Vanderbilt Study Shows Sharp Decline In Cardiac Device Infections with TYRX AIGISRx Antibacterial Envelope

Patients at high risk for surgical site infection following Cardiac Implantable Electronic Device (CIED) implantation with TYRX, Inc.'s AIGISRx Antibacterial Envelope experienced significantly reduced risk of device infection compared to patients implanted without AIGISRx. Results of a retrospective cohort study of CIED implantations, including pacemakers and implantable defibrillators, were published online in the journal of Pacing and Clinical Electrophysiology (PACE).

Matthew J. Kolek, MD, William F. Dresen, MD, Quinn S. Wells, MD, and Christopher R. Ellis, MD, from the Vanderbilt Heart and Vascular Institute, conducted the study of surgical site infections following pacemaker or implantable cardioverter defibrillator (ICD) implantation.

Researchers compared the incidence of CIED infection in 260 patients with recognized risk factors for CIED infection and who had a CIED implanted with the AIGISRx Envelope, to a control cohort of 639 patients matched for the presence of these recognized risk factors for CIED infection who had a CIED implanted without the AIGISRx Envelope.
Key findings of the study included:

• After a minimum of 90-days of follow-up, the incidence of CIED infection was significantly lower in the group that received an AIGISRx Envelope 0.4% vs. 3.0%, OR = 0.13 [0.02-0.95] p=0.04). The risk of a CIED infection remained significantly lower in patients with an AIGISRx, even adjusting for propensity score and propensity score matching.
• Patient and procedure characteristics used to identify patients at high risk for CIED infection were diabetes, renal insufficiency, anticoagulation, chronic corticosteroid use, fever, or leukocytosis at the time of implantation, prior CIED infection, ≥ 3 leads, pacemaker dependence, or early pocket re-entry.
• While the incidence of individual risk factors differed between the groups, the 260 patients who received an AIGISRx Envelope and the 639 patients in the control cohort both had a mean of 2.8+/- 1.2 predefined risk factors for CIED infection.
• Minocycline and rifampin, the antibiotics released by the AIGISRx Envelope, are active against the majority of pathogens isolated from patients in the control group who developed a CIED infection.

"CIED-related infections have contributed significantly to patient mortality and health care costs as they have risen rapidly over the last decade," stated Dr. Ellis. "As a result, there has been a concerted effort and focus within the cardiac community to find ways to reduce these infections. A previously published retrospective cohort study showed there was a low CIED infection rate associated with the use of the minocycline and rifampin-impregnated AIGISRx Envelope, and

other published studies have identified patient-specific and procedural risk factors for CIED infections. So, we set out to examine the ability of the AIGISRx Envelope to reduce CIED infections at our own Institution compared to a matched cohort of control patients."

Dr. Ellis concluded, "Our findings clearly showed that patients whose CIED implantation included the use of the AIGISRx Envelope experienced a significantly lower rate of infection compared to a matched cohort of patients who underwent implantation without the antibacterial device."

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