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Real-world experience of cefiderocol in France from the PROVE (retrospective cefiderocol chart review) study

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OBJECTIVES

We aimed to describe usage of cefiderocol, post commercialisation, for the treatment of patients with Gram-negative bacterial infections from 10 French centres, who were included in the ongoing PROVE study.

METHODS

Design: ongoing, international, retrospective, medical chart review study.

Inclusion criteria: adult hospitalised patients treated with cefiderocol consecutively for ≥72 hours (November 2020–June 2023).

Endpoints: patient and pathogen characteristics, hospitalisation course, antibiotic treatment patterns, clinical cure, and 14-day and 30-day all-cause mortality (ACM). Clinical cure was defined as resolution or improvement of signs/symptoms at the end of treatment (EOT), as judged by the physician; patients who died during therapy or had a relapse or reinfection due to the same pathogen after EOT during current hospitalisation were considered as clinical failure. ACM included patients who died during their hospitalisation.

RESULTS

Patient characteristics (N=129)*		Main comorbidities	
Age, median (Q1–Q3), years	57 (45–69)	Diabetes (uncomplicated)	28 (21.7%)
Sex, male	95 (73.6%)	Chronic pulmonary disease	24 (18.6%)
CCI score, median (Q1–Q3)	1 (0–3)	Peripheral vascular disease	15 (11.6%)
		Congestive heart failure	14 (10.9%)

ICU stay	Organ support^	Mechanical ventilation	Vasopressor use
58.9% (n=76)	38.0% (n=49)	31.8% (n=41)	20.9% (n=27)

Hospitalisation course	
➢ Hospital stay, median (Q1–Q3), days	60.0 (33–100)
➢ Infection-associated ICU stay, median (Q1–Q3), days	48.5 (23–87)

Cefiderocol use	
➢ Cefiderocol treatment, median (Q1–Q3), days	13 (8–16)
➢ Time from index culture to cefiderocol start, median (Q1–Q3), days	4.0 (3–6)

CCI, Charlson Comorbidity Index; COVID-19; coronavirus disease 2019; ICU, intensive care unit; Q, quartile.
*One patient, who received cefiderocol in compassionate use/early access programme, was a protocol violation; data will be excluded from further analyses.
^Organ support was present at the time when cefiderocol was initiated or within two days of cefiderocol initiation.

Index culture pathogen	n (%)	14-day ACM n (%)	30-day ACM n (%)
Monomicrobial Gram-negative infection	94 (72.9)	14 (14.9)	18 (19.1)
P. aeruginosa	59 (45.7)	6 (10.2)	8 (13.6)
Enterobacterales	13 (10.1)	1 (7.7)	2 (15.4)
A. baumannii	13 (10.1)	3 (23.1)	3 (23.1)
S. maltophilia	6 (4.7)	3 (–$)	4 (–$)
Other*	3 (2.3)	1 (–$)	1 (–$)
Polymicrobial Gram-negative infection	35 (27.1)	3 (8.6)	7 (20.0)

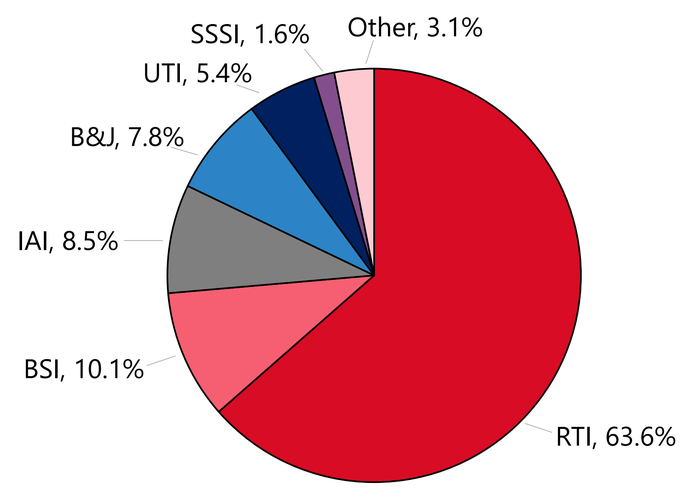
*_Burkholderia cepacia_ complex (2), _Achromobacter_ spp. (1).
$% is not calculated with patient numbers <10.

