Poster 649

IDWeek 2022 October 19–23. 2022 Washington DC, USA

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Cefiderocol in Treating Patients Confirmed with Gram-negative Infections in US Hospital During January 2020–Jun 2021

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Purpose

- Cefiderocol is a siderophore cephalosporin that has broad activity against Gramnegative pathogens, including carbapenem-resistant isolates, through its unique mode of cell entry [1].
- It was approved in November 2019 by the US Food and Drug Administration to treat adult patients with complicated urinary tract infection, hospital-acquired bacterial pneumonia, and ventilator-associated bacterial pneumonia caused by Gramnegative pathogens such as Acinetobacter baumannii complex, Pseudomonas aeruginosa, Stenotrophomonas maltophilia, Escherichia coli, Enterobacter cloacae complex, and Klebsiella pneumoniae [2].
- This study describes the demographic and clinical characteristics and outcomes of patients with microbiologically confirmed infections during the initial phase of the commercialization of cefiderocol.

Methods

Study design:

A retrospective study of an existing healthcare database

Data source

- Since 2012, the Premier Healthcare Database (PHD) has collected anonymized patient-level data for the detailed daily service received during hospitalization from over 1000 geographically diverse non-profit, non-governmental, and community and teaching hospitals and health systems in rural and urban communities in the US [3].
- The present analysis is based on a subset of 442 hospitals that provided microbiology test results for Gram-negative pathogens, including specimen site, pathogen, and drug sensitivity for hospitalized patients from January 2018 to June 2021

Study population:

- Hospitalized patients with laboratory-confirmed Gram-negative infections in US hospitals treated with cefiderocol consecutively for ≥3 days between March 2020 and June 2021, during the overlapping period of the coronavirus disease 2019 (COVID-19) pandemic, as part of routine clinical care captured by the PHD, were included.
- Index day is the day that is closest to cefiderocol treatment initiation with a positive culture for Gram-negative pathogen(s). The index day could be either before cefiderocol initiation or the day when the first culture was obtained after cefiderocol initiation if no microbiology evaluation was performed prior to cefiderocol use.
- Index cultures were all cultures taken on the index day.
- Index pathogens were the Gram-negative pathogens identified from the index culture(s).
- Carbapenem resistance of the index pathogen was based on the susceptibility test for pathogens against doripenem, imipenem, meropenem, or ertapenem (excluded for A. baumannii and P. aeruginosa). The pathogen was deemed carbapenem resistant if the susceptibility test result was resistant or intermediate.
- Infection sites were based on the sites from which positive cultures were taken.

Study variables:

- Demographic and clinical characteristics, e.g., age, sex, comorbidity, COVID-19 status, intensive care unit stay, and mechanical ventilation.
- Cefiderocol usage, e.g., when it started, treatment days, and number of antibiotics used before initiation.
- Microbiology profiles, e.g., type of pathogen(s), carbapenem resistance status, and culture site.
- 14-day and 28-day in-hospital all-cause mortality, defined as any death that occurred during hospitalization within 14 days or 28 days after cefiderocol initiation.

