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Cefiderocol in clinical practice for bone and joint infections: insights from the PROVE study

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BACKGROUND

- Bone and joint infections (BJI), including septic arthritis, prosthetic joint infections, and osteomyelitis, are a significant cause of morbidity and mortality [1].
  - Although Gram-positive organisms predominate, Gram-negative pathogens, including Enterobacterales and non-fermenters such as *Pseudomonas aeruginosa*, are increasingly reported in BJI [1,2].
  - BJI pose significant treatment challenges requiring prolonged durations of therapy, with treatment success rates of 82–100% reported in Gram-negative infections [1,3].
- The siderophore cephalosporin cefiderocol has demonstrated potent *in vitro* activity against a broad spectrum of Gram-negative bacteria, including strains with carbapenem resistance.
  - In the European Union, cefiderocol is approved for the treatment of infections due to aerobic Gram-negative organisms in adults with limited treatment options [4].
  - In addition, cefiderocol is approved in the United States for the treatment of complicated urinary tract infections (including pyelonephritis) and hospital-acquired and ventilator-associated bacterial pneumonia [5].
- This subgroup analysis of data from the PROVE study [6] examined clinical outcomes for patients with BJI who received treatment with cefiderocol.

METHODS

Design

- International
- Observational chart review
- Real-world cefiderocol use

Inclusion criteria

- Adults hospitalised between Nov 2020 and Jul 2024
- Confirmed Gram-negative bacterial infection
- Cefiderocol treatment for ≥72 hours

Descriptive data

- Baseline demographics
- Clinical characteristics
- Cefiderocol use
- Clinical cure[a]
- Clinical response[b]
- All-cause mortality[c]

In this analysis, data were collected from patients hospitalised due to bone and joint infections.
Presented data have been revised since abstract submission.

Use QR code to access manuscript [6].

[a]Resolution or improvement of infection signs or symptoms without evidence of later relapse or death.
[b]Resolution or improvement of signs or symptoms at end of treatment as judged by the physician, excluding patients who died during therapy.
[c]Including patients who died during their hospitalisation.

RESULTS

- A total of 54 patients were enrolled in PROVE with BJI and comprised the patient population for this analysis.
  - Median (interquartile range [IQR]) patient age was 58.0 years, and 68.5% of patients were male (**Table 1**).
- Approximately two-thirds (66.7%) of patients were enrolled in the United States (**Figure 1**).
- Pre-existing medical conditions, which could predispose patients to BJI, were common (**Table 1**).
  - At hospital admission, 13.0% of patients had sepsis, and 1.9% had septic shock.
  - Only 11.1% of patients required intensive care unit stay at the time of cefiderocol initiation, and 7.4% required organ support.

Table 1. Patient demographics and baseline characteristics for patients with bone and joint infections in the PROVE study (2020–2024; N=54)

Characteristic	Patients with bone and joint infections (N=54)
Median (IQR) age, years	58.0 (46.0–67.0)
Age ≥65 years, n (%)	18 (33.3)
Male, n (%)	37 (68.5)
Any pre-existing medical conditions, n (%)	46 (85.2)
Diabetes	19 (35.2)
Peripheral vascular disease	11 (20.4)
Musculoskeletal abnormality/degenerative disease	11 (20.4)
Moderate-to-severe CKD	9 (16.7)
Any medical condition at admission, n (%)	
Sepsis	7 (13.0)
Septic shock	1 (1.9)
Severity of illness, n (%)	
ICU stay at time of cefiderocol initiation	6 (11.1)
Any organ support at time of cefiderocol initiation	4 (7.4)
Monomicrobial infections, n (%)	35 (64.8)
Polymicrobial infections[a], n (%)	19 (35.2)
Patients had the same pathogen (index culture) prior to the current hospitalisation, n (%)	
None	32 (59.3)
Yes, previously colonised	3 (5.6)
Yes, previously infected	16 (29.6)
Unknown	7 (13.0)
Number of risk factors for carbapenem-resistant Gram-negative bacterial infection	
0	5 (9.3)
1	15 (27.8)
2	19 (35.2)
3	12 (22.2)
≥4	3 (5.6)
Treatment characteristics	
Median (IQR) time from culture to first cefiderocol dose, days	5.0 (0–8.0)
Median (IQR) duration of cefiderocol use, days	22.5 (12.0–40.0)
Gram-negative combination therapy, n (%)	25 (46.3)
Reason for cefiderocol use (as per eCRF), n (%)	
Documented infection	44 (81.5)
Empirical use	4 (7.4)
Salvage therapy	5 (9.3)
Other/unknown	1 (1.9)
Median (IQR) time from admission to cefiderocol initiation, days	5.0 (4.0–8.0)
Median (IQR) total length of stay, days	44.0 (22.0–61.0)
Discharge status, n (%)	
In-hospital death	6 (11.1)
Home	23 (42.6)
Healthcare facility (including nursing home)	24 (44.4)

