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Zero Infections in High-Risk Cardiac Device Replacements with TYRX Antibacterial Envelope

Use of TYRX, Inc.'s AIGISRx® Antibacterial Envelope reduced major infection rates by 100% in patients undergoing Cardiovascular Implantable Electronic Device (CIED) replacement procedures compared to case-matched retrospective control patients. Investigators presented new interim results from the Citadel / Centurion Clinical Study today at the Late Breaking Clinical Trials session at the European Heart Rhythm Association (EHRA), EUROPACE 2013.

The Citadel / Centurion study is a prospective, multicenter clinical study in patients at high-risk for CIED infection who have their CIED implanted with the AIGISRx Antibacterial Envelope. The aim of the study is to evaluate the impact of the AIGISRx Antibacterial Envelope on major device infection and mechanical complication rates in the 12-months after implantation. Investigators at 55 US centers enrolled patients who were at high-risk for device infection because they were undergoing a CIED replacement procedure with either an implantable cardioverter-defibrillator (ICD), (Citadel), or a cardiac resynchronization therapy (CRT) device (Centurion).

Additional results from a planned interim analysis of the primary endpoints for the first 1,000 eligible patients after 90-days of follow up were presented by Dr. Charles A. Henrikson, the Chief of Electrophysiology at the Oregon Health Sciences University.

Key study highlights included:

- The Centurion arm of the study enrolled patients undergoing CIED replacement with a CRT and the AIGISRx Antibacterial Envelope, and compared them to case-matched control patients undergoing CIED replacement with a CRT and no AIGISRx.
- Case-matched controls were selected in reverse chronologic order, from the period before the AIGISRx was first implanted at each study site.
- The primary endpoints of the study were major CIED infection and CIED mechanical complication rates.
- An interim analysis of 3-month follow-up data from the first 1,000 eligible Citadel / Centurion patients demonstrated that there were no major infections in the 597 Centurion patients in this cohort (0.0%). A total of 532 Centurion patients had cased-matched controls.
- When the 532 Centurion patients implanted with the AIGISRx were compared to the 532 control patients who did not receive AIGISRx (6 major CIED infections), there were significantly fewer major CIED infections in the group that received the AIGISRx (0.0% vs. 1.2%; P=0.03).
- There was no significant difference in the frequency of CIED mechanical complications in the group implanted with the AIGISRx, compared to the control patients who did not receive the AIGISRx (P=0.23).

“We continue to see that CIED infections are on the rise, are associated with significant morbidity, mortality, and cost, and present substantial challenges to patients, as well as the physicians who provide them care,” stated Charles A. Henrikson, MD, FHRS, Oregon Health Sciences University, Portland, Oregon. “The Citadel / Centurion study is a large prospective study enrolling patients at community, academic, and VA medical centers which will provide us with very useful clinical information on the use of the AIGISRx Antibacterial Envelope when used in a variety of patients at high risk for CIED infection.”

The Citadel / Centurion study is registered in the ClinicalTrials.gov registry of federally and privately supported clinical trials conducted in the US and around the world (www.ClinicalTrials.gov).

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