THE VALLEY HEALTH SYSTEM STUDY WITH THE TYRX™ ANTIBACTERIAL ENVELOPE*

High-Risk Patients Implanted with the TYRX Antibacterial Envelope are Signifcantly Less Likely to Develop Cardiac Implantable Electronic Device (CIED) Infection than Comparatively Low-Risk Cohorts[1]

DESIGN

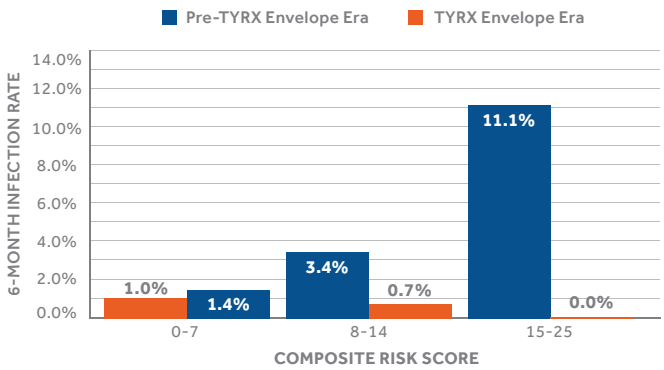
A retrospective, dual-cohort study was conducted in a large population of patients undergoing CIED procedures to determine the effect of the TYRX Antibacterial Envelope on CIED Infection rates, utilizing a novel scoring index to risk-stratify patients based on the specific combination of risk factors, rather than just the absolute number of risk factors.[1]

6-MONTH CIED INFECTION RATE: STRATIFIED BY DEVICE AND PROCEDURE TYPE(%)[1]

	Procedure Type			
Device	***DeNovo***	**Generator**	**Upgrade**	**Other**
CRT-D	4.0%	3.1%	3.9%	33.0%
ICD	1.5%	1.7%	18.2%	0.0%
PM†	0.8%	0.3%	0.0%	0.0%
CRT-P‡	0.0%	0.0%	0.0%	0.0%

Infection rates were higher in the Implantable Cardioverter Defibrillator (ICD) and Cardiac Resynchronization Therapy Defibrillator (CRT-D) groups, and in upgrade and early pocket re-exploration group.
† Pacemaker ‡ Cardiac Resynchronization Therapy Pacemaker

6-MONTH CIED INFECTION RATE: LIMITED TO ICD AND CRT-D PATIENTS[1]



Pre-TYRX Envelope, n	204	416	27
TYRX Envelope, n	140	292	24
TYRX Envelope Use, n(%)	47 (34%)	16 (40%)	21(88%)

A composite risk score was created by weight, adjusting for the seven risk factors: 3 groups emerged—low-risk (score 0-7; 1% infection), medium risk (score 8-14; 3.4% infection), and high risk (score ≥ 15; 11.1% infection).

METHODS

Two cohorts of patients who underwent CIED procedures were identified: 1,651 patients before the introduction of the TYRX Envelope at the site (January 2007-October 2009) and 1,240 patients after the introduction of the TYRX Envelope (October 2009-September 2011), including 275 patients who received the TYRX Envelope. Using propensity-score matching, the 275 patients who received the TYRX Envelope were matched to 275 patients prior to the introduction of the TYRX Envelope.[1]

RESULTS

Compared to patients who did not receive a TYRX Envelope, those who did receive the Envelope were more likely to have the following risk factors associated with an increased risk of an infection: early pocket re-exploration, male gender, diabetes, device upgrade, congestive heart failure (CHF), hypertension, GFR < 60ml/min. All these variables have been associated with CIED Infection.[1]

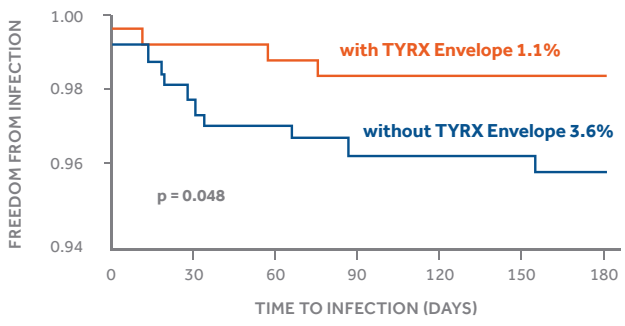
The 6-month infection rate was significantly lower in patients who received a TYRX Envelope, compared to propensity score matched patients who did not (1.1% vs. 3.6%, p=0.048).[1]

CONCLUSIONS

The TYRX Envelope reduced infections by 79% and 100% in the medium and high-risk groups, respectively.[1]

There were ~70% fewer infections in patients who received the TYRX Antibacterial Envelope, compared to those who did not, across all device types.[1]

CIED INFECTION DURING THE 6 MONTHS FOLLOWING CIED IMPLANTATION AS A FUNCTION OF ENVELOPE USE[1]



*Study performed utilizing the TYRX™ Non-Absorbable Antibacterial Envelope.

1. Mittal S et al. *Heart Rhythm*. 2014;11(4):595-601.

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