non-invasive imaging can facilitate the diagnosis, but tissue biopsy remains the gold standard for both obtaining a definitive diagnosis of amyloidosis and classifying the amyloid subtype. Since patients undergoing CIED implantation are often older and have electrical or structural heart disease, we postulated that tissue biopsy of the subcutaneous pocket during device implantation may allow for facile detection of otherwise undiagnosed amyloidosis.

**Objective:** To evaluate the feasibility of adipose tissue sampling from the chest wall pocket during CIED implantation.

**Methods:** Patients with clinical/imaging characteristics suggestive of amyloidosis, but without a diagnosis, underwent excisional biopsy of chest wall subcutaneous adipose tissue from the newly created CIED pocket at the time of device implant (Figure). Samples were analyzed with Congo red staining and mass spectrometry for subtyping.

**Results:** The study cohort included 18 patients receiving pacemakers (n = 9) or ICDs (n = 9) with mean age 71 years, 83% (n = 15) male, 44% (n = 8) with AF, and average LV wall thickness of 1.3 cm. Each biopsy took under 2 minutes to acquire. Of the entire cohort, 17% (n = 3) of the patients had adipose samples that were Congo red positive, consistent with amyloidosis. The average LV wall thickness of the 3 patients with biopsy-proven amyloidosis was 1.5 cm. All 3 patients were ultimately diagnosed with transthyretin (ATTR) amyloidosis (2 wild-type, 1 hereditary) and treated with the novel transthyretin-binding medication, tafamadis.

**Conclusion:** Adipose tissue excisional biopsy of the newly created chest wall pocket can be easily, safely, and quickly performed (within 2 minutes) at the time of CIED implantation. Timely histopathological confirmation of amyloidosis in these at-risk patients permitted early initiation of disease-modifying agents. These data warrant a large prospective trial in patients with risk factors for amyloidosis undergoing CIED implantation.

**Background:** Infection risk mitigation for cardiovascular implantable electronic device (CIED) implantation includes guideline recommended use of pre-op IV antibacterial prophylaxis (IV ABX). Antibacterial biologic porcine extracellular matrix CIED envelopes hydrated with antibiotics combined with IV ABX may reduce CIED infection rates.

**Objective:** Report real world data on CIED infection risk reduction practices in a multicenter trial dataset.

**Methods:** A post-hoc analysis of 1102 patients in the CARE & SECURE studies assessed observational data on IV ABX, antibacterial biologic envelope usage and infection outcomes.

**Results:** Compliance with guideline IV ABX was 96.6% (range 11 - 100%), similar to WRAP IT (94.2%) but varied by site - 100%: 23 sites, ≥90%: 32 sites, ≥80%: 36 sites. Sites with higher compliance (≥80% IV ABX use) had lower CIED infection rates than sites with <80% compliance (0.9% vs 2.9%) (Figure 1A). These differences were more pronounced when antibacterial biologic envelopes were used with IV ABX (≥80% vs <80% (0.8% vs 5.6%) (Figure 1B). In sites with IV ABX compliance ≥80%, the use of an antibacterial vs saline-only hydration envelope was associated with a trend toward a lower infection rate (0.8% vs 1.1%) (Figure 1C). These findings suggest that the use of antibacterial envelopes without IV ABX is not sufficient to reduce CIED infections.

**Conclusion:** A concerning number of patients undergoing CIED implantation did not receive guideline recommended IV ABX and had a higher infection rate. These real world observations align with the current guideline recommendations for IV ABX use during CIED implantation and support the use of antibacterial biologic envelopes as an adjunct (not substitute) infection prevention strategy. The role of infection risk factor characteristics and the role of antibacterial biologic envelope usage in potentially mitigating CIED infections warrant further investigation.

**Figure 1**
patients often have pacemakers or implantable cardioverter defibrillators (ICDs), collectively known as cardiac implantable electronic devices (CIEDs), for treatment of bradycardia or ventricular arrhythmias. In addition to these functions, many modern CIEDs collect objective data about spontaneous cardiac electrical activity - including the presence and burden of PVCs. However, the performance of CIEDs for quantifying PVC burden remains unclear.

