Poster 1865

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Real-world cefiderocol outcomes in the treatment of *Stenotrophomonas* spp. infections: data from the PROVE study

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BACKGROUND

- Gram-negative *Stenotrophomonas* spp. have emerged as significant opportunistic pathogens owing to their intrinsic multidrug resistance, which limits treatment options [1].
  - *Stenotrophomonas* spp. are increasingly implicated in infections among clinically vulnerable patients [2]; however, evidence-based recommendations regarding optimal treatments are lacking [3].
- Cefiderocol is a siderophore cephalosporin antibiotic with potent activity against a broad range of Gram-negative bacteria, including carbapenem-resistant (CR) strains.
  - It is approved in the European Union for the treatment of infections due to aerobic Gram-negative organisms in adults with limited treatment options [4].
  - In the United States, cefiderocol is indicated for the treatment of complicated urinary tract infections (including pyelonephritis) and hospital-acquired and ventilator-associated bacterial pneumonia [5].
- This subgroup analysis of the PROVE study [6] examined clinical outcomes of individuals with infections caused by *Stenotrophomonas* spp. who received treatment with cefiderocol.

METHODS

Figure 1. PROVE study (2020–2024) *Stenotrophomonas* spp. subgroup analysis methodology [6]

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 with infections caused by *Stenotrophomonas* spp.
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

