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Intravenous Ceftaroline in Extremely Premature Neonates With Coagulase-Negative Staphylococci Septicemia: A Report of 2 Cases

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Sepsis is one of the primary causes of newborn morbidity and mortality, particularly in preterm infants, and coagulase-negative staphylococci (CoNS) is a major cause of bacterial infections in the neonatal intensive care unit (NICU). The treatment of late-onset neonatal staphylococcal sepsis is challenging owing to increased minimum inhibitory concentrations and the potential side effects of vancomycin. Herein, we describe 2 cases of extremely preterm newborns treated with intravenous (IV) ceftaroline (6 mg/kg/dose every 8 hours) for late-onset neonatal staphylococcal sepsis. Both cases were diagnosed with bacteremia and treated with ceftaroline. However, one of the patients died, most likely from sepsis or other factors, including chronic lung illness and prematurity, despite sterile blood cultures after starting the ceftaroline treatment. Large-scale randomized studies are required to examine the optimal dosing, safety, and effectiveness of IV ceftaroline for sepsis caused by CoNS in neonates.

ABBREVIATIONS ABSSSIs, acute bacterial skin and skin structure infections; CABP, community-acquired bacterial pneumonia; CBC, complete blood count; CoNS, coagulase-negative staphylococci; CRP, C-reactive protein; DOL, day of life; ESBL, extended-spectrum beta-lactamase; FDA, US Food and Drug Administration; IV, intravenous; MIC, minimum inhibitory concentration; MRSA, methicillin-resistant *Staphylococcus aureus*; NICU, neonatal intensive care unit; PLT, platelet; UVC, umbilical venous catheter; WBC, white blood cell

KEYWORDS bacteremia; coagulase-negative staphylococci; ceftaroline; neonatal intensive care unit; premature neonates; sepsis

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Introduction

Neonatal sepsis remains a leading cause of neonatal morbidity and mortality.[1–3] Coagulase-negative staphylococci (CoNS), a common cause of bacterial infection encountered in the neonatal intensive care unit (NICU), are the second most common etiology of late-onset sepsis in very low birth weight infants admitted to the NICUs in the United States and United Kingdom.[1,2] Antimicrobial resistance is of increasing concern among neonatologists and a primary focus of clinical and microbiologic research among pediatric infectious disease specialists.[1,2] Ceftaroline, a newer cephalosporin with broad-spectrum bactericidal activity, is US Food and Drug Administration (FDA) approved for the treatment of acute bacterial skin and skin structure infections (ABSSSIs) caused by methicillin-resistant *Staphylococcus aureus* (MRSA) and community-acquired bacterial pneumonia (CABP) caused by *Streptococcus pneumoniae* and other susceptible bacteria in children aged 2 months or older.[3]

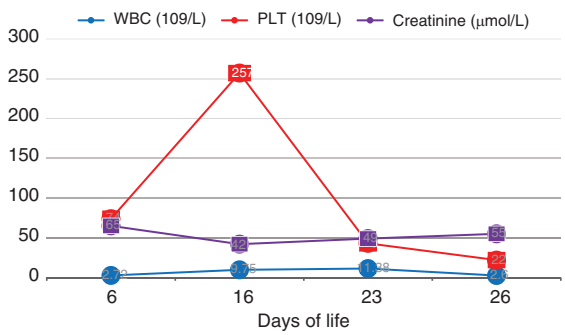
Studies on the safety and efficacy of ceftaroline in neonates and infants are lacking, and the use of ceftaroline in extremely premature neonates with sepsis due to CoNS has not been reported so far. Moreover, few published cases reported the use of ceftaroline in treating MRSA septicemia in neonates.[4] We usually prescribe vancomycin, linezolid, or daptomycin in treating CoNS infections. Herein, we report 2 unique cases of premature neonates who received ceftaroline for persistent CoNS infections.

Case 1

A 900-g 27-week-old female was born to a 31-year-old female by spontaneous delivery. The Apgar scores were 7 and 8 at 1 and 5 minutes, respectively. The infant experienced respiratory distress and was transported to a Level III NICU, where surfactant was administered via the endotracheal route, and the infant was placed on a mechanical ventilator. An umbilical venous catheter (UVC) was placed, blood cultures and complete blood counts (CBCs) were obtained, and ampicillin (50 mg/kg/dose intravenous [IV] every 12 hours) and gentamicin (5 mg/kg/dose IV every 48 hours) were started empirically. A brain ultrasonography performed on day of life (DOL) 3 showed

