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Sonication of Explanted Cardiac Rhythm Management Devices for the Diagnosis of Pocket Infections and Asymptomatic Bacterial Colonization

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Abstract

Background—Correct diagnosis of the causative organism is critical for the treatment of pacemaker and defibrillator pocket infections. No gold standard for this exists, although swab and tissue cultures are frequently used. The purpose of this study was to determine the value of ultrasonication of explanted generators in the diagnosis of pocket infections and asymptomatic bacterial colonization.

Methods—Samples were prospectively collected during pacemaker and defibrillator generator extractions for elective replacements, upgrades, or pocket infections. The devices were placed in an ultrasonicator for 5 minutes and the fluid sent for culture, along with swab and tissue cultures.

Results—Eighty-two patients with pacemakers (n = 46) or defibrillators (n = 36) underwent generator explantation, 66 of these for elective reasons and 16 for pocket infection. In patients with pocket infection, 15 (94%) received a definitive bacterial diagnosis using a combination of all three-culture modalities. Cultures were positive in 15 sonicated fluid, 13 tissue, and 11 swab samples, with *Staphylococcus aureus* and other skin flora commonly seen. In asymptomatic patients, 14 (21%) had positive cultures. Cultures were positive in 11 sonicated fluid, eight tissue, and two swab samples. Skin flora was commonly seen, but three of the sonicated fluid cultures grew gram-negative rods. No patients with asymptomatic colonization developed clinical infection during the follow-up period.

Conclusions—Ultrasonication is an inexpensive and simple technique that improves the bacteriologic diagnosis of device pocket infections. It also identifies a significant proportion of patients with asymptomatic colonization, although this is not a marker of future pocket infection.

Keywords

ultrasonication; device infection; pocket infection

Introduction

Infections of pacemakers and implantable cardioverter-defibrillators (ICDs) have increased over the last several years. This is partly due to the dramatic growth in utilization of these devices. However, the rise in infections is proportionally greater.¹ This is likely due to multiple factors, including increasing age and comorbidities in recipients of these devices. While most infections are due to skin flora, more unusual organisms such as gram negatives, are also seen and antibiotic resistance is common.^{2,3} Correct diagnosis of a causative organism is important in order to institute appropriate antimicrobial therapy. Tissue culture is the most accurate means currently available for diagnosis of pacemaker and ICD pocket infections. Approximately two of three clinically infected patients receive a bacteriologic diagnosis based upon tissue culture results.⁴ Swab cultures are commonly performed but have been shown to have very poor yield.⁴

There are several reasons why the diagnostic yield of these cultures is low. The infectious organisms tend to have low virulence. Clinically infected patients often receive antibiotics prior to explantation of the device, which can clear or partially clear the infection in the tissue. However, bacteria may continue to exist in biofilms on the surface of prosthetic materials.^{5,6} Sonication has been used as a method to dislodge bacteria from infected prostheses, and has been shown to increase diagnosis of causative organisms.⁷⁻⁹ This particularly has higher yield in patients who had previously been treated with antibiotics. This technique has not been evaluated in patients with infected implantable cardiac rhythm management devices.

While asymptomatic bacterial colonization of pacemakers and ICDs has been described, the significance of this is not entirely clear.¹⁰ We hypothesized that sonication of explanted cardiac rhythm management devices would improve the diagnosis of both pocket infections and asymptomatic bacterial colonization over tissue culture and swab culture alone. Further, we wished to identify causative organisms and predisposing factors for asymptomatic colonization, and assess the risk for future infection.

Methods

Sampling

From November 2007 until December 2008, devices were prospectively collected from patients undergoing device explantation. This included patients who were undergoing explantation for device infection and those undergoing elective generator changes or elective device upgrades. Patients were excluded who had signs or symptoms of infection without evidence of pocket infection. Information was collected regarding the patients' device history, comorbidities, medications, and symptomatology. The institutional review board of the University of Virginia approved this study.