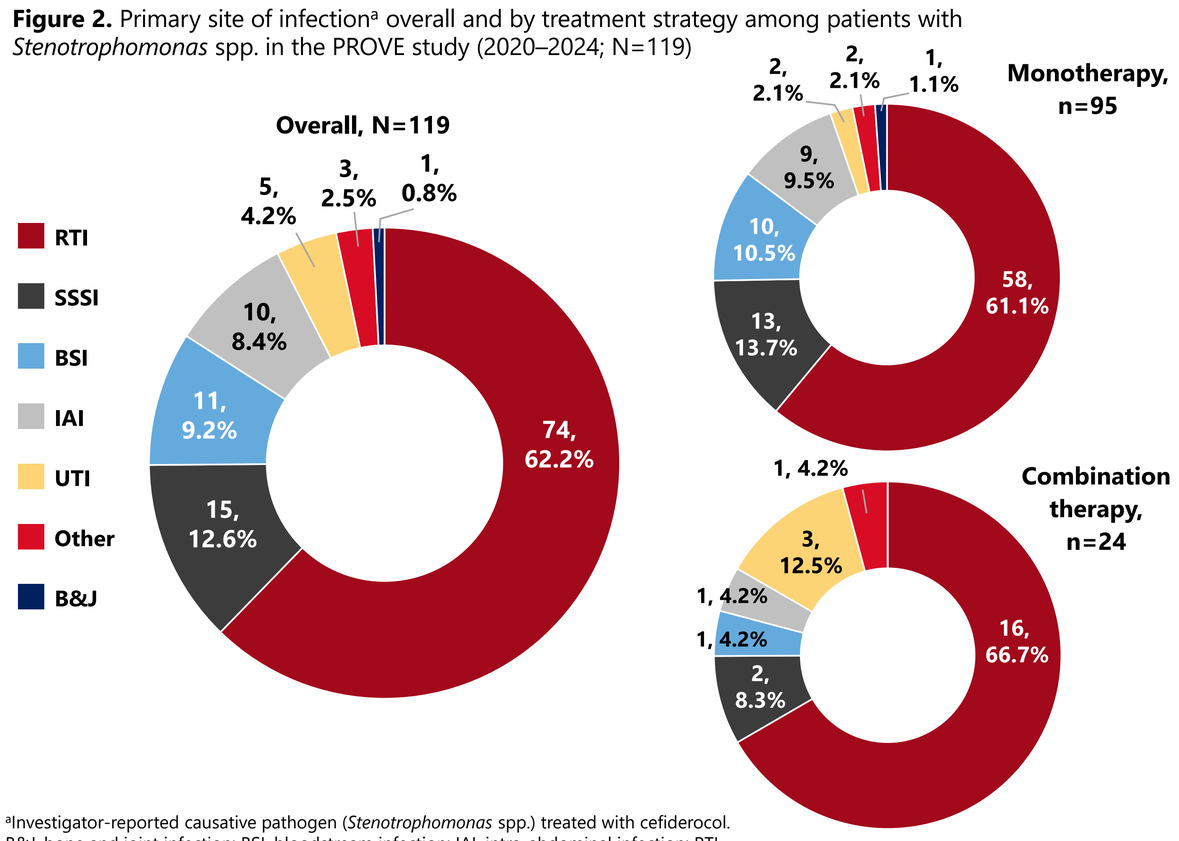
Baseline characteristics

- Patients (N=119) had a median (interquartile range [IQR]) age of 60.0 (47.0–67.0) years, and 66.4% were male (**Table 1**).
  - In total, 73.9% of patients required an intensive care unit stay at the time of cefiderocol initiation, while 63.0% and 49.6% received mechanical ventilation and vasopressors, respectively.
  - Overall, 9.2% of patients had sepsis at admission, with 7.6% having septic shock; 31.1% of patients were immunocompromised.
  - Median (IQR) length of hospital stay (admission to discharge) was 75.0 (39.0–114.0) days.
  - Overall, 66.4% of patients had ≥2 risk factors for acquiring CR Gram-negative infection.
- The respiratory tract was the main primary site of infection (**Figure 2**).
- Most patients (63.0%) received documented treatment; 22.7% of patients received salvage therapy (**Table 1**).
- Median (IQR) time from culture to first cefiderocol dose was 5.0 (3.0–8.0) days, and duration of cefiderocol use was 11.0 (7.0–15.0) days.
- Among 58 patients with microbiological results, 57 (98.3%) were susceptible to cefiderocol.
- Monotherapy was the predominant treatment strategy (79.8% of patients vs 20.2% who received combination therapy) (**Table 1**).
  - Patients given combination therapy were more likely to have comorbidities and polymicrobial infections, and to be receiving salvage treatment.

Clinical outcomes

- Clinical cure was attained by 67.4% [95% confidence interval (CI) 57.0%; 76.6%] of patients with *Stenotrophomonas* spp. infection who received cefiderocol monotherapy compared with 50.0% [95% CI 29.1%; 70.9%] of those who received combination treatment and 63.9% [95% CI 54.6%; 72.5%] of patients overall (**Figure 3**).
- Clinical response to cefiderocol at end of treatment occurred in 72.3% of patients overall (74.7% and 62.5% of patients given monotherapy vs combination therapy, respectively).
- Day 30 all-cause mortality rates were 29.5% with cefiderocol monotherapy and 33.3% with combination therapy.

Figure 2. Primary site of infection[a] overall and by treatment strategy among patients with *Stenotrophomonas* spp. in the PROVE study (2020–2024; N=119)



[a]Investigator-reported causative pathogen (*Stenotrophomonas* spp.) treated with cefiderocol. B&J, bone and joint infection; BSI, bloodstream infection; IAI, intra-abdominal infection; RTI, respiratory tract infection; SSSI, skin and skin structure infection; UTI, urinary tract infection.

CONCLUSION

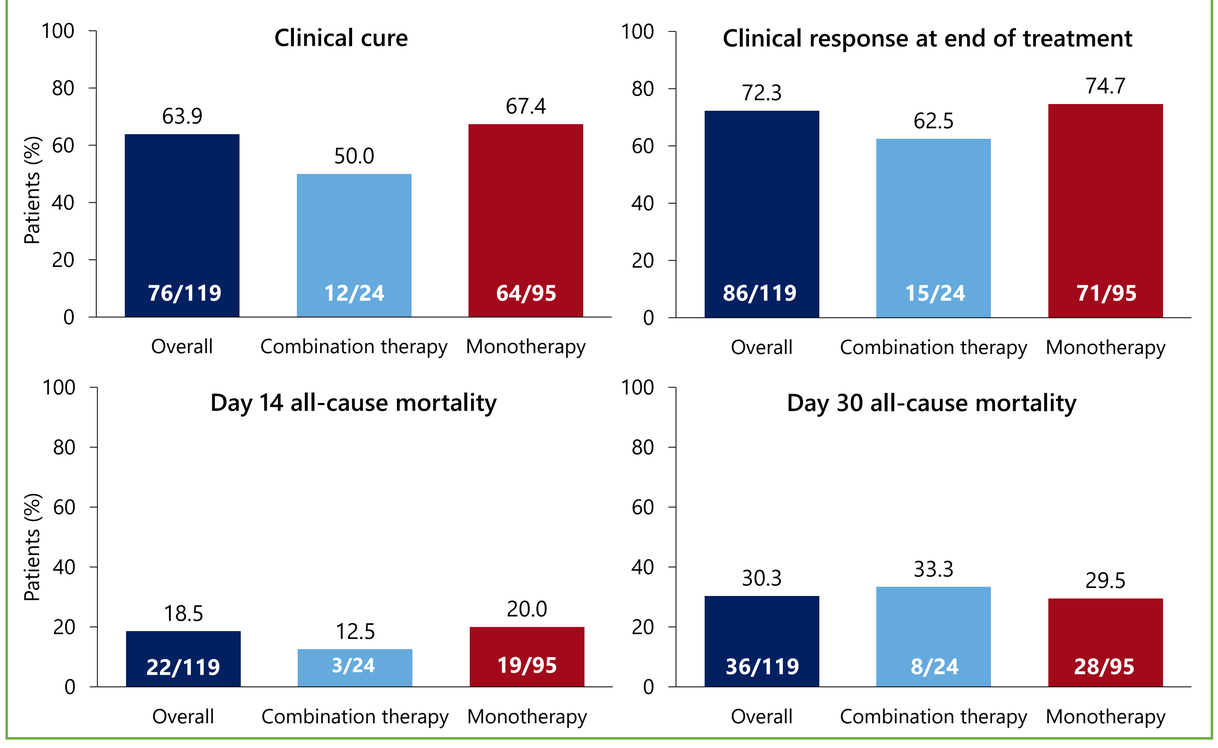
- Cefiderocol demonstrated meaningful clinical outcomes in this population infected with a difficult-to-treat pathogen.
  - Baseline clinical characteristics showed that patients with *Stenotrophomonas* spp. in the PROVE study were a high-severity population, demonstrating real-world use of cefiderocol in critically ill patients.
  - The rate of susceptibility to *Stenotrophomonas* spp. infection was high (98.3%) in patients with microbiological results.
- In this large cohort of patients with *Stenotrophomonas* spp. infections treated with cefiderocol, relatively few individuals received Infectious Diseases Society of America guideline-recommended combination therapy [7].
  - No obvious differences were observed between outcomes with cefiderocol monotherapy and combination therapy.