Table 1. Patient demographics and clinical characteristics

	(N=187)	COVID-19 (N=45)	Non-COVID-19 (N=142)	<i>P</i> value (COVID-19	Gram-negative pathogen from index culture	Overall (N=187)	COVID-19 (N=45)	Non-COVID-19 (N=142)
	n (%)	n (%)	n (%)	vs. non- COVID-19)		n (%)	n (%)	n (%)
Race					Patients with selected index pathogens (polymicrol	counted in each	ch case)	
White	138 (73.8)	36 (80.0)	102 (71.8)	0.08	Any Acinetobacter baumannii	19 (10.2)	5 (11.1)	14 (9.9)
Black	22 (11.8)	2 (4.4)	20 (14.1)		Any Pseudomonas aeruginosa	97 (51.9)	15 (33.3)	82 (57.8)
Other	8 (4.3)	4 (8.9)	4 (2.8)		Any Stenotrophomonas maltophilia	38 (20.3)	4 (8.9)	34 (23.9)
Unable to determine	19 (10.2)	3 (6.7)	16 (11.3)		Any Klebsiella pneumoniae	23 (12.3)	6 (13.3)	17 (12.0)
Age (years)					Non-fermenters	145 (77.5)	24 (53.3)	121 (85.2)
Mean (SD)	58.6 (15.3)	60.9 (13.4)	57.9 (15.8)	0.25	Carbapenem resistance status	- (- /	(/	()
Median (Q1–Q3)	60 (48–70)	62 (51–70)	58.5 (47–69)	0.30	Any carbapenem resistance	137 (73.3%)	18 (40 0%)	119 (83.8%)
Minimum, maximum	21, 89	21.0, 84	22.0, 89		Carbapenem suscentible only	20 (10 7%)	12 (26 7%)	8 (5 6%)
Sex					Not available	30 (16.0%)	15 (33 3%)	15 (10.6%)
Female	76 (40.6)	21 (46.7)	55 (38.7)	0.35	Number of nathogens from the index culture(s)	00 (10.070)	10 (00.070)	10 (10.070)
Male	111 (59.4)	24 (53.3)	87 (61.3)		1 nathogen	140 (74.9)	35 (77.8)	105 (73.9)
Admission source					2 pathogens	36 (10 3)	9(20.0)	27 (10.0)
Nonhealthcare facility point of origin (Home)	110 (58.8)	32 (71.1)	78 (54.9)	0.16	2 pathogens	9 (1 3)	$\frac{3}{20.0}$	7(4.0)
Transfer from SNF or ICF	25 (13.4)	4 (8.9)	21 (14.8)		4 pathogona	0 (4.3)	1(2.2)	7 (4.9)
Transfer from hospital or different facility	52 (27.8)	9 (20.0)	43 (30.3)		4 patriogens	3 (1.0)	0 (0.0)	3 (2.1)
Admission type		4 (0,0)	40 (0.0)	0.00	Any blood	24 (12.8)	7 (15 6)	17 (12 0)
Scheduled admission (elective)	14 (7.5)	1 (2.2)	13 (9.2)	0.03	Ring blood Blood only	24 (12.0)	7 (15.0) 5 (11.1)	17 (12.0)
Emergency, Trauma Center, or Orgent	173 (92.5)	44 (97.8)	129 (90.9)		Any reeniretery	10 (9.0)	3(11.1)	13 (9.2)
Charison Comorbidity Score	20(24)	4.4.(2.0)	2.0.(2.4)	0.62	Any respiratory	113 (00.4)	32(71.1)	01(07.0)
Median (SD)	3.9 (3.1)	4.1 (3.0)	3.9 (3.1)	0.63	Respiratory only	101 (54.0)	29 (64.4)	72 (50.7)
Minimum movimum	3 (1-6)	4 (2–6)	3 (1-6)	0.54	Any urinary	24 (12.8)	4 (8.9)	20 (14.1)
Minimum, maximum	0, 15	0, 12	0, 15			17 (9.1)	3 (6.7)	14 (9.9)
		<i>(</i> 01 1)	77 (54 2)	<0.01	Any wound	19 (10.2)	1 (2.2)	18 (12.7)
No	FIG (03.1)	41 (91.1)	FT (54.2)	<0.01	vvound only	10 (5.3)	1 (2.2)	9 (6.3)
INU	09 (30.9)	4 (0.9)	00 (40.0)		Any other sites	27 (14.4)	4 (8.9)	23 (16.2)
TCO stay during the hospitalization	147 (79.6)	41 (01 1)	106 (74 7)	0.02	Other sites only	24 (12.8)	4 (8.9)	20 (14.1)
res No	147 (70.0)	41 (91.1)	100(74.7)	0.02	Number of culture sites			
NU Number of Orem perstine entities initiated befor	40 (21.4)	4 (0.9)	30 (23.4)		1 site	170 (90.9)	42 (93.3)	128 (90.1)
Number of Gram-negative antibiotics initiated befor		(ION	47 (42.0)	-0.01	2 sites	14 (7.5)	3 (6.7)	11 (7.8)
0	18 (9.6)	$\Gamma(2.2)$	17 (12.0)	<0.01	3 sites	3 (1.6)	0 (0.0)	3 (2.1)
1	26 (13.9)	2 (4.4)	24 (16.9)		Number of pathogens and number of culture sites			
2	26 (13.9)	2 (4.4)	24 (16.9)		1 pathogen 1 site	136 (72.7)	35 (77.8)	101 (71.1)
3	31 (16.6)	9 (20.0)	22 (15.5)		1 pathogen 2 sites	3 (1.6)	0 (0.0)	3 (2.1)
>3	86 (46.0)	31 (68.9)	55 (38.7)		1 pathogen 3 sites	1 (0.5)	0 (0.0)	1 (0.7)
Days from admission to cefiderocol initiation					2 pathogens 1 site	27 (14.4)	6 (13.3)	21 (14.8)
Mean (SD)	19.3 (31.5)	22.9 (16.4)	18.1 (34.9)	0.21	2 pathogens 2 sites	8 (4.3)	3 (6.7)	5 (3.5)
Median (Q1–Q3)	11 (4–23)	22 (14–27)	8 (4–18)	0.00	2 pathogens 3 sites	1 (0.5)	0 (0.0)	1 (0.7)
Minimum, maximum	1, 274	1, 92	1, 274		3 pathogens 1 site	6 (3.2)	1 (2.2)	5 (3.5)
Days on cefiderocol					3 pathogens 2 sites	2 (1.1)	0 (0.0)	2 (1.4)
Mean (SD)	11.0 (8.8)	8.8 (5.8)	11.7 (9.5)	0.02	3 pathogens 3 sites	1 (0.5)	0 (0.0)	1 (0.7)
Median (Q1–Q3)	8 (5–14)	6 (5–10)	9.5 (6–15)	0.04	4 pathogens 1 site	1 (0.5)	0 (0.0)	1 (0.7)
Minimum, maximum	3, 66	3, 24	3, 66		4 pathogens 2 sites	1 (0.5)	0 (0.0)	1 (0.7)

