Generic vs. Branded Tigecycline for MDR-GNB & NTM Infections: A Comparative Safety and Efficacy Analysis

Sirijatuphat R (rujipas.sir@mahidol.ac.th), Sathienluckana S, Suputtamongkol Y Faculty of Medicine Siriraj Hospital, Mahidol University, Bangkok, Thailand

Background & Rationale

Escalating MDR-GNB and NTM prevalence has placed tigecycline—a broad-spectrum glycylcycline with activity against MDR organisms—among the few remaining salvage options in critically ill patients. While generic formulations offer substantial cost advantages in resource-limited healthcare settings, real-world clinical comparative data on their efficacy and safety against original branded formulations remain scarce. This study addresses that evidence gap from a major Thai tertiary center.

Objectives

- Compare 30-day all-cause mortality between generic and branded tigecycline cohorts.
- Assess clinical response rates in hospitalized adults with MDR-GNB or NTM infections.
- Characterize and compare safety profiles, including key laboratory adverse event markers.
- Identify independent predictors of mortality using multivariate LASSO regression.

Study Design

Single-center retrospective cohort, July 2024–July 2025, Siriraj Hospital, Thailand

Population

N= 135 hospitalized adults on tigecycline ≥ 48h for confirmed MDR-GNB or NTM infections

Cohorts

Generic Tygin® (n= 27) vs. Branded Tygacil® (n= 108)

Analysis

Penalized logistic regression (LASSO) to adjust for confounders and identify mortality predictors

Key Outcomes

51.9%

Generic 30-Day Mortality

Tygin® cohort (n= 27); numerically lower than branded arm

63.9%

Branded 30-Day Mortality

Tygacil® cohort (n= 108); difference not statistically significant

59.1%

Non-NTM Generic Mortality

vs. 66.3% branded in non-NTM subset (p= 0.366)

48.1%

Generic Adverse Events

vs. 70.4% in branded group (p= 0.018)

Multivariate LASSO regression confirmed that tigecycline formulation was **not an independent predictor of mortality**. Higher APACHE II scores and Charlson Comorbidity Index were the primary independent determinants of 30-day all-cause death.

Parameter	Generic	Branded
Sample size (n)	27	108
Median age (years)	62	75
Gender distribution (% male)	74%	57%
Primary infection type (% *A. baumannii*)	63%	82%
Median APACHE II score	16	17
Median Charlson Comorbidity Index	5	5
Concomitant colistin use (%)	66.7%	86.1%

Safety Profile & Confounding Considerations

Observed Safety Differences

The generic cohort demonstrated a statistically significant reduction in overall adverse event incidence (48.1% vs. 70.4%; p= 0.018). Median BUN levels were significantly lower in the generic group (p= 0.021), as were median AST elevations (p= 0.048), suggesting attenuated hepatorenal toxicity signals. However, these differences are substantially confounded by baseline imbalances: the branded cohort was notably older (median 75 vs. 62 years) and had significantly higher rates of concomitant nephrotoxic colistin use (86.1% vs. 66.7%), both of which independently elevate the risk of renal and hepatic adverse events.

Pathogen Distribution & NTM Sub-Analysis

Dominant Pathogen

Acinetobacter baumannii was the most frequent causative organism in both cohorts, consistent with its role as a leading MDR-GNB in Southeast Asian ICU settings and its intrinsically limited treatment options.

NTM Sub-Analysis

The single NTM-associated death occurred in a person living with HIV who developed disseminated *M. simiae* complicated by superimposed bacterial infection—a clinical scenario where host immunosuppression, not formulation, dominated the outcome trajectory.

Disease Severity

High baseline APACHE II scores and elevated Charlson Comorbidity Index across both cohorts underscore that patients receiving tigecycline represent a critically ill population where underlying morbidity burden overwhelms formulation-specific effects on survival.

Conclusions & Clinical Implications

Comparable Efficacy

Generic tigecycline (Tygin®) demonstrated clinical efficacy outcomes statistically equivalent to branded Tygacil® across primary and secondary endpoints. Formulation type was not an independent predictor of 30-day all-cause mortality after adjustment for baseline confounders.

Disease Severity is the Determinant

Therapeutic outcomes in both cohorts were driven by underlying illness severity—specifically APACHE II score and comorbidity burden—rather than the specific tigecycline formulation administered. Clinicians should contextualize outcome data accordingly.

Viable Cost-Effective Alternative

Generic tigecycline represents a clinically viable, cost-effective salvage therapy option. In resource-constrained healthcare systems, substituting branded formulations with generics may meaningfully expand patient access to this critical antibiotic class without compromising safety or efficacy.

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