for work-up of a patient with suspected CDI, and outlines recommendations as to when a device should be extracted.

Work-up of a pt. suspected of having CDI include at least 2 sets of blood cultures before the start of antibiotics, our data show that

**TABLE 3** Lead cultures from the patients who met criteria for extraction

| Lead culture organism | Number (N = 29) |
|---|---|
| *Staphylococcus aureus* | 10 |
| CoNS[a] | 8 |
| Pseudomonas | 2 |
| *Candida parapsilosis* | 1 |
| *Enterococcus faecalis* | 1 |
| Negative lead culture | 7 |

[a]CoNS Coagulase (-) Staphylococcus.

**TABLE 4** Lead cultures from the patients who did not meet criteria for extraction

| Organisms | Number (N = 18) |
|---|---|
| *Staphylococcus aureus* | 1 |
| Coagulase Negative Staphylococci | 7 |
| Gram-negative rod (Subculture growth of Serratia) | 1 |
| Diphtheroid | 2 |
| Negative culture | 7 |

**TABLE 5** Patients who did not meet criteria for CIED extraction, N = 30

| | |
|---|---|
| Unknown culture from outside hospital | 2 |
| Positive Gram stain with Gram-Positive Cocci with negative cultures | 1 |
| Lead vegetations with no true bacteremia (Coagulase-negative Staphylococci in 1/2 bottles) | 5 |
| Lead vegetations with negative blood cultures | 4 |
| Suspected Pocket Infection (Not proven) | 17 |
| No explanation for extraction | 1 |

all 95 pts included in our study had blood cultures drawn prior to the extraction. The guidelines also recommend that lead cultures be done at the time of extraction, our data show that lead cultures were done in 47/95 (49.2%), and of those 33/47 (70.2%) were positive. This overall yield of lead cultures is similar to the one found in another study[18] in which 854/1204 (70.9%) had positive lead cultures; in this large study blood cultures were consistent with lead cultures in 124/359 (35%), similarly our rate of concordant cultures was 41%. The authors of the study[18] concluded that blood cultures were potentially contaminated, and emphasized the importance of doing lead cultures as recommended in the guidelines. Contamination of either blood or lead cultures can explain the discrepancy between blood and lead culture results, discrepancy between blood and lead cultures was especially striking in our patients who did not meet criteria for extraction; in this group, 11/18 (61%) had positive lead cultures but none of them had concordant positive blood cultures, and 9/11 (82%) grew skin organisms such as CoNS and diphteroids, supporting the notion of possible contamination.

Positive blood cultures with negative lead cultures were seen in 7/17 (41%); this fact could be explained by the fact that most blood cultures are taken prior to the administration of antibiotics, and that device extraction lags in time and often takes place days after start of antibiotics, causing lead sterilization at the time of extraction.

A preprocedural TEE is recommended in patients suspected of having CDI,[19] TEE is useful in establishing the diagnosis of CIED-related endocarditis and or lead infection. This procedure can provide information about the presence and size of vegetations and describes valvular malfunction and perivalvular abscess when present.

High adherence to guidelines recommendation for an echocardiogram was seen; overall 86/95 (90.5%) had a TEE prior to extraction. The procedure yielded valuable clinical information as expected: endocarditis was diagnosed in 38/95 (40%), similarly in another study,[20] 88% of pts with a device pocket infection had evidence of intravascular lead involvement. Chua et al[21] found that 64/123 (52%) of their pts with CDI had an echocardiogram, 37% had TTE and 8% had TEE, of these patients 13 were found to have vegetations on leads, valves, or both.

Pocket cultures were done in 31/95 (32%) pts, although pocket infection was suspected in 41/95 (43%) pts, of which 24 were from the group who met criteria for extraction and 17 from the group who did not meet criteria; 21/31 (67%) yielded positive cultures.

Complete removal of CIED is recommended when there is a localized pocket infection, even in the absence of systemic infection.[22] In our patients meeting guidelines criteria for extraction, a diagnosis of pocket infection was made in 21/65 (32%). In a large series over a 20-year experience, Gomes[9] found that 40.7% of their pts had a pocket infection as the indication for extraction. In the cohort described by Chua et al,[23] 69% of their patients presented with symptoms of pocket site infection and cultures of the pocket were positive in 81%.

Data on CIED extraction when there is no clear indication for extraction are lacking. In our patients, 30/95 (31.5%) did not have an indication for extraction as outlined by the guidelines, and 17/30 (56.6%) had a diagnosis of pocket infection that could not be verified either clinically or microbiologically. The guidelines do not recommend CIED removal if there is a superficial or incisional infection at the pocket site; without a clear involvement of the device, we could not verify whether there was a superficial infection or device involvement in these 17 pts.

In 9/30 (30%) pts, vegetations were seen on leads when echocardiogram was done, but no microbiological or other evidence of infection was present. In a study by Downey et al[23] analyzing CIED patients who had vegetations or strands found on TEE, the authors concluded that when there is no suspicion or microbiological proof for an infectious process, the mass found on TEE is unlikely to be the sole harbinger of infection and the finding should not be the cause for removal of the device.[23] It seems that our 9 cases with lead vegetations represent similar cases and therefore in these cases there was no indication for extraction; 4 pts had device extraction without a clearly outlined indication. The fact that 31.5% of our cohort had a device extraction without a clear indication is disturbing, Gomes described in his cohort[9] that of 558 pts 367 devices were extracted as a result of infection and in the rest of his cohort devices were extracted for various other reason but without outlining clinical details making it possible that some devices were extracted without a clear indication to do so.

Limitations of our study include the fact that the study was a retrospective study from a single center and therefore results may not be applied to other institutions. Some clinical information was missing owing to the retrospective nature of the study and it is possible that clinicians did not document enough information as a reason for device extraction. Data on original device placement were available in only half of the patients, as patients were transferred from other institutions. This article reveals that there are many device extractions without meeting to the guidelines of the American Heart association and the Heart Rhythm Society.

## 5 | CONCLUSIONS

Our study found that compliance with guidelines work-up recommendations was not uniformly followed; high compliance was noted

with obtaining blood cultures and ECHO but lower compliance with pocket and lead cultures. We found that 31% of the CIED were extracted without a clear indication per the guidelines. Better compliance with the recommendation could prevent unnecessary device extraction, hence reducing the possibility of complications and cost.

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## CONFLICT OF INTEREST

Authors declare no conflict of interests for this article.

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