

The Clinical Value and Medical Cost Savings of Taurolidine/Heparin for Reduction in Catheter-related Bloodstream Infections in Adults Receiving Hemodialysis via a Central Venous Catheter

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Background

- Patients receiving hemodialysis through a central venous catheter (CVC) are at high risk for bloodstream infections due to frequent vascular access via the CVC.
- Current practice is to lock the catheter with a heparin solution following a hemodialysis administration to prevent thrombosis, but heparin does not have antimicrobial properties.
- There are approximately 36,000 cases of catheter-related bloodstream infections (CRBSIs) per year in the US, with the highest rates reported in Black and Hispanic populations.
- CRBSIs are associated with increased morbidity, mortality, healthcare utilization, and costs.
- In November 2023, the US FDA approved a taurolidine/heparin catheter lock solution (DefenCath™) for the prevention of CRBSIs in adult patients receiving hemodialysis through a CVC.
- In this study, a patient-level simulation was utilized to estimate the occurrence of CRBSIs and their downstream consequences (i.e., mortality, clinical events, and health system costs) for adult patients initiating hemodialysis through a CVC.

Objective

- Estimate the clinical outcomes and cost savings of a taurolidine/heparin catheter lock solution relative to a heparin only catheter lock solution for the reduction of catheter-related bloodstream infections in adult patients receiving hemodialysis through a central venous catheter

Methods

- A patient-level simulation was chosen to model heterogenous patients with dynamic characteristics (e.g., patient age is updated over time). Unlike a Markov cohort model that is memoryless, a patient-level simulation tracks individual patients over time which allows for modeling of nuanced clinical pathways that better approximate real-world disease progression.
- The model took a health system perspective with a 10-year horizon in the base case.
- Time was modeled continuously, and therefore a cycle length was not specified.
- Model outcomes included CRBSIs, CRBSI-related hospitalizations and intensive care unit (ICU) stays, CRBSI-related deaths, and direct medical costs.
- Outcomes were compared between a model pathway that used the taurolidine/heparin catheter lock solution to a model pathway that used the heparin only catheter lock solution.
- The patient-level simulation was parametrized using patient-level data from the LOCK-IT 100 taurolidine/heparin Phase 3 clinical trial, real-world data from the Premier Healthcare Database, estimates from the literature, and clinical expert opinions.
- Patients could start receiving hemodialysis either as an outpatient or an inpatient. For the base case, all patients started the model receiving outpatient hemodialysis.

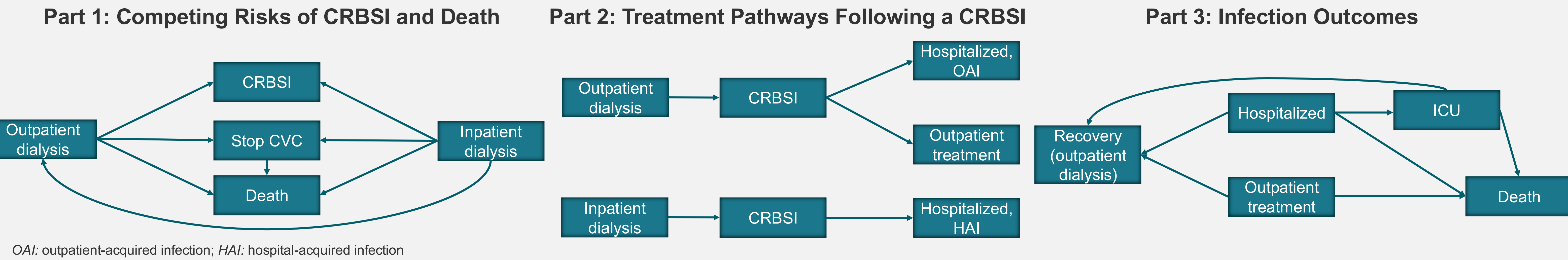
Model Component	Taurolidine/heparin's Value Based on Clinical Trial and Real-World Data
CRBSIs	Taurolidine/heparin reduces the probability of a CRBSI
Hospitalizations	Fewer CRBSIs result in fewer CRBSI hospitalizations
ICU stays	Fewer CRBSI hospitalizations result in fewer ICU stays
Death	Fewer ICU stays results in fewer CRBSI-related deaths
Dialysis Setting	Probabilities of CRBSI, CRBSI-related hospitalization, ICU admission, and CRBSI-related death vary across inpatient and outpatient dialysis settings

