Poster 93

IDWeek, October 21–24, 2026
Washington DC, USA

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Clinical Outcomes After Cefiderocol Therapy for *Pseudomonas* spp. Infections: Results from a Systematic Literature Review

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INTRODUCTION

- Multidrug-resistant (MDR), carbapenem-resistant (CR), and difficult-to-treat resistant (DTR) *Pseudomonas aeruginosa* are a major threat to human health in the USA, with few antibiotic options available.[1–3]
- Of particular concern are metallo-β-lactamase-producing CR and DTR strains of *P. aeruginosa*, against which cefiderocol is active *in vitro* and an approved treatment option.[2,3]

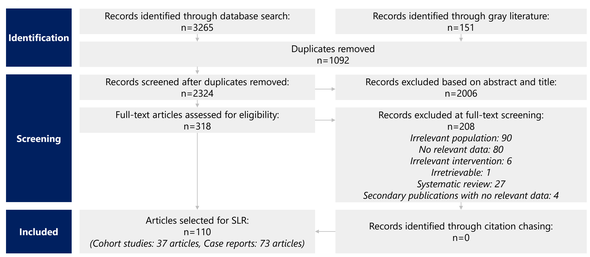
OBJECTIVES

- To review the clinical evidence on cefiderocol treatment in patients with MDR *Pseudomonas* spp. infections in a systematic literature review (SLR).

METHODS

- Comprehensive database searches were conducted on November 7, 2025 using PubMed, Embase, and the Cochrane Library, with further searches of selected infectious disease journals, websites, congress proceedings, societies, international health organizations, and clinical study reports.[4]
- Articles were independently screened and extracted for analysis by 2 reviewers based on relevance to inclusion criteria. All extracted data were checked for accuracy and relevance and complied with PRISMA guidelines (**Figure 1**). Data from eligible case reports and cohort studies were extracted into a spreadsheet categorized by pathogen, patient population or subgroup, date of data collection, and outcome.

Figure 1. PRISMA flow of literature



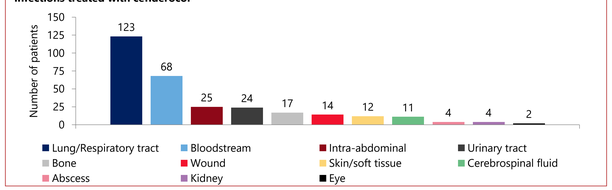
In this SLR, 110 articles were reviewed (73 case reports and 37 cohort studies) from 2324 search records.

RESULTS

Case reports

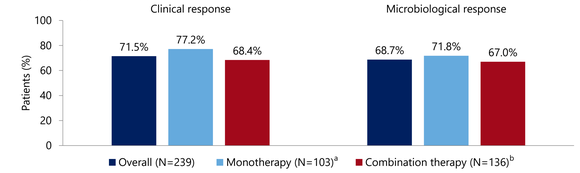
- The 73 case reports included 239 patients with *P. aeruginosa* or other *Pseudomonas* spp. infections treated with cefiderocol between 2017 and 2024. Median age was 58 years (range: 1 month to 94 years; age not reported for 23 patients), with 13 children and 203 adults. There were 147 male (61.5%) and 52 female (21.8%) patients; information was unknown for 40 patients (16.7%).
- Most patients were treated in the USA (n=63), followed by Spain (n=60), France (n=44), Italy (n=34), Germany (n=18), UK (n=10), and 1 patient each from 8 other countries; location was not reported for 2 cases.
- Most patients had *P. aeruginosa* infections; 6 patients were infected with *P. putida* and 1 patient with *P. fluorescens*. Co-infecting pathogens were present in 62 patients, including *Klebsiella* spp. (n=19), *Stenotrophomonas maltophilia* (n=8), *Acinetobacter* spp. (n=8), *Enterobacter cloacae* (n=3), and *Pseudomonas* spp. (n=3), among other Gram-negative, Gram-positive, and fungal species. Most patients had respiratory tract infections (n=123) and bloodstream infections (n=68) (**Figure 2**).

Figure 2. Site of infection in case reports of patients with *Pseudomonas aeruginosa* or *Pseudomonas* spp. infections treated with cefiderocol



- Cefiderocol was administered as monotherapy in 103 patients (43.1%), and 136 patients (56.9%) received combination therapy, most commonly with colistin (n=48) or polymyxin (n=12), amikacin (n=22), meropenem (n=18), fosfomycin (n=16), ceftolozane-tazobactam (n=16), and/or ceftazidime-avibactam (n=10). Treatment duration ranged between 1 and 169 days (median: 14 days), although information was not available in some reports.
- Of the 239 patients, 171 (71.5%) had a favorable clinical response to cefiderocol treatment; clinical response was not reported for 2 cases. Among patients with reported information, clinical response rate was 77.2% (78/101) for cefiderocol monotherapy and 68.4% (93/136) for cefiderocol combination therapy (**Figure 3**). Where information was reported, microbiological response rates of 71.8% (61/85) and 67.0% (75/112) were found with cefiderocol monotherapy and combination therapy, respectively (**Figure 3**).
- All-cause mortality (ACM) was 21.3% (51/239), 168 patients survived (70.3% [168/239]), and information was unclear for 5 patients.