Table 1. Demographics and infection characteristics by treatment strategy among patients with *Stenotrophomonas* spp. in the PROVE study (2020–2024; N=119)

Parameter	Treatment strategy		
	Overall (N=119)	Monotherapy (n=95)	Combination therapy (n=24)
Demographics			
Age (years), median (IQR)	60.0 (47.0–67.0)	60.0 (49.0–67.0)	60.5 (42.5–67.0)
≥65 years old, n (%)	42 (35.3)	36 (37.9)	6 (25.0)
Sex, male, n (%)	79 (66.4)	62 (65.3)	17 (70.8)
Country enrolled, n (%)			
United States	55 (46.2)	45 (47.4)	10 (41.7)
France	16 (13.4)	12 (12.6)	4 (16.7)
Germany	13 (10.9)	10 (10.5)	3 (12.5)
Italy	7 (5.9)	3 (3.2)	4 (16.7)
Spain	21 (17.6)	18 (18.9)	3 (12.5)
United Kingdom	7 (5.9)	7 (7.4)	0
Pre-existing medical conditions, n (%)			
Any pre-existing condition	110 (92.4)	87 (91.6)	23 (95.8)
Diabetes	20 (16.8)	14 (14.7)	6 (25.0)
Chronic pulmonary disease	26 (21.8)	18 (18.9)	8 (33.3)
Congestive heart failure	17 (14.3)	13 (13.7)	4 (16.7)
Medical condition at admission, n (%)			
COVID-19	17 (14.3)	12 (12.6)	5 (20.8)
Sepsis	11 (9.2)	7 (7.4)	4 (16.7)
Septic shock	9 (7.6)	8 (8.4)	1 (4.2)
Immunocompromised patients, n (%)	37 (31.1)	33 (34.7)	4 (16.7)
Severity of illness			
ICU stay at time of cefiderocol initiation, n (%)	88 (73.9)	70 (73.7)	18 (75.0)
Any organ support at cefiderocol initiation, n (%)	77 (64.7)	61 (64.2)	16 (66.7)
Type of organ support, n (%)			
Mechanical ventilation	75 (63.0)	59 (62.1)	16 (66.7)
Continuous renal replacement therapy/dialysis	28 (23.5)	21 (22.1)	7 (29.2)
ECMO	14 (11.8)	7 (7.4)	7 (29.2)
Vasopressor use	59 (49.6)	46 (48.4)	13 (54.2)
Reason for cefiderocol use (as per eCRF[a], n (%)			
Documented infection	75 (63.0)	62 (65.3)	13 (54.2)
Empirical use	11 (9.2)	9 (9.5)	2 (8.3)
Salvage therapy	27 (22.7)	18 (18.9)	9 (37.5)
Other/unknown	6 (5.0)	6 (6.3)	0
Infection type, n (%)			
Monomicrobial	61 (51.3)	52 (54.7)	9 (37.5)
Polymicrobial	58 (48.7)	43 (45.3)	15 (62.5)

[a]Reported by the investigator. Documented infection: the pathogen and susceptibilities were known, and cefiderocol use was not due to failure of a prior antibiotic regimen. Empirical use: cefiderocol use started before the pathogen, and/or susceptibilities were available to help guide the choice. 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 if there was an adequate response before the next course of antibiotic would be considered salvage. Other/unknown: any other reason provided by the physician. COVID-19, coronavirus disease 2019; eCRF, electronic case report form; ECMO, extracorporeal membrane oxygenation; ICU, intensive care unit; IQR, interquartile range.

Figure 3. Outcomes by cefiderocol treatment strategy and infection type among patients with *Stenotrophomonas* spp. in the PROVE study (2020–2024; N=119)



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Conflict of interest

JFT: reports lecture fees for Shionogi, Pfizer, Advanz Pharma, Mundipharma, Gilead, Merck, bioMérieux, and Qiagen. JT-C: has received fees from Shionogi for consulting or training activities as well as compensation for attending conferences. IM: has received honoraria from Shionogi for consulting, training, and conference participation. EK: has served as a speakers' bureau member for Shionogi. ASH, KG, STN: employees of Shionogi.

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