RES-119

Study of Prescribing Patterns and Effectiveness of Ceftolozane/Tazobactam [C/T] Real-World Analysis (SPECTRA) Results by BMI

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Background

We aimed to describe the prescribing patterns and clinical outcomes among patients exposed to ceftolozane/tazobactam (C/T) in seven countries between 2016 and 2020, specifically reporting the results stratified by body mass index (BMI) weight from the Study of Prescribing patterns and Effectiveness of Ceftolozane/Tazobactam Real-world Analysis (SPECTRA)—ie, treatment duration, timing of C/T initiation, and the rank of C/T as a therapy option for patients categorized by BMI. These insights on prescribing patterns are critical for understanding the clinical implications of C/T use in diverse patient populations.

Methods

SPECTRA is a multicenter, real-world study in patients (≥18 years of age) treated with ≥48 hours of C/T in a hospital setting in seven countries: Australia, Austria, Germany, Mexico, Spain, Italy, and the UK. Retrospective data were extracted from medical records from 6 months prior to the index date (first date of antibiotic treatment) for 30 days from the last dose of C/T, or until death. Here we report subcategorical results of prescribing patterns and clinical outcomes among patients treated with C/T reported according to BMI [Normal weight (BMI ≥18.5 and <25 Kg/m²), Overweight (BMI ≥25 and <30 Kg/m²), and Obese (BMI ≥30 Kg/m²)].

Results

Of 617 total patients, BMI was collected for 469 (**Table 1**). All-cause in-hospital mortality and clinical success were 19.0% and 64.6% for the obese patients, respectively (**Table 2**). The median treatment duration for ceftolozane/tazobactam (C/T) was 10.5 days for normal weight patients, 10.0 days for overweight patients, and 15.0 days for obese patients. Additionally, C/T was initiated as the first therapy in 21.1% of normal weight patients, 33.3% of overweight patients, and 25.3% of obese patients. *Pseudomonas aeruginosa* (PsA) was detected in 84.4% of overweight patients and 87.9% of obese patients, respectively (**Table 3**). Multidrug resistant (MDR) PsA was found in 9.2% of overweight patients and 6.9% of obese patients, respectively.

Table 1. Demographics and patient characteristics of patients with BMI from SPECTRA by country

Total patient population	Australia	Austria	Germany	Italy	Mexico	Spain	UK	Total
	N=59	N=12	N=29	N=57	N=59	N=313	N=88	N=617
Age (years)[a]								
N	59	12	29	56	57	309	87	609
Missing	0	0	0	1	2	4	1	8
Mean (SD)	52.3 (16.4)	66.5 (14.9)	56.1 (16.7)	60.1 (15.1)	55.2 (18.1)	61.5 (15.7)	45.0 (17.7)	57.4 (17.3)
Median	53	66.5	57	61.5	60	64	44	59
Q1; Q3	37.0; 64.0	59.5; 78.5	46.0; 69.0	50.0; 72.5	43.0; 67.0	51.0; 73.0	28.0; 59.0	45.0; 71.0
Min; Max	19; 85	33; 84	24; 81	21; 87	19; 86	18; 89	19; 83	18; 89
Age ≥90 years	0	0	0	1	2	4	1	8
Gender								
Male	40 (67.8%)	6 (50.0%)	20 (69.0%)	39 (68.4%)	31 (52.5%)	213 (68.1%)	55 (62.5%)	404 (65.5%)
Female	19 (32.2%)	6 (50.0%)	9 (31.0%)	18 (31.6%)	28 (47.5%)	100 (31.9%)	33 (37.5%)	213 (34.5%)
Height (cm)								
n	54	12	21	51	59	191	87	475
Missing	5	0	8	6	0	122	1	142
Mean (SD)	175.6 (26.6)	170.5 (9.7)	174.8 (8.0)	170.4 (9.1)	167.8 (10.5)	167.9 (8.8)	168.6 (12.5)	169.5 (13.1)
Median	171.5	172	175	170	167	169	170	170
Q1; Q3	167.0; 180.0	162.5; 179.0	170.0; 181.0	163.0; 178.0	160.0; 172.0	162.0; 174.0	161.0; 178.0	163.0; 175.0
Min; Max	141.8; 300.0	154.0; 185.0	155.0; 185.0	147.0; 185.0	150.0; 198.0	142.0; 200.0	115.0; 195.0	115.0; 300.0
Weight (kg)								
n	59	12	21	51	59	204	87	493
Missing	0	0	8	6	0	109	1	124
Mean (SD)	74.7 (20.4)	67.9 (16.3)	81.8 (39.3)	72.3 (15.3)	72.5 (15.9)	75.7 (19.4)	67.4 (16.8)	73.5 (19.7)
Median	72	72	70	70	71	73.1	64.4	70.2
Q1; Q3	61.0; 85.0	53.5; 82.0	65.0; 86.0	62.0; 80.0	60.0; 80.0	65.0; 84.8	55.3; 76.4	61.0; 82.0
Min; Max	35.0; 133.0	40.4; 89.0	40.0; 240.0	35.0; 120.0	37.0; 115.0	33.0; 170.0	43.4; 150.8	33.0; 240.0
BMI (kg/m²)								
n	54	12	21	51	59	185	87	469
Missing	5	0	8	6	0	128	1	148
Mean (SD)	25.0 (7.5)	23.3 (5.5)	27.1 (14.0)	24.8 (4.2)	25.7 (4.6)	26.9 (6.8)	23.8 (5.4)	25.6 (6.7)
Median	24.7	22.4	23.1	24.7	25.4	26	22.7	25
Q1; Q3	19.9; 28.0	18.5; 26.2	20.5; 29.1	21.8; 26.8	23.4; 27.7	22.9; 29.4	19.8; 25.8	21.6; 28.2
Min; Max	9.4; 46.6	17.0; 33.1	14.9; 83.0	12.1; 38.3	15.2; 38.6	12.9; 68.1	15.4; 42.2	9.4; 83.0
Previous care setting								
Home/community	50 (84.7%)	8 (66.7%)	14 (48.3%)	44 (77.2%)	47 (79.7%)	260 (83.1%)	72 (81.8%)	495 (80.2%)
Other hospital	8 (13.6%)	3 (25.0%)	7 (24.1%)	10 (17.5%)	6 (10.2%)	27 (8.6%)	12 (13.6%)	73 (11.8%)
Other skilled care facility	1 (1.7%)	0	7 (24.1%)	3 (5.3%)	0	23 (7.3%)	1 (1.1%)	35 (5.7%)
Unknown	0	1 (8.3%)	1 (3.4%)	0	6 (10.2%)	3 (1.0%)	3 (3.4%)	14 (2.3%)