Figure 3. Clinical and microbiological response in case reports of patients with *Pseudomonas aeruginosa* or *Pseudomonas* spp. infections

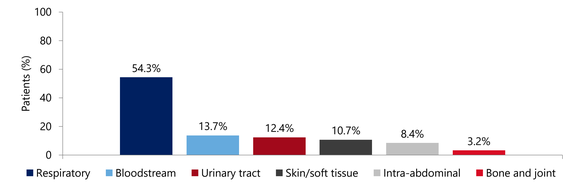


[a]Information on clinical response was not known for 2 patients, and on microbiological response for 18 patients.
[b]Information on microbiological response was not known for 24 patients.

Cohort studies

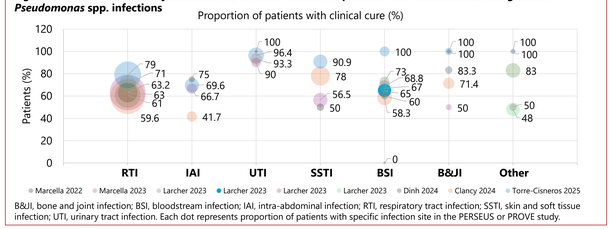
- In the 37 cohort studies, 803 patients were infected by *P. aeruginosa* or other *Pseudomonas* spp. Where information was available, all patients were adults, and 70.9% (569/803) were male.
- The most common infection site was the respiratory tract, followed by bloodstream and urinary tract (**Figure 4**).

Figure 4. Site of primary infection in cohort studies of patients with *Pseudomonas aeruginosa* or *Pseudomonas* spp. infections treated with cefiderocol



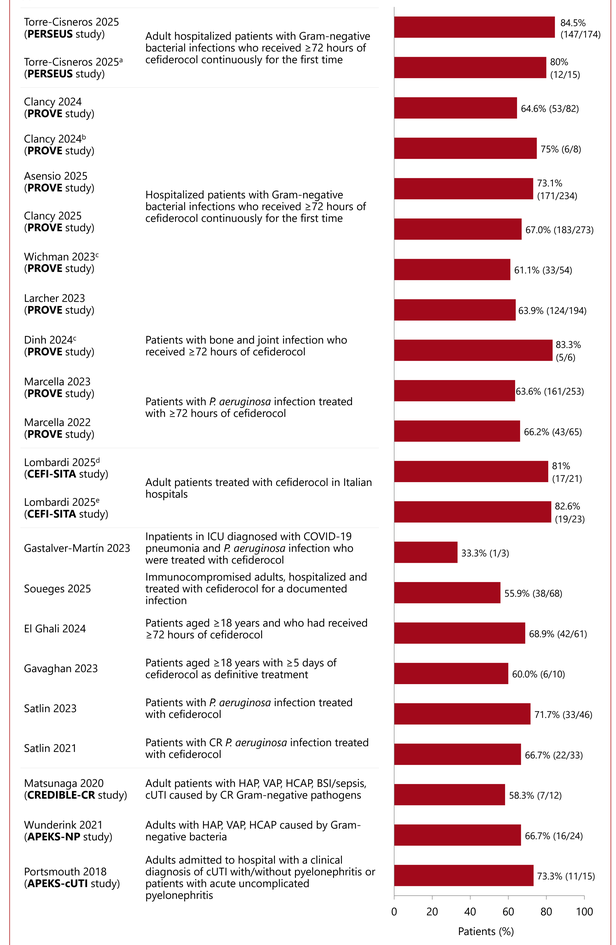
- Co-infections were reported in 9 studies, and polymicrobial infections were present in 20.7%–32.5% of patients. The most common additional Gram-negative bacteria included Enterobacterales (13.3%–26.1%), *S. maltophilia* (8.3%–9.7%), and *Acinetobacter baumannii* (4.0%–8.5%).
- Cefiderocol monotherapy was administered to 29.0%–67.8% of patients. Treatment duration was reported in 5 publications and varied across studies from 3–7 days to a median of 22.5 days (range: 1–132).
- The highest clinical response/cure rate in patients with *Pseudomonas* spp. infections was reported by Torre-Cisneros (84.5% [147/174]), and the lowest rate was reported by Gastalver-Martín (33.3% [1/3]) (**Figure 5**). In the PROVE study reports, clinical cure rates were between 61.1% (33/54) and 83.3% (5/6). In the largest subset, 67.0% (183/273) achieved clinical cure (**Figure 5**). In randomized controlled studies, in smaller patient numbers, clinical cure or response rate was between 58.3% (7/12) and 73.3% (11/15) (**Figure 5**).
- Clinical cure rates by infection site were reported in 6 publications (**Figure 6**).

