

ANTIBACTERIAL ENVELOPE IS ASSOCIATED WITH MEDICAL COST SAVINGS IN PATIENTS AT HIGH-RISK FOR CARDIOVASCULAR IMPLANTABLE ELECTRONIC DEVICE INFECTION

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ABSTRACT

Introduction: Recent clinical studies (Citadel/Centurion studies) demonstrated that the TYRX™ Antibacterial Envelope (TYRX) was associated with a significantly reduced rate of major Cardiovascular Implantable Electronic Device (CIED) Infections relative to published controls among patients at high-risk for CIED Infection. The objective of this analysis is to quantify the hospital perspective economic impact associated with TYRX use, based upon the reduction in CIED infections demonstrated in the Citadel/Centurion studies.

Methods: A decision tree model was developed based on the population of 1,129 high-risk CIED implant patients (40.7% ICD and 59.3% CRT) and TYRX use infection rates of 0.22% for ICD and 0.60% for CRT sourced from the Citadel/Centurion studies results. An infection rate of 2.22% for both ICD and CRT was sourced from the same published control utilized in the Citadel/Centurion studies. The model assumed that patients with major infections received inpatient treatment consisting of CIED extraction and replacement, per guideline recommendations. Inpatient hospital costs, specific for Medicare ICD and CRT patients but independent of TYRX use, were sourced from the Premier Healthcare Database as \$75,697 and \$87,533 for ICD and CRT-D, respectively. The TYRX cost was specified as \$1,000.

Results: Per 1,129 patients, use of TYRX was associated with 20 fewer CIED infections (5 vs. 25). The total TYRX cost of \$1,129,000 was offset by a \$1,644,975 reduction in total CIED infection-related hospital costs, for a net cost savings of \$515,975 or \$457 per patient.

Conclusions The low rate of major CIED infection rate observed among a high-risk CIED population in the Citadel/Centurion studies was associated with large reductions in hospital costs. The reduction in CIED infection-related hospital costs was greater than the TYRX costs, resulting in overall cost savings.

BACKGROUND

- Implantation of a CIED is associated with a risk of device-related bacterial infection, which in turn is associated with substantial morbidity, mortality, and costs.¹⁻³
- TYRX™ Antibacterial Envelopes are designed to stabilize CIED placement and elute antibiotics locally to help reduce CIED infection
- Published retrospective studies have indicated low CIED infection rates with TYRX in patients at high-risk for infection.⁴⁻⁶
- The prospective Citadel/Centurion studies of high-risk patients indicated lower ICD and CRT replacement infection rates with TYRX⁷ compared with a published benchmark infection rate.⁸
- The objective of this study was to quantify the hospital perspective economic impact associated with the reduction in CIED infections among high-risk patients enrolled in the Citadel/Centurion studies who received TYRX Antibacterial Envelopes.

METHODS/DESCRIPTION

- An Excel-based decision tree model with structurally identical decision tree arms for intervention (With TYRX (Figure 1)) and control (Without TYRX (Figure 2)) was designed with a US hospital perspective.
- Model inputs are presented in Table 1. The number of high-risk patients and the ICD/CRT proportions corresponded to the patients enrolled in the Citadel/Centurion studies with TYRX use.⁷ Intervention CIED infection rates were sourced from the Citadel/Centurion studies.⁷ Control infection rates for all CIEDs were sourced from a published analysis of patients implanted with ICDs.⁸ Costs were sourced from a retrospective analysis of the 2012 Premier Healthcare Database, and reflected hospital costs for Medicare patients inflated to February 2016 values.^{9,10} Costs reflected a single inpatient hospital stay with presence of infection diagnosis (ICD-9 996.61) and generator replacement procedures for ICD (ICD-9 00.51, 00.52) or CRT-D (37.94, 37.96, 37.98) which aligns with recommended major CIED infections treatment of device extraction per the American Heart Association guidelines.¹¹ The TYRX cost was supplied by the manufacturer.
- A one-way sensitivity analysis was conducted to examine the effect variations in control infection rate had on model results. Intervention infection rates and costs were held constant. The low variation was identified as the control infection rate at which costs to the hospital were approximately net neutral. The high variation was 4.0% based on studies demonstrating CIED infection rates of 3.6% and 4.3% in high-risk patients.^{5,6}