[a]For patients aged 90 or older the HCP was asked not to enter the exact age and to check a specific box. Therefore, patients aged 90 or older are included in "Missing" and are not taken into account in the calculation of mean, median, etc.

Table 2. Clinical outcomes of patients with BMI from SPECTRA

	Normal weight	Overweight	Obese
	N=194	N=159	N=79
All-cause in-hospital mortality			
Yes	36 (18.6%)	34 (21.4%)	15 (19.0%)
(95% CI)	(13.3%, 24.8%)	(15.3%, 28.6%)	(11.0%, 29.4%)
No	158 (81.4%)	125 (78.6%)	64 (81.0%)
(95% CI)	(75.2%, 86.7%)	(71.4%, 84.7%)	(70.6%, 89.0%)
If yes: Time from the index date to death (days)			
n	36	34	15
Missing	0	0	0
Mean (SD)	49.1 (106.2)	29.7 (22.0)	43.7 (25.2)
Median	24.5	23	39
Q1; Q3	13.0; 46.0	13.0; 44.0	26.0; 65.0
Min; Max	3; 645	3; 89	11; 102
Time from the first dose of C/T to death (days)			
n	36	34	15
Missing	0	0	0
Mean (SD)	35.6 (106.5)	21.4 (20.0)	22.5 (14.0)
Median	10	16	21
Q1; Q3	5.5; 17.5	7.0; 26.0	11.0; 33.0
Min; Max	2; 635	2; 89	3; 49
Index infection considered as a clinical success by the investigator			
Yes	133 (68.6%)	108 (67.9%)	51 (64.6%)
(95% CI)	(61.5%, 75.0%)	(60.1%, 75.1%)	(53.0%, 75.0%)
No	40 (20.6%)	40 (25.2%)	19 (24.1%)
(95% CI)	(15.2%, 27.0%)	(18.6%, 32.6%)	(15.1%, 35.0%)
Unknown	21 (10.8%)	11 (6.9%)	9 (11.4%)
(95% CI)	(6.8%, 16.1%)	(3.5%, 12.0%)	(5.3%, 20.5%)
If yes[a]:			
Missing	0	0	0
No additional GN antibacterial therapy required for a minimum of 48 hours targeted to index infection after a minimum of 48 hours of C/T not including discharge antibiotics or de-escalation	86 (64.7%)	60 (55.6%)	32 (62.7%)
No death attributed to GN infection	72 (54.1%)	55 (50.9%)	29 (56.9%)
No further inpatient antibiotic treatment for exacerbation of respiratory infection ≤28 days of stopping C/T	40 (30.1%)	33 (30.6%)	17 (33.3%)
Resolution of exacerbation of chronic respiratory infection	30 (22.6%)	14 (13.0%)	7 (13.7%)
Discharge from hospital, ICU, or step-down unit signifying clinical stability	101 (75.9%)	78 (72.2%)	38 (74.5%)
No need for re-operation for source control	27 (20.3%)	25 (23.1%)	12 (23.5%)
Documented microbiological eradication	38 (28.6%)	30 (27.8%)	15 (29.4%)
Documented microbiological eradication (as reported by investigator)			
No	135 (69.6%)	118 (74.2%)	55 (69.6%)
Yes	38 (19.6%)	30 (18.9%)	15 (19.0%)
Unknown	21 (10.8%)	11 (6.9%)	9 (11.4%)
Ceftolozane/tazobactam: Treatment duration (days) (treatment interruptions not included)			
n	194	158	79
Missing	0	1	0
Mean (SD)	15.5 (17.3)	14.9 (39.4)	18.5 (15.8)
Median	10.5	10	15
Q1; Q3	7.0; 17.0	6.0; 15.0	8.0; 22.0
Min; Max	3; 169	3; 496	3; 79
Time from index hospitalization admission to C/T initiation (days)			
n	194	159	79
Missing	0	0	0
Mean (SD)	31.8 (73.4)	24.3 (24.9)	28.8 (29.7)
Median	14	16	22
Q1; Q3	5.0; 30.0	8.0; 34.0	5.0; 41.0
Min; Max	0; 826	0; 156	0; 142
Time from the first MB sample for index infection to C/T initiation (days)[a]			
N	130	109	58
Missing	64	50	21
Mean (SD)	8.6 (14.5)	6.3 (6.7)	21.3 (89.1)
Median	5	4	5
Q1; Q3	1.0; 12.0	2.0; 10.0	2.0; 11.0
Min; Max	–8; 100	–5; 34	–2; 679
Ceftolozane/tazobactam: Rank of initiation			
First	41 (21.1%)	53 (33.3%)	20 (25.3%)
Second	50 (25.8%)	43 (27.0%)	21 (26.6%)
Third	34 (17.5%)	25 (15.7%)	17 (21.5%)
Fourth	34 (17.5%)	16 (10.1%)	8 (10.1%)
Fifth	17 (8.8%)	15 (9.4%)	4 (5.1%)
Sixth or more	18 (9.3%)	7 (4.4%)	9 (11.4%)