Specimen Collection

Removal of the devices was performed under sterile conditions. After explantation, each device was placed in a sterile container with 100 mL of sterile saline. This container was then placed in a sonicator for 5 minutes at $42 \pm 6\%$ kHz (FS20H, Fisher Scientific, Inc.,

Pittsburgh, PA, USA). The fluid was then sent to the laboratory for culture. At the time of device collection, a swab specimen was obtained from the deep pocket after device removal, as well as a piece of the fibrous capsule (at least 1.5 cm²) for tissue culture. If any leads were explanted as part of a device upgrade or due to infection, they were also sent for culture. All samples were transported to the laboratory within 8 hours.

Definitions

Clinical Pocket Infection—This was defined as local erythema, edema, pain, warmth, or discharge from the device pocket. This may or may not have been associated with systemic symptoms, sepsis, or endocarditis.

Positive Culture—There is no gold standard for bacterial diagnosis of either pocket infections or asymptomatic bacterial colonization. Results were considered to be definitively positive in infected patients if the patient had two concordant cultures from separate modalities. This could include any of the pocket, blood, or lead-tip cultures. Results are reported as the most specific speciation recorded by the clinical laboratory.

Asymptomatic Bacterial Colonization—These patients had no evidence of clinical pocket infection or systemic infection, but had positive pocket cultures.

Patient Care

Patients Undergoing Explantation for Pocket Infection—All patients were placed on antibiotic therapy prior to explantation. The patients were placed on broad-spectrum antibiotics unless positive blood cultures were obtained to define appropriate therapy. Patients who were device dependent underwent placement of temporary wires and were admitted to the cardiac care unit during antibiotic therapy. Clinical care during device extraction, including debridement and drain placement, was left to the discretion of the operating physician. The duration of antibiotic therapy prior to device reimplantation was left to the discretion of the physician.

Patients Undergoing Elective Generator Replacement—The patients received intravenous antibiotics at the time of their procedures. Patients received cephazolin, unless they had penicillin or cephalosporin allergies, in which case they received vancomycin. At the end of the procedures, the pockets were flushed with antibiotic-containing solution prior to placing the new device in the pocket and closure. Patients undergoing generator change were discharged after the procedure. Patients undergoing device upgrade were admitted overnight. They received chest radiographs and wound checks the following morning. They also received intravenous antibiotics for 24 hours during the admission. Administration of oral antibiotics after discharge was at the discretion of the implanting physician.

Follow-Up

Patients were seen in follow-up at 2 weeks and 3 months and monitored for signs of device infection. Patients with ICDs were then seen every 3 months in follow-up and those with pacemakers were seen annually. Records from all visits with an electrophysiologist, general

cardiologist, or primary-care physician within our institution were reviewed for evidence of infection. Records from outside institutions were also reviewed if available.

Statistical Analysis

Continuous variables are expressed as mean $\pm$ standard deviation. Categorical variables are expressed as numbers and percentages. The statistical significance of differences between groups was tested using the unpaired Student's *t*-test or Fisher's exact test. We performed multivariable logistic regression modeling to test contributions of clinical characteristics to the outcome of pocket infection or asymptomatic colonization.

Results

Over 13 months, from November 2007 until December 2008, specimens from 82 patients were collected, including the device, tissue, and swab. Sixty-six patients underwent device removal for elective reasons and had no clinical signs of infection. The remaining 16 patients underwent device removal for clinical pocket infection. The mean age of all patients was 70.1 ± 17.9 years, and 28 patients (34.1%) were female. Pacemakers were explanted from 46 patients (56.1%) and ICDs from 36 patients (43.9%). The clinical characteristics of the infected and elective patient groups are listed in Table I. In univariate analysis, the only significant difference between the two groups was age of the generator, with the patients undergoing elective generator replacements having older devices (5.7 ± 6.0 vs. 3.2 ± 4.9 years; $P = 0.036$). There were trends toward fewer previous generator changes and a higher proportion of ICDs in the elective group.

