VANDERBILT HEART AND VASCULAR INSTITUTE STUDY WITH THE TYRX™ ABSORBABLE AND NON-ABSORBABLE ANTIBACTERIAL ENVELOPES

High-Risk Patients with the TYRX Antibacterial Envelopes Experienced Fewer Cardiac Implantable Electronic Device (CIED) Infections Versus Patients Without These Envelopes[1,2]

DESIGN

A retrospective, matched-cohort study was performed to compare the incidence of CIED Infection in patients receiving a CIED with or without the TYRX Absorbable Antibacterial Envelope or the TYRX Non-Absorbable Antibacterial Envelope.[1,2]

METHODS

Surgical procedures, medications, and patient characteristics significantly increase the risk of CIED-related Infection.[1,2]

- The following risk factors were used to identify patients at high-risk for CIED Infection: generator change or device/lead revision; early pocket re-entry < 72 hours; renal insufficiency (serum creatinine ≥ 1.5mg/dL); diabetes mellitus; systemic anticoagulation with heparin, warfarin or novel oral anticoagulants; chronic corticosteroid use; the presence of ≥ 3 leads (cardiac resynchronization or abandoned leads); prior CIED Infection; fever (≥ 100.5° F) or leukocytosis (≥ 11,000 WBCs/μL) at time of implantation; and pacemaker dependence.[1,2]
- Patients with ≥ 2 risk factors received either the TYRX Absorbable Antibacterial Envelope, the TYRX Non-Absorbable Antibacterial Envelope, or no TYRX Envelope in the control group.[1,2]

A total of 488 TYRX Absorbable and Non-Absorbable Antibacterial Envelopes were implanted from November 1, 2009 to June 30, 2014.[1,2]

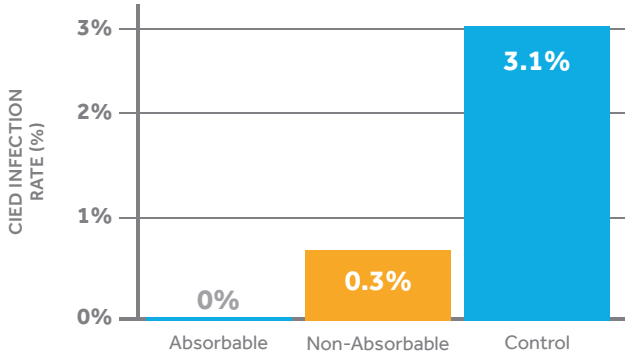
- The incidence of CIED Infection in 488 TYRX Envelope recipients (135 receiving the Absorbable Envelope, 353 receiving the Non-Absorbable Envelope) was compared to 638 controls.[1,2]
- While the incidence of individual risk factors differed between the groups, the mean (standard deviation) number of risk factors was equivalent among the groups: 3.1 (1.4) for the Absorbable Envelope, 3.2 (1.3) for the Non-Absorbable Envelope, and 3.1 (1.3) for the control group, p=0.30.[1,2]

RESULTS

After a minimum of 90 days post-implantation, the incidence of CIED Infection was significantly lower in the groups that received either the TYRX Absorbable or TYRX Non-Absorbable Envelope, compared to the control group:[1,2]

- 0 (0%) infection in the TYRX Absorbable Antibacterial Envelope group (p=1)
- 1 (0.3%) infection in the TYRX Non-Absorbable Antibacterial Envelope group (p=0.03)
- 20 (3.1%) infections in the control group (p=0.002)

SIGNIFICANT REDUCTION IN CIED INFECTION RATE[1]



The results were adjusted using Propensity Score Matching (PSM) to control for risk factors as a confounding factor.

- **All TYRX Envelope recipients vs. control:** In a PSM cohort of 334 TYRX Antibacterial Envelope recipients (either Absorbable or Non-Absorbable) and 334 controls, the incidence of CIED Infection was 0 (0%) and 11 (3.3%) respectively, p=0.001.[1,2]
- **TYRX Absorbable Envelope recipients vs. control:** In a PSM cohort of 125 TYRX Absorbable Envelope recipients and 125 controls, the incidence of CIED Infection was 0 (0%) and 6 (4.8%) respectively, p=0.03.[2]

CONCLUSIONS

There was a 90% to 100% reduction in CIED Infection in high-risk patients who received either the TYRX Absorbable Antibacterial Envelope or the TYRX Non-Absorbable Antibacterial Envelope compared to those who did not. Using PSM to control for risk factors, there was a 100% reduction in CIED Infection.[1,2]

1. Kolek MJ et al. *Pacing Clin Electrophysiol.* 2013;36(3):354-361. **2.** Patel NJ et al. Efficacy of a Bioabsorbable Antibacterial Envelope to Prevent CIED Infections in High-Risk Patients. Oral presentation at Heart Rhythm Society Annual Scientific Sessions, *Heart Rhythm* May Supplement. 2015;12(5).

Medtronic TYRX, Inc. 1 Deer Park Drive, Suite G | Monmouth Junction, NJ | Medtronic CRHF/ Infection Control
TYRX Customer Service: 800.848.9300 Technical Support/Services: 800.505.4636 (Brady) and 800.723.4636 (Tachy) | www.TYRX.com
UC201503786bEN

Medtronic