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Outcomes of Cefiderocol Treatment in US Patients with Respiratory Tract Infections: Subgroup Analysis of the PROVE Observational Study

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INTRODUCTION

Inappropriate antibiotic treatment for respiratory tract infections (RTIs) caused by carbapenem-resistant Gram-negative bacteria (CR-GNB), particularly those of nosocomial origin or complicated by sepsis or septic shock, are associated with increased morbidity and mortality.[1–3]

OBJECTIVES

To evaluate the clinical outcomes in US patients with RTIs who were treated with cefiderocol in the retrospective PROVE study.

METHODS

Study design: International, observational, medical chart review study (November 2020 to July 2024).

Patients: Hospitalized patients with RTIs treated with cefiderocol for the first time for at least 72 hours.

Data collection: Demographics, baseline clinical characteristics, hospitalization characteristics, and cefiderocol use.

Outcomes: Clinical cure, clinical response, and all-cause mortality (ACM) at days 14 and 30. Clinical cure was defined as resolution or improvement of clinical signs and symptoms reported by the investigator, excluding patients with relapse during hospitalization and those who died during therapy. Clinical response was defined as resolution or improvement of clinical signs and symptoms at end of treatment as judged by the physician, excluding patients who died during therapy. ACM included patients who died during their hospitalization.

Statistics: Only descriptive statistics were used.

Table 1. Demographics and hospitalization characteristics of patients with RTIs treated with cefiderocol

	All patients (N=266)
Age (years), median (IQR)	**59.5** (46.0–68.0)
≥65 years, n (%)	**89** (33.5)
Sex (male), n (%)	**158** (59.4)
Any pre-existing concomitant condition,[a] n (%)	**258** (97.0)
Chronic pulmonary disease	**93** (35.0)
Diabetes mellitus	**56** (21.1)
Moderate or severe renal disease	**52** (19.5)
Congestive heart failure	**50** (18.8)
Structural lung disease[b]	**12** (4.5)
COVID-19[c]	**37** (13.9)
Sepsis at admission	**40** (15.0)
Septic shock at admission	**22** (8.3)
No sepsis at admission	**204** (76.7)
≥1 risk factor for CR-GNB infection, n (%)	**257** (96.6)
Hospitalization (days), median (IQR)	
Time from index culture to cefiderocol initiation	**4.0** (3.0–6.0)
Total hospital length of stay	**42.0** (23.0–75.0)
Infection-related length of stay	**22.0** (14.0–48.0)

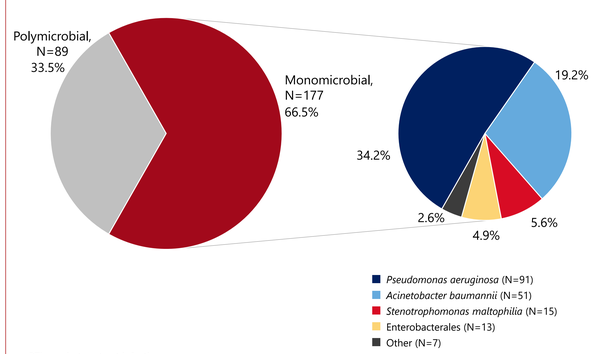
[a]Patients could have had >1 condition.
[b]Includes bronchiectasis and/or emphysema.
[c]Reported as concomitant condition; patients with admission diagnosis of COVID-19 are not included.
COVID-19, coronavirus disease-2019; CR, carbapenem resistant; GNB, Gram-negative bacteria; IQR, interquartile range; RTI, respiratory tract infection.

RESULTS

- Of 266 patients, the median (interquartile range [IQR]) age was 59.5 (46.0–68.0) years, 158 (59.4%) were male, 93 (35.0%) had chronic pulmonary disease, and nearly all patients (96.6%) had ≥1 risk factor for CR-GNB infections (**Table 1**).

- Infection type and distribution of pathogens are shown in **Figure 1**. Almost 90% of Gram-negative infections were carbapenem resistant (i.e., 89.5% [n=238]). Of 89 patients with polymicrobial infections, *Pseudomonas aeruginosa* (n=66), *Acinetobacter baumannii* (n=50), and Enterobacterales (n=51) were most common.

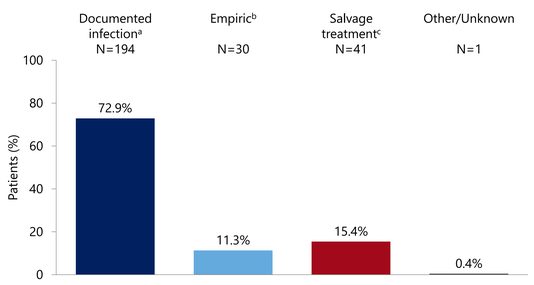
Figure 1. Infection type (%) in patients with RTIs (N=266)



RTI, respiratory tract infection.