Patients Undergoing Explantation for Pocket Infection

Of the 16 patients who had clinical pocket infections, 15 (94%) had a definitive bacteriologic diagnosis (at least two culture results concordant) and one received a probable diagnosis (one positive culture result revealing a typical organism). Results are shown in Table II. Culture results were positive in 15 sonicated fluid cultures, 13 tissue cultures, and 11 swab cultures. Fourteen of the sonicated fluid cultures were concordant with at least one other culture. One of the sonicated fluid cultures showed gram-negative rods while the blood and lead-tip cultures showed methicillin-sensitive *Staphylococcus aureus* (MSSA). All of the positive tissue cultures were concordant with other cultures. All but one of the positive swab cultures was concordant with other cultures. In one case, the swab culture showed coagulase-negative *Staphylococcus* species while the tissue and sonicated fluid culture showed *Micrococcus* species. The majority of the positive cultures demonstrated typical organisms, including *S. aureus* and *Staphylococcus epidermidis*.

All of the patients with clinical infections were on antibiotics prior to explantation of the device (6.6 ± 5.0 days). There was no relationship between the length of antibiotic treatment and the likelihood of the cultures being positive. One patient died of sepsis during the hospitalization 2 weeks after explantation. Nine patients did not have reimplantation of a device electively. Of the six who did, one patient was reimplanted on the contralateral side the same day as the extraction, and the remaining patients were reimplanted 3 or more days

after extraction. The average follow-up for the patients who were reimplanted was 292.4 ± 201.5 days. No recurrent infections were seen in these patients during this time.

Patients Undergoing Elective Generator Replacement

At least one of the three culture modalities was positive in 14 of the 66 patients (21%). The fluid from the sonicated device was positive in 11 patients and the tissue culture was positive in eight patients. The sonicated fluid culture and the tissue culture were both positive in five cases. In four of those cases, both cultures produced the same organism. In the fifth case, two different organisms were identified. The swab culture was positive in only two patients. Both of those patients also had positive tissue and sonicated fluid culture, and all three were concordant in each patient. The most common organism identified was *Propionibacterium acnes*. Other common skin flora was also seen. Three of the sonicated fluid cultures also identified gram-negative rods. The culture results are listed in Table III.

The average time of follow-up was 311 ± 144 days. No patients were diagnosed with device-related infections at their follow-up visits. At least 3-month follow-up was obtained on all but three patients. Sixty-three patients were seen at 2 weeks and then at 3 months by a device nurse, general cardiologist, or electrophysiologist at the University of Virginia. Two patients left the area after their procedure and received all follow-up at other institutions. A third patient was asymptomatic at his 2-week follow-up visit, but then was lost to follow-up. None of these three patients who were lost to follow-up were diagnosed with asymptomatic colonization. Three patients died during the follow-up period, two from malignancies and one related to heart failure.

Patients with asymptomatic colonization trended toward being younger, male, having ICDs, diabetes mellitus, and high-grade renal insufficiency. Univariate analysis showed that patients with asymptomatic colonization had generators that had been in place for shorter periods of time (3.6 ± 3.3 years) than those without colonization (6.2 ± 4.0 years; $P = 0.026$). Multivariable analysis using a stepwise selection process showed no other factor to be significantly different. Comparison of the clinical characteristics between the two groups is shown in Table IV. The sensitivity and specificity of swab, tissue, and sonicated fluid cultures are shown in Table V.