Figure 1: With TYRX (Intervention) Decision Tree

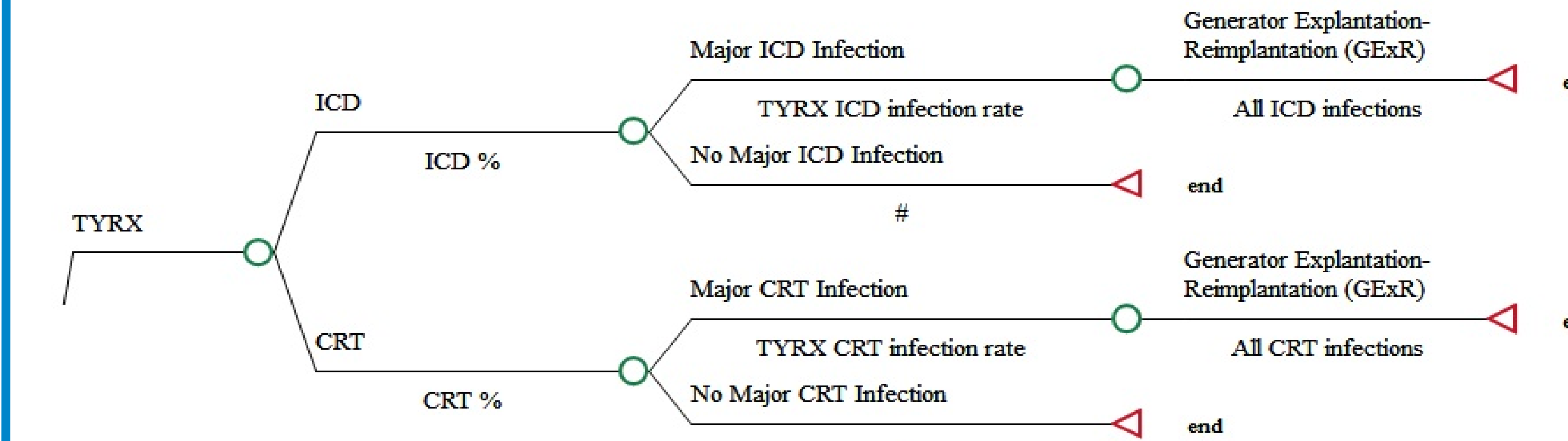


Figure 2: Without TYRX (Control) Decision Tree

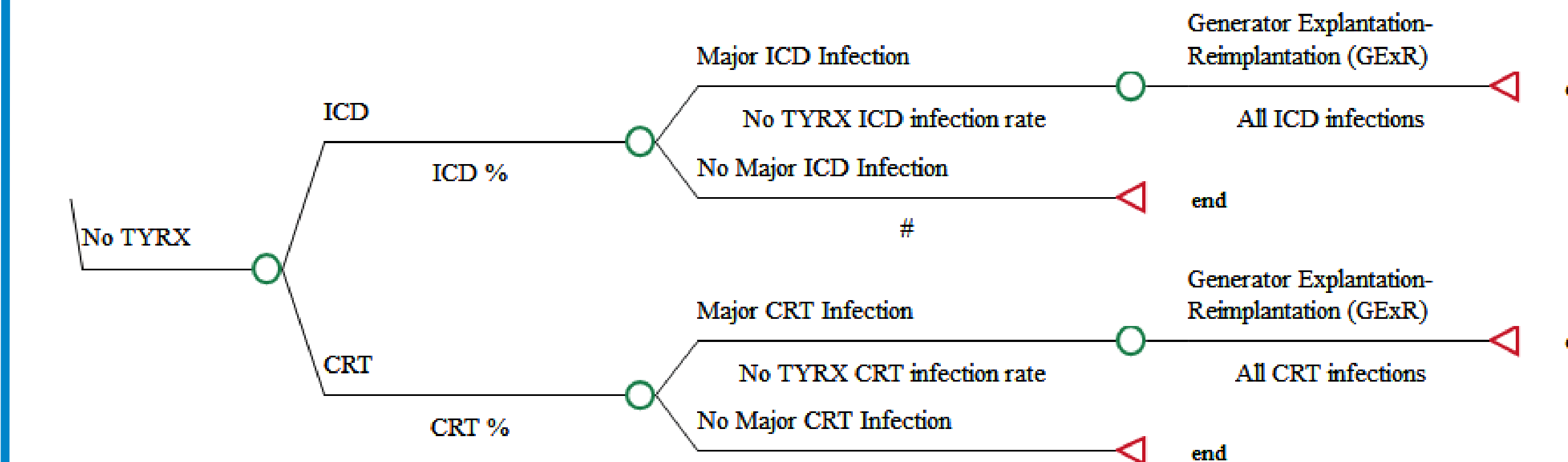


Table 1: Model Inputs

	Values		Source
High-Risk CIED Patient Population			
Number of Patients	1,129		7
% ICD	41%		7
% CRT	59%		7
CIED 12-month Major Infection Rates			
With TYRX	ICD	CRT	7
	0.22%	0.60%	
Without TYRX	ICD	CRT	8
	2.22%	2.22%	
Infection Intervention & TYRX Costs			
	ICD	CRT	
Infection	\$75,696.84	\$87,533.09	9,10
TYRX	\$1,000		Manufacturer

RESULTS

- Base case results are presented in Table 2. Per 1,129 patients, use of TYRX was associated with 20 fewer CIED infections (5 vs. 25). The TYRX Antibacterial Envelope costs of \$1,129,000 were offset by a \$1,644,975 reduction in CIED infection-related costs, for a net cost savings of \$515,975, or \$457 per patient.
- Alternate analysis results are presented in Table 3. At a control infection rate of 1.67%, the cost of TYRX is near equal to reduction in CIED infection-related costs (net cost savings \$2,315, or \$2 per patient). At a control infection rate of 4%, the use of TYRX was associated with 40 fewer CIED infections (45 vs. 5) and a net cost savings of \$2,178,366, or \$1,929 per patient, an over 4-fold savings increase compared to the base case.

Table 2: Base Case Model Results

	With TYRX		Without TYRX		Difference	
	All	Per Patient	All	Per Patient	All	Per Patient
Number of Patients	1,129		1,129			
Major CIED Infections	*All	Per Patient	*All	Per Patient	*All	Per Patient
	5	0.0044	25	0.0222	-20	-0.0178
Infections by CIED Type	*All Patients		*All Patients		*All Patients	
ICD	1		10		-9	
CRT	4		15		-11	
Costs	All	Per Patient	All	Per Patient	All	Per Patient
Total	\$1,557,344	\$1,379	\$2,073,319	\$1,836	(\$515,975)	(\$457)
Infections	\$428,344	\$379	\$2,073,319	\$1,836	(\$1,644,975)	(\$1,457)
