EP News: Quality Improvement and Outcomes

John N. Catanzaro, MD, FHRS,* Anne Marie Smith, MBA,† Javed M. Nasir, MD‡

*From the *University of Florida Health, Jacksonville, Florida, †Heart Rhythm Society, Washington, District of Columbia, and ‡David Grant USAF Medical Center, Travis Air Force Base, Fairfield, California.*

This is the second in a series of **Heart**Rhythm quarterly features, highlighting science relevant to quality improvement. The focus of this feature is the prevention of cardiac implantable electronic device infection.

Antibacterial envelope to prevent cardiac implantable device infection

Taraki et al (N Engl J Med 2019;380:1895, PMID 30883056) conducted a prospective, international, randomized controlled trial to assess the safety and efficacy of an absorbable, antibiotic-eluting envelope in reducing the incidence of cardiac implantable electronic device (CIED) infection. Patients undergoing generator change, device upgrade, device revision, or implantation of a new cardiac resynchronization therapy – defibrillator were included. The primary end point was major CIED infection, resulting in system extraction or revision, infection recurrence after discontinuing long-term antibiotic therapy, or death within 12 months of implantation. There were 6983 patients randomized in a 1:1 ratio to receive the envelope or not. All received standard strategies to prevent infection, and >98% of both groups received preoperative antibiotics. The primary end point of major CIED infection occurred in 0.7% of patients with an envelope and 1.2% of patients without (hazard ratio 0.60; 95% confidence interval 0.36–0.98; $P = .04$). Subgroup analysis did not identify any characteristics associated with benefit from the envelope. *The authors conclude that adjunctive use of an antibacterial envelope reduced the incidence of major CIED infection by 40%.*

PERSPECTIVE: Impressively, this trial demonstrated a 40% risk reduction with only a 1.2% infection risk in the control group. However, with an absolute risk reduction of 0.5% and a Number Needed to Treat (NNT) of ~200, there is a need to better understand the cost-effectiveness and optimal patient selection for the envelope.

Preoperative antibiotics and cardiovascular implantable electronic device infection: A cohort study in veterans

Alzahrani et al (Pacing Clin Electrophysiol 2018;41:1513, PMID 30221380) conducted a retrospective cohort analysis of the VA system to assess whether vancomycin use was associated with an increased risk of cardiovascular implantable electronic device (CIED) infection when compared to cefazolin or other beta-lactam antibiotics. The primary outcome was CIED infection identified by administrative codes. Patients who received a combination of antibiotics including vancomycin were included in the vancomycin group. Among 10,454 CIED procedures, vancomycin was used in 40.6%. The CIED infection rate was significantly higher in patients who received vancomycin (1.01% vs 0.34%; $P < .001$), and this persisted after logistic regression. Limitations include the predominantly male veteran population and potential for unmeasured confounding by indication, especially that many patients receive vancomycin if they have known Methicillin-resistant Staphylococcus aureus (MRSA) colonization. *The authors conclude that among patients who received surgical site infection prophylaxis for CIED placement or revision, there was (1) an unanticipated high rate of vancomycin use and (2) a 3-fold increase in the incidence of subsequent CIED infection in vancomycin recipients.*

PERSPECTIVE: Professional society guidelines recommend beta-lactam antibiotics preoperatively and reserve vancomycin for penicillin allergies, although some advocate for use when MRSA colonization is present or with high local resistance. We should consider vancomycin use carefully, as there remains concern of less effective alternate antibiotics.

Use of antimicrobial agent pocket irrigation for cardiovascular implantable electronic device infection prophylaxis: Results from an international survey

Given that local antibiotic usage for cardiovascular implantable electronic device (CIED) infection prophylaxis, in particular pocket irrigation, is a well-known strategy but with little data on its clinical effectiveness, Zheng et al (Pacing Clin Elect 2018;41:1298, PMID 30109698) sent an anonymous voluntary online survey to 2092 arrhythmia-oriented cardiologists in 51 countries to assess practice patterns. There were 487 responses, and 87% of respondents report using intraoperative antimicrobial agent pocket irrigation and/or an antimicrobial eluting pouch in an attempt to reduce CIED infection. The majority of respondents (54%) believe that antimicrobial agent pocket irrigation is effective in reducing CIED infection. Bacitracin (48%), vancomycin (39%), and cephalosporin (29%) are the most commonly chosen antibiotics. A majority of the respondents are unaware of the cost of using antimicrobial agent pocket irrigation (69%), and neither are they concerned (67%). *Based on these findings, the authors conclude that while there are little clinical data to support or discourage practice, the antimicrobial agent pocket irrigation for CIED infection prophylaxis is currently widely used.*

PERSPECTIVE: While the effect of antimicrobial agent pocket irrigation was not studied directly in the Prevention of Arrhythmia Device Infection (PADIT) Trial, it did not show benefit of the combination of preprocedural cefazolin plus vancomycin, intraprocedural bacitracin pocket wash, and 2-day postprocedural oral cephalexin when compared to preprocedural cefazolin. Further research for standardization is warranted.

Address reprint requests and correspondence: Ms Anne Marie Smith, Heart Rhythm Society, 1325 G Street, NW, Suite 400, Washington, DC 20005. E-mail address: amsmith@hrsonline.org.

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