Discussion

There are several reasons why ultrasonication of infected implanted devices might increase diagnostic yield. Organisms exist in biofilms on the surface of implanted devices.⁵⁻⁷ Particularly, infections with low-virulence organisms are likely to have negative tissue and swab cultures. This has been shown in both the orthopedic literature, as well as in the cardiac rhythm management literature.^{4,7} Tissue culture is often used for pocket infections, but has a diagnostic yield of only 69%. Swab culture results are even poorer (31%).⁴ Ultrasound dislodges the biofilm, allowing cultures to identify causative organisms and antibiotic susceptibility testing to be performed.⁷⁻⁹ In addition, ultrasound may increase bacterial growth by increasing oxygen and nutrient transport to the cells.¹¹ A large study of explanted orthopedic prostheses demonstrated that the sensitivity and specificity of ultrasonication were 78.5% and 99.2% versus those of tissue culture which were 60.8% and

98.8%, respectively, in infected patients.⁷ In particular, increased diagnostic yield was seen in patients who had received antibiotics prior to explantation. An *in vitro* study of infected generators demonstrated that the use of sonication yielded similar results to incubation alone.¹² No studies to date have evaluated the use of ultrasonication to increase the rate of diagnosis of clinical pacemaker and ICD infections.

While appropriate device infection management is benefitted by identification of a causative organism, the significance of asymptomatic colonization is not entirely clear.¹⁰

Asymptomatic colonization of prosthetic materials occurs with skin flora often described as a colonizer. However, most device-related infections also tend to be skin flora, raising the possibility that at least some patients with asymptomatic colonization actually have subclinical infections that will become clinical infections given time.¹³ Pichlmaier et al. demonstrated that 47.2% of asymptomatic patients receiving routine generator changes had evidence of bacterial DNA on their devices.¹⁰ Interestingly, many of the samples demonstrated mixed flora, and many of the bacteria identified were not those usually found in device-related infections. *Pseudomonas* was found in 16% of positive cultures. Staphylococci were found in only 3.7% of patients, but this group included all of the patients who ultimately did develop device pocket infections.

In our small sample of patients with pocket infections, sonicated fluid cultures demonstrated a diagnostic yield that was consistent with that seen from tissue cultures. Both were superior to swab cultures. The combined use of sonicated fluid cultures, tissue cultures, blood cultures, and lead-tip cultures resulted in a bacterial diagnosis in all patients with pocket infections. Our study also demonstrates that ultrasonication of cardiac rhythm management devices increases the diagnosis of asymptomatic colonization over tissue culture alone. Culture swabs were only positive in two patients, both of whom had positive tissue and sonicated fluid cultures. Swab cultures have low sensitivity and these patients likely have a low bacterial burden compared to infected patients, accounting for the particularly low yield.

The most commonly identified organisms in infected patients were skin flora, including *S. aureus* and coagulase-negative *Staphylococcus* sp. The most commonly identified organisms in colonized patients were also skin flora, particularly *P. acnes* and coagulase-negative *Staphylococcus* sp. This highlights the importance of appropriate skin preparation prior to device implantation. Coagulase-negative *Staphylococcus* sp. are well known to cause clinical device infections.^{2,14} *Propionibacterium acnes* is a less common cause of clinical infections.^{15,16} In addition, sonicated fluid cultures did identify gram-negative rods in three asymptomatic patients and in one infected patient, although none in sufficient quantity to speciate. The infected patient also grew MSSA from the other cultures, which was likely the infectious organism, and suggests that asymptomatic colonization can coexist with pocket infections. Gram-negative device pocket infections are unusual, although asymptomatic colonization with gram negatives is clearly described.^{3,10} Polymicrobial infections may also occur. None of the asymptomatic patients in this study developed clinical infection during the follow-up period, and no factors were found to correlate with the risk of asymptomatic bacterial colonization.

Limitations

There are a number of limitations to our study. The sample size was relatively small. There were trends toward factors such as device type, diabetes, and renal failure correlating with increased risk of colonization, and these factors may have gained statistical significance with a larger sample size. As there is no true gold standard for organism identification, contamination of the samples cannot be completely ruled out, especially in cases where more than one organism was identified. There was operator variability in the use of antibiotic therapy after device implantation. In addition, the follow-up period for monitoring was relatively short. It may be that indolent infections may become clinically manifest over time.