[a]Includes *Acinetobacter* spp. (10), *Pseudomonas* spp. (10), Enterobacterales (13), any *Stenotrophomonas maltophilia* (1), other non-fermenter Gram-negative bacteria (5; [*Achromobacter* spp. 4, *Burkholderia* spp. 1]). CKD, chronic kidney disease; eCRF, electronic case report form; ICU, intensive care unit; IQR, interquartile range.

CONCLUSIONS

- In this subgroup of patients treated with cefiderocol for BJI, high clinical cure rates and low mortality were observed.
- Patients were predominantly treated for documented infections, with a high use of combination therapy.
- Compared with other cohorts from the PROVE study, patients with BJI were a low-severity population despite the presence of BJI-specific risk factors.
- Cefiderocol was observed to be effective for BJI across pathogen types.

- Infections were predominantly monomicrobial (64.8%) (**Figure 2**).
  - Carbapenem-resistant infections were observed in 91% of patients with monomicrobial infection and 73.6% of those with polymicrobial infection.
- Cefiderocol was primarily used for documented infections (81.5% of patients), with a median duration of use of 22.5 days, a relatively high use of combination regimens (46.3%), and a median total length of hospital stay of 44.0 days.
- Overall, 83.3% of patients with BJI achieved clinical cure (**Figure 3A**), and 88.9% had a clinical response at end of treatment with cefiderocol (**Figure 3B**), with 14- and 30-day all-cause mortality of 3.7% and 11.1%, respectively (**Figure 3C**).
  - Clinical outcomes stratified by monotherapy or combination therapy are shown in **Table 2**.
- Clinical cure in patients with monomicrobial infections ranged from 81.3% to 100% depending on pathogen; clinical cure was numerically lower in those with polymicrobial infections (**Figure 3A**).

Figure 1. Country of enrolment among patients with bone and joint infections in the PROVE study (2020–2024; N=54)

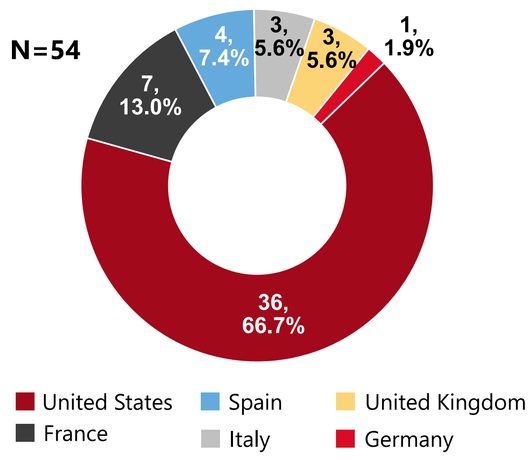


Figure 2. Primary cause of infection among patients with bone and joint infections in the PROVE study (2020–2024; N=54)