TYRX	\$1,129,000	\$1,000	\$0	\$0	\$1,129,000	\$1,000

Table 3: Sensitivity Analysis – Control Infection Rates

	Without TYRX				Difference (Compared to TYRX)			
	Low (1.67%)		High (4.0%)		Low (1.67%)		High (4.0%)	
Number of Patients	1,129							
Infection Rate	*All		Per Patient		*All		Per Patient	
Major CIED Infections	19		0.0167		45		0.0399	
	-14		-0.0122		-40		-0.0354	
Infections by CIED Type	*All Patients				*All Patients			
ICD	8		18		-7		-17	
CRT	11		27		-7		-23	
Costs	All	Per Patient	All	Per Patient	All	Per Patient	All	Per Patient
Total	\$1,559,659	\$1,381	\$3,735,710	\$3,309	(\$2,315)	(\$2)	(\$2,178,366)	(\$1,929)
Infections	\$1,559,659	\$1,381	\$3,735,710	\$3,309	(\$1,131,315)	(\$1,002)	(\$3,307,366)	(\$2,929)
TYRX	\$0	\$0	\$0	\$0	\$1,129,000	\$1,000	\$1,129,000	\$1,000

*May not sum exactly due to rounding

CONCLUSIONS

- The low rate of major CIED infection rate observed among a high-risk CIED population in the Citadel/Centurion studies was associated with large reductions in hospital costs.
- In the sensitivity analysis, a nearly 2-fold increase in the control infection rate was associated with an over 4-fold increase in net cost savings with TYRX use. A control infection rate greater than 1.67% was associated with net cost savings.

LIMITATIONS

- All model inputs were point estimates based on the Citadel/Centurion studies, published study data, and the cost database analysis. In reality, the infection rates and interventions costs can and do vary substantially, with corresponding impacts on model results.
- The major CIED infection intervention rates were based on low, single digit "N" counts.
- The model costs did not account for any payer reimbursement.

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DISCLOSURES

Jessica Lopatto: Salary – Medtronic
 Grant R. Simons: - Research Support: TYRX Inc.