Conclusions

Ultrasonication of pacemaker and ICD generators increases the diagnosis of pocket infection and asymptomatic colonization over tissue culture and swab culture alone. Patients with asymptomatic colonization, however, did not develop future pocket infection. Further studies will be needed to determine if ultrasonication is superior to tissue culture in the bacteriologic diagnosis of pocket infections. However, this is a simple and inexpensive technique that, when used appropriately, can enhance the diagnosis of pocket infections, and thereby, improve antimicrobial therapy for patients.

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Table I

Clinical Characteristics of the Patients Undergoing Device Extraction for Elective Generator Replacement or Pocket Infections

	Elective Generator Replacement (N = 66)	Pocket Infection (N = 16)	P Value
Age (years)	70.8 ± 18.1	67.2 ± 17.4	0.47
Gender			
Female	21 (31.8%)	7 (43.8%)	0.81
Male	45 (68.2%)	9 (56.3%)	0.43
Device explanted			
Pacemaker	34 (51.5%)	12 (75%)	0.86
ICD	32 (49.5%)	4 (25%)	0.20
Duration of implant (years)	5.7 ± 6.0	3.2 ± 4.9	0.036
Previous generator changes	12 (18.2%)	7 (43.8%)	0.97
Comorbidities			
Diabetes mellitus	16 (24.2%)	5 (31.2%)	0.77
Hypertension	51 (77.3%)	9 (56.3%)	0.32
Hyperlipidemia	35 (53.0%)	7 (43.8%)	0.45
Chronic renal insufficiency (Stage 4/5)	9 (13.6%)	2 (12.5%)	0.64
Coronary artery disease	35 (53.0%)	7 (43.8%)	0.45
Congestive heart failure	43 (65.2%)	9 (56.3%)	0.47
Medications			
Angiotensin-converting enzyme inhibitor	30 (45.5%)	6 (37.5%)	0.46
Angiotensin receptor blocker	12 (18.2%)	2 (12.5%)	0.48
β-blocker	46 (69.7%)	13 (81.3%)	0.72
Aspirin	40 (60.6%)	10 (62.5%)	0.62
Plavix	3 (4.5%)	2 (12.5%)	0.94
Coumadin	27 (40.9%)	5 (31.2%)	0.43
Amiodarone	11 (16.7%)	2 (12.5%)	0.54
Chronic oral steroids	1 (1.5%)	0 (0%)	0.81

Table II

Culture Results from Patients with Device Pocket Infection

Patient	Swab Culture	Tissue Culture	Sonicated Fluid Culture	Blood Culture	Lead-Tip Culture
1	MRSA	MRSA	MRSA	MRSA	MRSA
2	Negative	Negative	Coagulase-negative <i>Staphylococcus</i> sp.	Negative	Coagulase-negative <i>Staphylococcus</i> sp.
3	MSSA	MSSA	Negative	MSSA	MSSA
4	MRSA	MRSA	MRSA	MRSA	MRSA
5	Coagulase-negative <i>Staphylococcus</i> sp.	<i>Micrococcus</i> sp.	<i>Micrococcus</i> sp.	Negative	<i>Micrococcus</i> sp.
6	Negative	Negative	Coagulase-negative <i>Staphylococcus</i> sp.	Negative	Negative
7	Negative	Negative	Gram-negative rods	MSSA	MSSA
8	Coagulase-negative <i>Staphylococcus</i> sp.	Coagulase-negative <i>Staphylococcus</i> sp.; <i>Corynebacterium</i>	Coagulase-negative <i>Staphylococcus</i> sp.; <i>P. acnes</i>	Negative	Coagulase-negative <i>Staphylococcus</i> sp.; <i>Corynebacterium</i>
9	MRSA	MRSA	MRSA	Negative	Negative
10	<i>S. epidermidis</i>	<i>S. epidermidis</i>	<i>S. epidermidis</i>	Negative	Negative
11	<i>E. cloacae</i>	<i>E. cloacae</i>	<i>E. cloacae</i>	Negative	<i>E. cloacae</i>
12	<i>E. aerogenes</i>	<i>E. aerogenes</i>	<i>E. aerogenes</i>	Negative	<i>E. aerogenes</i>
13	MRSA	MRSA	MRSA	Negative	MRSA
14	Negative	<i>S. epidermidis</i>	<i>S. epidermidis</i>	Negative	Negative
15	<i>S. marcescens</i>	<i>S. marcescens</i>	<i>S. marcescens</i>	Negative	<i>S. marcescens</i>
16	MRSA	MRSA	MRSA	MRSA	MRSA

MRSA = methicillin-resistant *S. aureus*; MSSA = methicillin-sensitive *S. aureus*.