- Cefiderocol was administered for a median (IQR) duration of 9.0 (7.0–14.0) days, and in combination therapy for 24.1% of patients. Most patients (72.9%) received cefiderocol for a documented infection (**Figure 2**).

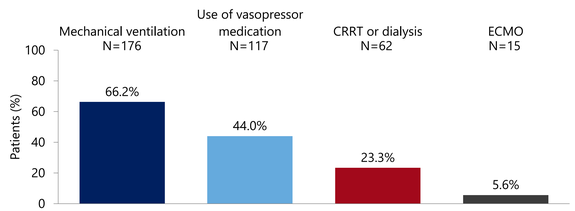
Figure 2. Reason for cefiderocol use (N=266)



[a]Documented infection: the pathogen and susceptibilities were known, and cefiderocol use was not due to failure of a prior antibiotic regimen.
[b]Empiric use: cefiderocol use started before the pathogen and/or susceptibilities were available to help guide the choice.
[c]Salvage therapy: cefiderocol was used after a prior antibiotic regimen had failed; patients usually received at least 3 days of prior antibiotic therapy to see whether there was an adequate response before the next course of antibiotic would be considered salvage.

- Almost three-quarters of patients (74.8%, N=199) were in the intensive care unit, and two-thirds (65.4%) received organ support and/or mechanical ventilation (66.2%) (**Figure 3**).

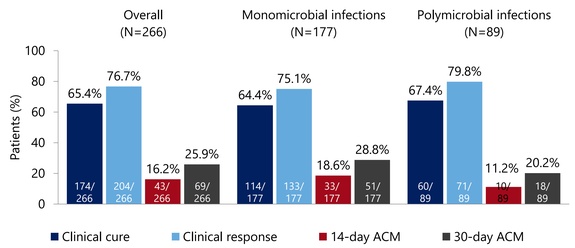
Figure 3. Severity of illness: receipt of organ support at initiation of cefiderocol (N=266)



CRRT, continuous renal replacement therapy; ECMO, extracorporeal membrane oxygenation.

- Overall clinical cure and response rates were 65.4% (174/266) and 76.7% (204/266), respectively. Clinical cure and clinical response rates were similar in monomicrobial (64.4% and 75.1%) and polymicrobial (67.4% and 79.8%) infections, respectively (**Figure 4**). Day 30 ACM was 25.9% overall.

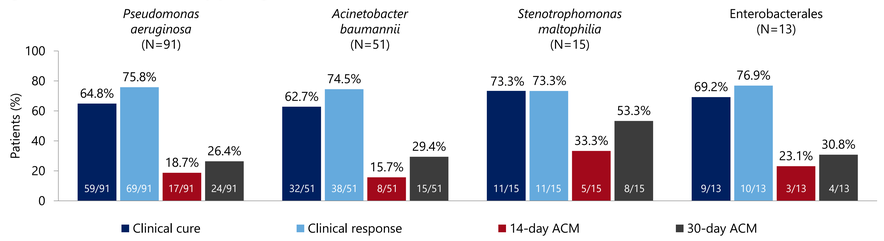
Figure 4. Clinical outcomes overall and by infection type



ACM, all-cause mortality.

- Clinical cure (62.7%–73.3%) and response (73.3%–76.9%) rates were similar in RTIs caused by various Gram-negative species (**Figure 5**).

Figure 5. Clinical outcomes by pathogen



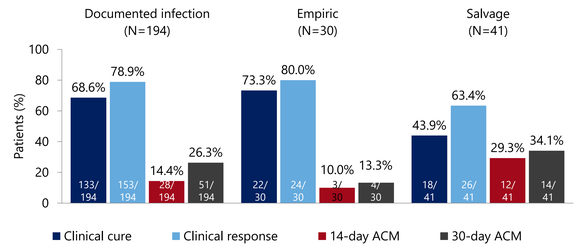
ACM, all-cause mortality.

CONCLUSIONS

- Cefiderocol treatment for RTIs caused mainly by non-fermenting GNB was beneficial, with good clinical response and clinical cure rates in a critically ill US population, particularly when CR pathogens were suspected or confirmed.
- Higher clinical cure rates were observed when patients received cefiderocol for documented infections or empirically than when it was received as salvage therapy.
- Favorable clinical cure and clinical response rates were observed even in patients with polymicrobial infections, similar to those observed in monomicrobial infections.
- Overall mortality rate (i.e., 25.9%) was similar to rates found in other clinical studies of RTIs.

- ACM at Day 30 was 13.3% for empiric treatment, 26.3% for documented infections, and 34.1% for salvage therapy (**Figure 6**).

Figure 6. Clinical outcomes by reason for cefiderocol use



ACM, all-cause mortality.

References

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Disclosures

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