Secondary Diagnoses

Fewer CRBSIs results in a lower the likelihood of post-CRBSI secondary diagnoses such as congestive heart failure, endocarditis, stroke, and myocardial infarction

Methods (Continued)

- While receiving dialysis, the model tracked competing risks of CRBSI and death. For those that were hospitalized due to their CRBSI, they could either recover to be discharged (and continue outpatient dialysis), die, or be admitted to the ICU. Patients admitted to the ICU could subsequently recover to be discharged (and continue outpatient dialysis) or die.
- The model simulated the trajectories for 1,000 heterogenous patients using parameterized time-to-event distributions. Baseline patient-level characteristics included age, sex, body mass index, race/ethnicity, and comorbidities (acute kidney injury, diabetes, and congestive cardiac failure).



Results

- Table 1 reports averted clinical events due to taurolidine/heparin adoption relative to heparin only for 1000 patients over time. Most events are averted within the first year due to the assumption that 75% of patients stop CVC dialysis within 1 year of initiation.

Table 1. Clinical Events Averted Per 1000 Patients for Taurolidine/Heparin Relative to Heparin Only				
Year	CRBSI	Hospitalization	ICU Stay	Death
1	62	52	27	7
3	95	80	42	13
5	114	96	50	15

- Table 2 reports cumulative cost savings over time due to taurolidine/heparin adoption, with cost savings for almost all direct medical cost categories; outpatient dialysis costs are an exception because taurolidine/heparin keeps patients in outpatient dialysis (i.e., out of the hospital and alive) at a higher rate than heparin.

Table 2. Per Patient Cumulative Cost Differences Over Time (Taurolidine/Heparin – Heparin Only)											
Year	Total	Hospitalization	ICU	Inpatient Dialysis	Outpatient Dialysis	Outpatient Treatment	CHF	Dysrhythmia	Endocarditis	MI	Stroke
1	-\$7,987	-\$4,199	-\$2,825	-\$381	-\$82	-\$18	-\$107	-\$214	-\$102	-\$23	-\$36
3	-\$12,452	-\$6,624	-\$4,529	-\$604	\$116	-\$28	-\$174	-\$348	-\$165	-\$38	-\$58
5	-\$14,808	-\$7,977	-\$5,519	-\$729	\$391	-\$34	-\$209	-\$419	-\$198	-\$45	-\$70
7	-\$16,265	-\$8,855	-\$6,164	-\$811	\$651	-\$37	-\$233	-\$467	-\$221	-\$50	-\$78
10	-\$17,746	-\$9,808	-\$6,799	-\$897	\$952	-\$41	-\$256	-\$514	-\$243	-\$55	-\$85

CEA: cost-effectiveness analysis, CHF: congestive heart failure, CRBSI: catheter-related bloodstream infection, ICER: incremental cost-effectiveness ratio, ICU: intensive care unit, MI: myocardial infarction

Conclusions

- A clinically realistic patient-level simulation informed by real-world data, patient-level clinical trial data, and clinician expert opinion demonstrated that, relative to heparin only, a taurolidine/heparin catheter lock solution resulted in fewer serious negative clinical events (i.e., CRBSIs, hospitalizations, ICU stays, and death) and substantial cost savings across multiple cost categories, including hospitalizations, ICU stays, inpatient dialysis, and post-CRBSI secondary diagnoses.
- Given the adverse impacts of CRBSIs to an already vulnerable and underserved hemodialysis patient population, stakeholders should prioritize reducing CVC infection risk with cost-effective products like a taurolidine/heparin catheter lock solution.

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