[a]Analysis includes only those with known status for clinical success. Responses of "Unknown" are considered as missing data.

Table 3. Some microbiology results of patients with BMI from SPECTRA

	Normal weight	Overweight	Obese
	N=194	N=159	N=79
Positive culture result			
Enterobacter cloacae			
Missing	64	50	21
No	130 (100%)	109 (100%)	58 (100%)
Yes	0	0	0
If yes, ESBL positive:			
No	0	0	0
Yes	0	0	0
Escherichia coli			
Missing	64	50	21
No	116 (89.2%)	99 (90.8%)	50 (86.2%)
Yes	14 (10.8%)	10 (9.2%)	8 (13.8%)
If yes, ESBL positive:			
No	7 (50.0%)	0	3 (37.5%)
Yes	7 (50.0%)	10 (100%)	5 (62.5%)
Klebsiella pneumoniae			
Missing	64	50	21
No	129 (99.2%)	109 (100%)	58 (100%)
Yes	1 (0.8%)	0	0
If yes, ESBL positive:			
No	0	0	0
Yes	1 (100%)	0	0
Pseudomonas aeruginosa			
Missing	64	50	21
No	22 (16.9%)	17 (15.6%)	7 (12.1%)
Yes	108 (83.1%)	92 (84.4%)	51 (87.9%)
If yes, ESBL positive:			
No	92 (85.2%)	75 (81.5%)	45 (88.2%)
Yes	16 (14.8%)	17 (18.5%)	6 (11.8%)
MDR Pseudomonas aeruginosa			
Missing	64	50	21
Yes	89 (68.5%)	80 (73.4%)	40 (69.0%)
No	19 (14.6%)	12 (11.0%)	11 (19.0%)
No positive culture result	22 (16.9%)	17 (15.6%)	7 (12.1%)
MDR Enterobacterales			
Missing	64	50	21
Yes	9 (6.9%)	10 (9.2%)	4 (6.9%)
No	13 (10.0%)	10 (9.2%)	8 (13.8%)
No positive culture result	108 (83.1%)	89 (81.7%)	46 (79.3%)

Conclusions

Our analysis shows that clinical outcomes, including all-cause in-hospital mortality and clinical success, were generally comparable across the different BMI categories. These findings suggest that C/T can be effectively utilized regardless of body weight, highlighting its potential role in treatment protocols for patients with varying BMI classifications.

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