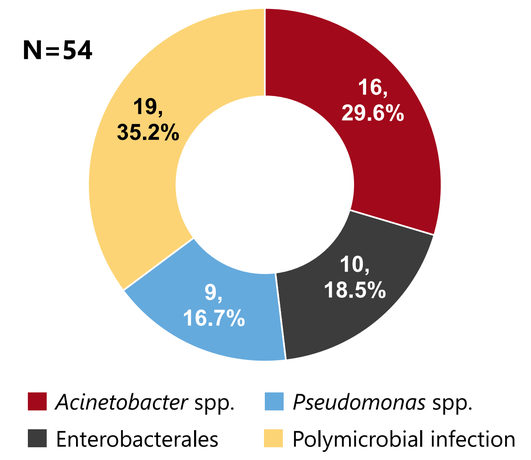
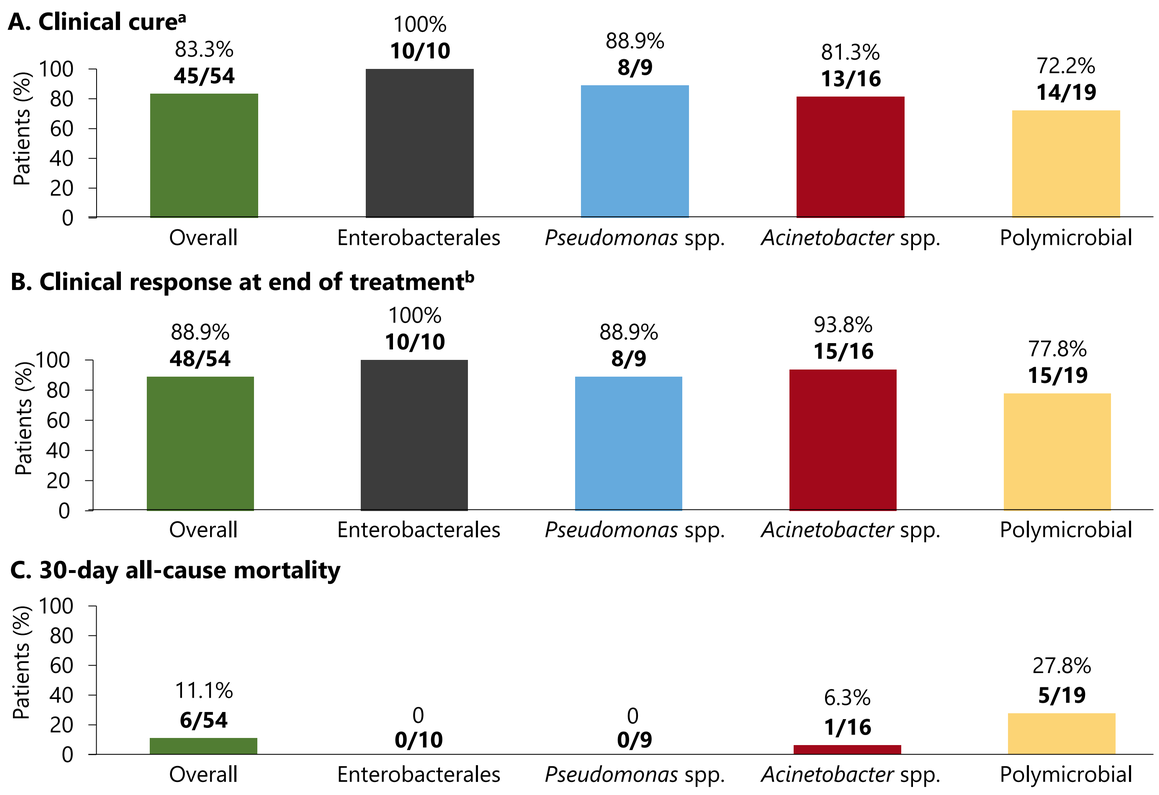


Figure 3. Clinical outcomes by pathogen among patients with bone and joint infections in the PROVE study (2020–2024; N=54)



Data are % [95% confidence interval].
[a]Patients were considered as clinically cured if the Principal Investigator reported the case to be resolved or improved, excluding those who relapsed.
[b]Patients were considered as having clinical response if the Principal Investigator reported the case to be resolved or improved at end of treatment.

Table 2. Clinical outcomes by monotherapy or combination therapy

	n/N, % [95% confidence interval]	
	Monotherapy (N=41)	Combination therapy (N=13)
Clinical cure[a]	35/41 **85.4** [70.8; 94.4]	10/13 **76.9** [46.2; 95.0]
Clinical response at end of treatment[b]	36/41 **87.8** [73.8; 95.9]	12/13 **92.3** [64.0; 99.8]
14-day all-cause mortality	2/41 **4.9** [15.3; 16.5]	0/13 **0** [0; 24.7]
30-day all-cause mortality	4/41 **9.8** [2.7; 23.1]	2/13 **15.4** [1.9; 45.5]

[a]Patients were considered as clinically cured if the Principal Investigator reported the case to be resolved or improved, excluding those who relapsed.
[b]Patients were considered as having clinical response if the Principal Investigator reported the case to be resolved or improved at end of treatment.

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Conflict of interest
KCM: consultant for Shionogi. AD: consultant for Shionogi. STN, SV, ASH: employees of Shionogi.

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