Objective: To determine the performance of CIEDs for quantifying PVC burden, compared to the reference standard of ambulatory cardiac monitoring.

Methods: We identified adult patients at Vanderbilt University Medical Center with CIEDs who underwent concurrent ambulatory cardiac monitoring with Holter or mobile cardiac telemetry monitoring. Patients who received PVC ablations or anti-arrhythmic medication changes during the CIED interrogation period of interest were excluded. We then extracted PVC burden data from CIED interrogation reports that corresponded to the ambulatory monitoring period.

Results: We identified 507 instances fitting the study criteria of a CIED with PVC burden data available with concurrent ambulatory cardiac monitoring. The median (IQR) PVC burden detected by ambulatory monitoring was 2.18% (0.10-10.06%). The median (IQR) PVC burden detected by CIED was 1.00% (0.11-4.41%). In general, the PVC burden detected by CIED underestimated that detected by ambulatory monitoring (Figure 1). Spearman’s correlation coefficient was 0.60. Furthermore, when defining a high PVC burden as >15% PVCs, PVC detection by CIED showed a sensitivity of only 0.16 and a specificity of 0.99. Defining high PVC burden as >10% instead resulted in a sensitivity of 0.28 and a specificity of 0.97. Receiver operating characteristic (ROC) curves (Figure 2) had an area under the curve (AUC) of 0.574 (95% CI: 0.535-0.612) using >15% PVCs as a threshold and 0.624 (95% CI: 0.584-0.663) using >10% as a threshold.

Conclusion: ICDs and pacemakers demonstrate poor sensitivity but high specificity for detecting PVCs. At this time, PVC burden data from ICDs and pacemakers should not be considered adequate to rule out a clinically relevant high PVC burden.

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NITRIC OXIDE RELEASING PACING LEAD TO PREVENT INFECTION IN CARDIAC PACING

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Background: Effective prevention of pacing lead infection could reduce morbidity and save lives. It has been demonstrated that nitric oxide (NO) can inhibit bacterial adhesion and reduce biofilm formation. We tested a diazeniumdiolated dibutylhexanediamine (DBHD/N2O2, a potent NO donor) coated pacing lead to prevent its bacterial infection.

Objective: NO releasing coating can prevent adhesion of bacterial biofilm and limit potential pacing lead infection.

Methods: Silicone pacing lead was coated with two layers of 25 weight% DBHD/N2O2 in carbosil and topped with one layer of plain carbosil. The NO release profile of the coated lead is measured with an ozone chemiluminescent method at 37°C in phosphate buffered saline (PBS, pH=7.4). In a bioreactor the lead is then exposed to bacterial cultures of S.aureus and P.aeruginosa and its antibacterial capacity evaluated by biofilm homogenization and plating on agar for CFU counting of viable bacteria per surface area. Complete pacing system with the DBHD/N2O2 coated pacing lead is then implanted in small animal model (rabbit) and tested for function and durability.

Results: Initial NO flux of DBHD/N2O2 coating was 0.8±0.1 [x1010 mol/min/cm2] and stayed between the effective range >0.5 flux unit for seven days. Preliminary results on coated catheter surfaces demonstrated almost 95% decrease of biofilm formation: 89±9.7 vs. 5.2±1.1 x103 CFU (P<0.001). In-vivo, cardiac pacing was properly functional in all subjects for over 6 months with mean impedance of 750 Ohm, average bipolar ventricular sensing of 9.2mV (min 7.4, max 12) and pacing threshold of 1.7V@0.4ms (min 0.2, max 2.7).

Conclusion: Presented study is the first to report of antimicrobial NO donor used for cardiac pacing devices. Pacing lead with DBHD/N2O2 coating demonstrated a potent antibacterial effect while retaining optimal pacing parameters. This effective elimination of biofilm formation can likely prevent potential clinical infection especially in complex pacing procedures or immunocompromised patients.