P value from χ^2 , t-test, or Wilcoxon rank sum test. Data are n (%) unless stated otherwise. COVID-19, coronavirus disease 2019; ICF, intermediate care facility, ICU, intensive care unit; Q, quartile; SD, standard deviation; SNF, skilled nursing facility.

Figure 1. Patient Attrition



Statistical analysis:

- Descriptive statistics are presented overall and by COVID status:
- Number (%) for categorical variables,
- medians) for continuous variables.

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- Mean, standard deviation (SD), median (interquartile range [IQR; Q1–Q3]) for continuous variables. • Univariate comparisons between non-COVID and COVID patients were conducted using a χ^2 test for categorical variables, a t-test (comparing means) and a Wilcoxon rank sum test (comparing

Table 2. Profile of Gram-negative pathogens treated with cefiderocol

P value from χ^2 . Data are n (%). COVID-19, coronavirus disease 2019.

Results

- Among 187 patients with microbiology results (Figure 1), the median age was 60 years (Table 1).
- The most frequent pathogens from the index cultures were *P. aeruginosa*, *S. maltophilia*, During the initial phase post approval, cefiderocol was most frequently used to treat critically K. pneumoniae, and A. baumannii (Table 2). ill patients (as shown by the high proportion of patients admitted to the ICU and/or receiving Nearly 75% of patients had one index pathogen. mechanical ventilation) with non-fermenters, and most frequently for respiratory tract 91% were collected from one culture site. infections.

 - Almost 30% of patients had either one pathogen identified in multiple culture sites, or In-hospital all-cause mortality was comparable with other studies [4–6], and appears to be multiple pathogens from ≥ 1 culture site. affected by infection characteristics, especially COVID-19 status.
- Overall crude 28-day in-hospital all-cause mortality for patients was 23.5% with 95% confidence interval (CI) of 17.4–29.5%. In-hospital all-cause mortality was as follows (**Table 3**):
 - Any *A. baumannii*: 8.3% (95% CI: 0–19.4%).
 - Any P. aeruginosa: 17.3% (95% CI: 9.9–24.8%).
 - Any S. maltophilia: 18.4% (95% CI: 6.1–30.7%).
- Any *K. pneumoniae*: 26.1% (95% CI: 8.1–44.0%). In-hospital all-cause mortality was markedly impacted by COVID-19 status.
 - Non-COVID-19 patients: 11.3% (95% CI: 6.1–16.5%).
 - COVID-19 patients: 62.2% (95% CI: 48.1–76.4%).
 - The difference remained the same for patients with bloodstream infection and respiratory
 - tract infection.