CONCLUSIONS

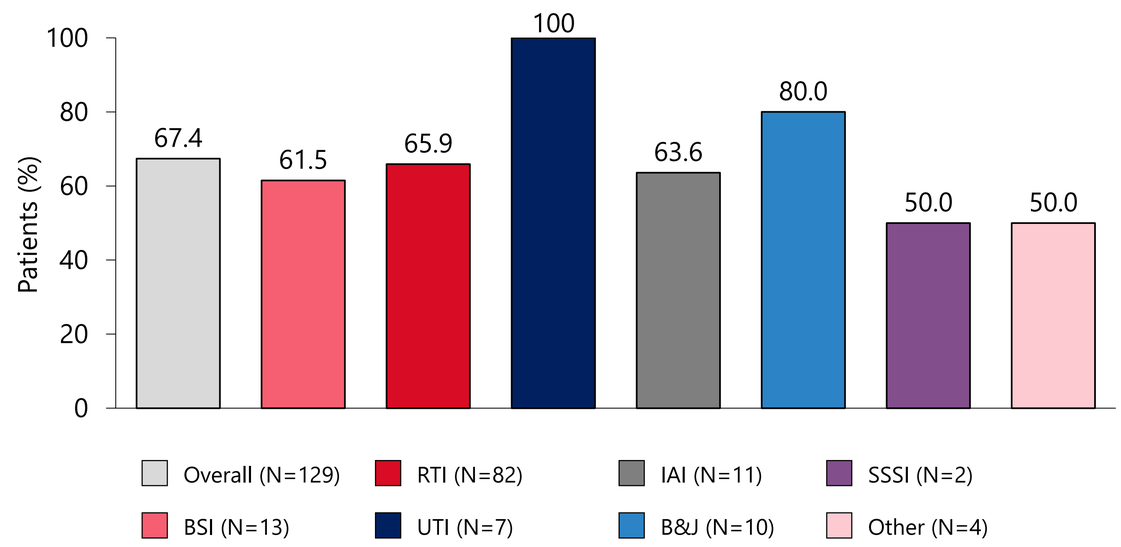
- This large cohort of real-world evidence post commercialisation of cefiderocol in France showed that cefiderocol was used primarily to treat respiratory infections and non-fermenter pathogens, including mainly *Pseudomonas* spp.
- A large proportion of patients responded to cefiderocol treatment and mortality rates overall were approximately 15% and 20% at days 14 and 30.

RESULTS CONT'D

Distribution of site of infection

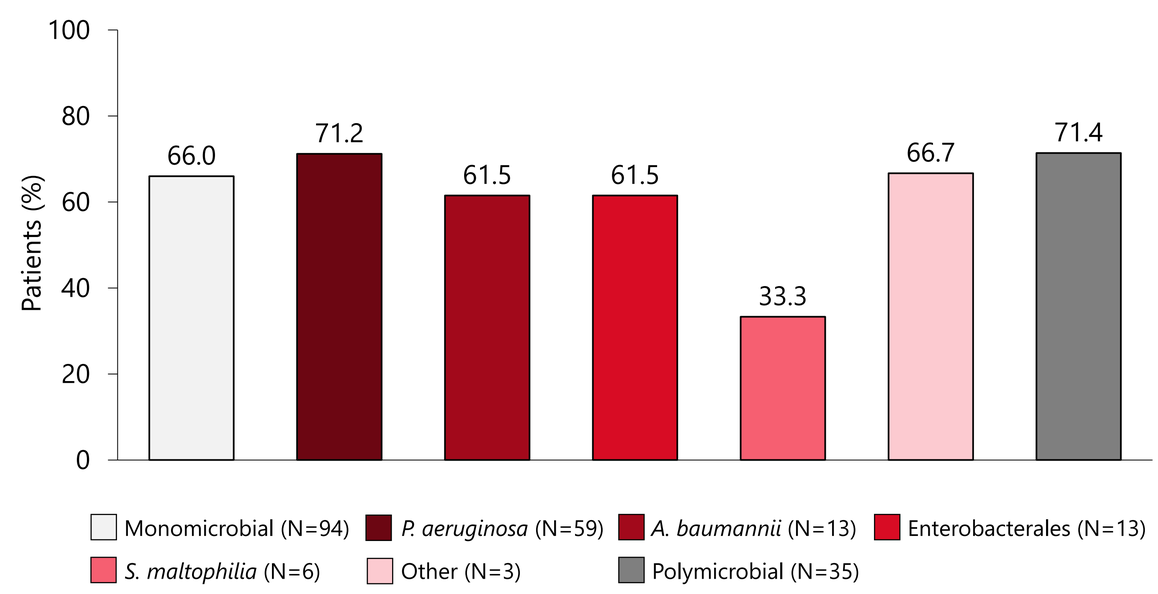


Clinical cure by infection site



BSI, bloodstream infection; B&J, bone and joint infection; IAI, intra-abdominal infection; RTI, respiratory tract infection; SSSI, skin and skin structure infection; UTI, urinary tract infection.

Clinical cure by index pathogen



Primary infection site*	14-day ACM n (%)	30-day ACM n (%)
Overall (N=129)	17 (13.2)	25 (19.4)
BSI (N=13)†	2 (15.4)	3 (23.1)
RTI (N=82)	13 (15.9)	18 (22.0)
UTI (N=7)	0 (0)	0 (0)
IAI (N=11)	2 (18.2)	4 (36.4)
B&J (N=10)	0 (0)	0 (0)
SSSI (N=2)	0 (0)	0 (0)
Other (N=4)†	0 (0)	0 (0)

*Driving the use of cefiderocol (includes monomicrobial and polymicrobial infections).
†There were no BSI or 'Other' polymicrobial infections.
BSI, bloodstream infection; B&J, bone and joint infection; IAI, intra-abdominal infection; RTI, respiratory tract infection; SSSI, skin and skin structure infection; UTI, urinary tract infection.
Owing to differential consent requirements between alive and deceased patients, mortality may be overestimated in this dataset by as much as 2.3%.

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