Figure 6. Clinical cure rates by infection site in cohort studies of patients with *Pseudomonas aeruginosa* or *Pseudomonas* spp. infections



B&JI, bone and joint infection; BSI, bloodstream infection; IAI, intra-abdominal infection; RTI, respiratory tract infection; SSTI, skin and soft tissue infection; UTI, urinary tract infection. Each dot represents proportion of patients with specific infection site in the PERSEUS or PROVE study.

Figure 5. Clinical response/cure rates in cohort studies of patients with *Pseudomonas aeruginosa* or *Pseudomonas* spp. infections treated with cefiderocol



[a]*P. putida* (12); *P. fluorescens/putida* (1); *P. fluorescens* (1); *P. nitroreducens* (1).
[b]*Stenotrophomonas maltophilia* co-infection.
[c]*Pseudomonas* spp. infection.
[d]Discharged patients are excluded from population.
[e]All patients.
BSI, bloodstream infection; COVID-19, coronavirus disease 2019; CR, carbapenem resistant; cUTI, complicated urinary tract infection; HAP, hospital-acquired pneumonia; HCAP, healthcare-associated pneumonia; ICU, intensive care unit; VAP, ventilator-associated pneumonia.

- ACM ranged from 0% (0/4) to 30.9% (21/68) at 28 days (**Figure 7**), and from 0% (0/6) to 60.0% (3/5) at 30 days (**Figure 8**).
- Adverse drug reactions were reported in 2 cohort studies. Larcher et al. (2023) reported liver enzyme elevation as a serious adverse event, and hypersensitivity reactions for 1.6% of patients. Satlin et al. (2023) reported 6.5% of patients having adverse events without specific details.

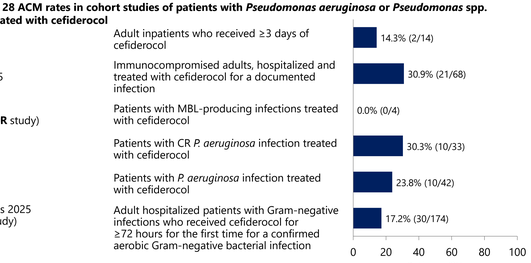
On-therapy resistance

- Among the 1042 infections reviewed, 8 (0.8%) had reported treatment-emergent resistance.

CONCLUSIONS

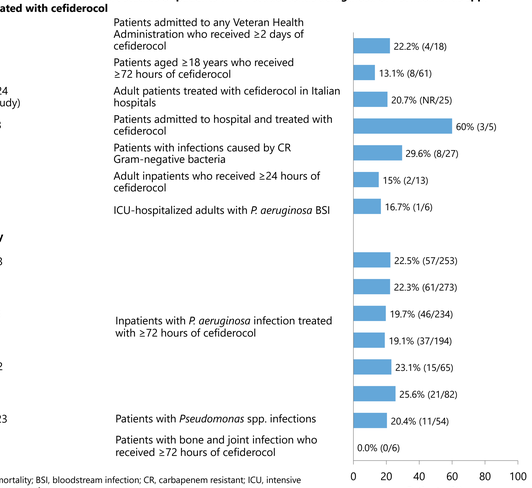
- Cefiderocol treatment was associated with favorable outcomes in patients with predominantly *P. aeruginosa* infections; outcomes were similar in case reports and cohort studies.
- Treatment-emergent cefiderocol resistance and adverse events were rarely observed.
- The findings should be interpreted with caution due to the large heterogeneity in the reported data.

Figure 7. Day 28 ACM rates in cohort studies of patients with *Pseudomonas aeruginosa* or *Pseudomonas* spp. infections treated with cefiderocol



ACM, all-cause mortality; CR, carbapenem resistant; MBL, metallo-β-lactamase.

Figure 8. Day 30 ACM rates in cohort studies of patients with *Pseudomonas aeruginosa* or *Pseudomonas* spp. infections treated with cefiderocol



ACM, all-cause mortality; BSI, bloodstream infection; CR, carbapenem resistant; ICU, intensive care unit; NR, not reported.

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Disclosures
AM, HR, HK are employees of Crystallise and were funded by Shionogi to conduct the research. KK, SL, ASH are employees of the Shionogi Group.
Acknowledgments
Editorial support was provided by Highfield, Oxford, UK; this support was funded by Shionogi & Co., Ltd., Osaka, Japan.