Table III

Culture Results from Patients Who Were Diagnosed with Asymptomatic Bacterial Colonization

Patient	Swab Culture	Tissue Culture	Sonicated Fluid Culture
1	Negative	Negative	<i>P. acnes</i>
2	Negative	<i>P. acnes</i>	Negative
3	Negative	Negative	<i>P. acnes</i>
4	Negative	<i>P. acnes</i>	Negative
5	Negative	Negative	<i>Micrococcus</i> sp.
6	Negative	<i>P. acnes</i>	<i>P. acnes</i>
7	Negative	Negative	Gram-negative rods
8	Negative	Negative	Coagulase-negative <i>Staphylococcus</i> sp.
9	Negative	<i>P. acnes</i>	<i>P. acnes</i>
10	Coagulase-negative <i>Staphylococcus</i> sp.	Coagulase-negative <i>Staphylococcus</i> sp.	Coagulase-negative <i>Staphylococcus</i> sp.
11	Negative	<i>P. acnes</i>	Gram-negative rods
12	Negative	Negative	Gram-negative rods
13	<i>S. epidermidis</i>	<i>S. epidermidis</i>	<i>S. epidermis</i>
14	Negative	<i>Corynebacterium</i>	Negative

Table IV

Comparison of Asymptomatic Patients with and Without Bacterial Colonization

	Positive Culture N = 14	Negative Culture N = 52	P Value
Age (years)	69.6 ± 18.0	71.1 ± 18.3	0.79
Gender			
Female	3 (21.4%)	18 (34.6%)	0.75
Device explanted			
Pacemaker	4 (28.6%)	30 (57.7%)	0.29
ICD	10 (71.4%)	22 (42.3%)	0.32
Duration of implant (years)	3.6 ± 3.3	6.2 ± 4.0	0.026
Previous generator changes	2 (14.3%)	18 (34.6%)	0.34
Comorbidities			
Diabetes mellitus	5 (35.7%)	11 (21.2%)	0.51
Hypertension	11 (78.6%)	40 (76.9%)	1.0
Hyperlipidemia	7 (50.0%)	28 (53.8%)	1.0
Chronic renal insufficiency (Stage 4/5)	4 (28.6%)	5 (9.6%)	0.21
Coronary artery disease	8 (57.1%)	27 (51.9%)	1.0
Congestive heart failure	11 (78.6%)	32 (61.5%)	0.65
Medications			
Angiotensin-converting enzyme inhibitor	8 (57.1%)	22 (42.3%)	0.60
Angiotensin receptor blocker	2 (14.3%)	10 (19.2%)	1.0
β-blocker	10 (71.4%)	36 (69.2%)	1.0
Aspirin	9 (64.3%)	31 (59.6%)	1.0
Plavix	1 (7.1%)	2 (3.8%)	0.53
Coumadin	5 (35.7%)	22 (42.3%)	1.0
Amiodarone	1 (7.1%)	10 (19.2%)	0.68
Chronic oral steroids	0 (0.0%)	1 (1.9%)	1.0

Table V

Comparison of Culture Modalities for Bacterial Diagnosis of Pacemaker and ICD Pocket Infections

	Sensitivity % (95% confidence interval)	Specificity % (95% confidence interval)
Sonicated fluid	88 (60–98)	83 (72–91)
Tissue	82 (54–95)	88 (77–94)
Swab	69 (41–88)	97 (89–99)