Table 3. Hospitalization Outcomes

COVID-19 N Row total, N % N in-hospital mortality N in-hospital mortality % row total (11.7-22.5) in-hospital mortality n % % row total (95% CI) 0.81 Overall 187 100 32 17.1 44 23.5 0.03 Time from admission to first Gram-negative culture (11.7-22.5) (17.4-29.6) (17.4-29.6) 0.81 52 weeks 158 84.5 18 11.4 29 18.4 0.01 52 weeks 29 15.5 14 44.3.3 15 51.7 c.0.1 52 weeks 29 15.5 14 8.7 8 14.2 2.2 weeks 14.3 76.5 22 15.4 29 20.3 2.2 weeks 14.3 76.5 22 15.4 29 20.3 2.4 weeks 184 98.4 32 17.4 44 23.9 2.4 weeks 184 98.4 32 17.4 44 23.9 2.4 weeks 184 98.4 32	P value	Characteristic	<u>Over</u>	all	14-day all-cause in-hospital mortality		28-day all-cause in-hospital mortality		
New total, OVID-19) Nov total, N % row total (95% c1) n % row total (95% c1) 0.81 Overall 187 100 32 17.1 44 23.5 0.03 Time from admission to first Gram-negative culture (11.7-22.5) (17.4-28.6) (12.3-24.4) 0.81 -22 weeks 158 84.5 18 11.4 29 18.4 -0.01 -22 weeks 128 67.9 11 8.7 18 14.2 -20.01 -22 weeks 127 67.9 11 8.7 18 14.2 -20.01 -22 weeks 127 67.9 11 8.7 18 14.2 -22 weeks 127 67.9 11 8.7 18 14.2 -22 weeks 143 76.5 22 15.4 29 20.3 -22 weeks 144 89.4 32 10 7.7 15 34.1 Time from index culture to first cerifatrocol dose -22 44.8 23 10 </th <th>COVID-19</th> <th></th> <th></th>	COVID-19								
$ \begin{array}{c c c c c c c c c c c c c c c c c c c $	vs. non- COVID-19)		Row total, N	%	n	% row total (95% Cl)	n	% row total (95% CI)	
0.03 0.81 $\leq 2 weeks$ 158 158 $\leq 2 weeks$ 158 158 $\leq 2 weeks$ 11.4 $\leq 2 weeks$ 29 $\leq 2 weeks$ 15 $\leq 2 weeks$ 14 $\leq 2 weeks$ 14 $\leq 2 weeks$ 15 $\leq 2 weeks$ 15 $\leq 2 weeks$ 15 $\leq 2 weeks$ 17 $\leq 2 weeks$ 127 $\leq 2 weeks$ 67.9 $\leq 2 weeks$ 14 $\leq 2 weeks$ 16 $\leq 2 weeks$ 17 $\leq 2 weeks$ 16 $\leq 2 weeks$ 16 $\leq 2 weeks$ 17 $\leq 2 weeks$ 16 $\leq 2 weeks$ 17 $\leq 2 weeks$ 16 $\leq 2 weeks$ 17 $\leq 2 weeks$ 16 $\leq 2 weeks$ 17 $\leq 2 weeks$ 18 $\leq 2 weeks$ 18 $\leq 2 weeks$ 16 $\leq 2 week$	0.81 <0.01	Overall	187	100	32	17.1 (11.7–22.5)	44	23.5 (17.4–29.6)	
$\begin{array}{c c c c c c c } 0.01 & 2 weeks $ 156 $ 94.5 $ 18 $ 11.4 $ 29 $ 18.4 $ (12.3-24.4) $ (12.3-24.4$	0.03	Time from admission to	o first Gram-nega	ative culture					
< 20 weeks 29 15.5 14 48.3 15 51.7 c.0.01 Time from admission to index culture (30.1-66.5) (33.5-69.9) 22 weeks 60 32.1 21 35.0 26 43.3 0.65 11me from first positive culture to first cerifderocol dose	0.81 <0.01	≤2 weeks	158	84.5	18	11.4 (6.4–16.4)	29	18.4 (12.3–24.4)	
Time from admission to index culture S2 weeks 127 67.9 11 8.7 18 14.2 S2 weeks 60 32.1 21 35.0 26 S2 weeks 143 76.5 22 15.3 34.1 S2 weeks 143 76.5 22 15.3 34.1 S2 weeks 144 23.9 34.1 S2 weeks 184 98.4 32 17.4 44 23.9 2.2 weeks 3 1.6 0 0.0 0 0.0 0.0 0.0 0.0 0.0 0.0 0.0 0.0 0.0 0.0 0.0 0.0 0.0 0.0 0.0 0.	<0.01	>2 weeks	29	15.5	14	48.3 (30.1–66.5)	15	51.7 (33.5–69.9)	
$\begin{array}{c c c c c c c c c c c c c c c c c c c $		Time from admission to	o index culture						
$\begin{array}{c c c c c c c c c c c c c c c c c c c $		≤2 weeks	127	67.9	11	8.7	18	14.2	
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$\begin{array}{c ccccccccccccccccccccccccccccccccccc$	0.65	Time from first positive	e culture to first o	cefiderocol dos	ie O	45.4			
$\begin{array}{c c c c c c c c c c c c c c c c c c c $		≤2 weeks	143	76.5	22	15.4	29	20.3	
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(274.72.2) (524.95.0)		Respiratory	20	64.4	16	(17.1-100.0)	20	(44.9-100.0) 60.0%	
		Respiratory	23	04.4	10	(37 1 72 2)	20	(52 1 95 9)	

CI, confidence interval; COVID-19, coronavirus disease 2019.

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Conclusion and Clinical Implications

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