a grade II intraventricular hemorrhage. On DOL 4, the baby was shifted to a high-frequency ventilator for 6 days, and ampicillin and gentamicin were replaced with linezolid (10 mg/kg/dose IV every 8 hours) and meropenem (40 mg/kg/dose IV every 8 hours) following an endotracheal culture positive for an extended-spectrum beta-lactamase (ESBL)–producing *Klebsiella pneumoniae*. On DOL 6, the UVC was removed and a peripherally inserted central catheter line was inserted. Additionally, linezolid was discontinued, whereas meropenem was continued for an additional 8 days. On DOL 10 the patient was shifted from a high-frequency ventilator to a conventional ventilator. On DOL 14, linezolid (10 mg/kg/dose IV every 8 hours) was reinitiated because the repeated blood culture was positive for *Staphylococcus epidermidis*. Moreover, the peripherally inserted central catheter line was removed. CBC showed a white blood cell (WBC) count of 10.8 × 10^9/L and a platelet (PLT) count of 27 × 10^9/L. A C-reactive protein (CRP) measurement was not obtained. On DOL 15, the neonate was extubated from the conventional ventilator; however, she developed episodes of apnea and was re-intubated and subjected to a complete septic workup on DOL 21. Treatment with meropenem (40 mg/kg/dose IV every 8 hours) was reinitiated, and linezolid was switched to vancomycin (15 mg/kg/dose every 12 hours) owing to persistent positive CoNS blood cultures that were unresponsive to linezolid. The laboratory results of the patient were as follows: WBC count, 3.68 × 10^9/L; neutrophils, 1.77%; lymphocytes, 1.25%; PLT count, 34 × 10^9/L; and vancomycin serum trough concentration, 12 mcg/mL (therapeutic goal: 10–20 mcg/mL). The tracheal culture was positive for *Klebsiella pneumoniae*, and the isolate was sensitive to meropenem, imipenem, amikacin, and gentamicin. In addition, the blood culture demonstrated persistent CoNS. Treatment with concurrent vancomycin and meropenem was continued for 16 days. However, the patient remained clinically ill with persistent positive CoNS results. On DOL 37, meropenem was discontinued, and vancomycin was replaced with daptomycin (10 mg/kg/dose IV every 24 hours) and linezolid (10 mg/kg/dose IV every 8 hours). CBC showed a WBC count of 3.88 × 10^9/L and a PLT count of 10 × 10^9/L with persistent staphylococci infection in the blood culture. Consequently, rifampicin (10 mg/kg/dose IV every 12 hours) was added to linezolid and daptomycin on DOL 40, and the CBC and blood cultures were repeated. The laboratory results were as follows: WBC, 4.54 × 10^9/L; CRP, 66.7 mg/L; neutrophils, 2.46%; lymphocytes, 0.93%; and PLT count, 33 × 10^9/L. The patient remained clinically ill with persistent staphylococci in the blood culture. On DOL 46, ceftaroline (6 mg/kg/dose IV every 8 hours) was added to linezolid, whereas daptomycin and rifampicin were discontinued. The repeated blood culture was sterile on DOL 48; however, the patient died on DOL 49. No adverse renal effects were observed during the entire therapy. Figure 1 shows the trend of WBC, PLT, and creatinine from admission until death. The results of cultures, organisms, and antimicrobial sensitivity are shown in Table 1.

Figure 1. Trends of WBC, PLT, and creatinine from admission until death.



PLT, platelet; WBC, white blood cell.

Case 2

An 890-g 26-week-old female was born to a 27-year-old female by cesarean delivery. The Apgar scores were 5 and 7 at 1 and 5 minutes, respectively. The neonate experienced respiratory distress and was transported to a Level III NICU, where surfactant was administered via the endotracheal route, and the infant was placed on a mechanical ventilator. An UVC was placed, a blood culture was performed, CBC was performed, and ampicillin (50 mg/kg/dose IV every 12 hours) plus gentamicin (5 mg/kg/dose IV every 48 hours) therapies were empirically initiated. The antibiotics were discontinued on the third DOL after a negative blood culture result. The patient was extubated to continuous positive airway pressure on DOL 5. A brain ultrasonography showed a grade III intraventricular hemorrhage. On DOL 6, the baby developed apnea and lethargy; treatment with cloxacillin (50 mg/kg/dose IV every 12 hours) and amikacin (15 mg/kg/dose IV every 36 hours) was initiated for suspected sepsis. The WBC and PLT counts were 2.72 × 10^9/L and 74 × 10^9/L, respectively, while the proportions of neutrophils and lymphocytes were 28.3% and 52.6%, respectively. A CRP measurement was not obtained. On DOL 8, the blood culture was positive for *S epidermidis* with a vancomycin minimum inhibitory concentration (MIC) of 2 mg/L. The culture was sensitive to vancomycin, linezolid, rifampicin, and daptomycin and resistant to oxacillin. Thus, the UVC was removed, and the antibiotics were switched to linezolid (10 mg/kg/dose IV every 8 hours) and piperacillin-tazobactam (100 mg/kg/dose IV every 12 hours). Repeated blood cultures on DOL 10 and 14 continued to be positive for *S epidermidis*. However, the clinical picture of the patient was unstable. Therefore, the infectious disease team suggested to continue piperacillin-tazobactam therapy for 6 days, which was then discontinued, followed by linezolid for 8 days. On DOL 16, linezolid

Table 1. Clinical Course of Neonate Described in Case 1

Day of Life	Culture	Organism	Vancomycin MIC, mg/L	Antimicrobial Sensitivity	Antimicrobial Resistance	Antibiotic
1	Blood (central) Tracheal	No growth *Klebsiella pneumoniae* ESBL				Ampicillin and gentamicin for 3 days
4	Blood (central)	No growth				Linezolid and meropenem for 2 days
6	Blood (central)	No growth				Meropenem for 8 days
8	Blood (central, peripheral)	*Staphylococcus hominis*	2	Vancomycin, linezolid, daptomycin	Cloxacillin, rifampicin, gentamicin	No change
14	Blood (central, peripheral)	*Staphylococcus epidermidis*	2	Vancomycin, linezolid, daptomycin, rifampicin	Cloxacillin, gentamicin	Linezolid for 7 days
16	Blood (peripheral)	*S epidermidis*	1	Vancomycin, linezolid, daptomycin	Cloxacillin, rifampicin, gentamicin	No change
21	Blood (peripheral) Tracheal Urine CSF	*Staphylococcus capris* *S epidermidis* *K pneumoniae* ESBL No growth No growth	1 1	Vancomycin, linezolid, daptomycin, rifampicin	Cloxacillin, gentamicin	Vancomycin and meropenem for 16 days
23	Blood (peripheral)	*S hominis*	1	Vancomycin, linezolid, daptomycin, rifampicin	Cloxacillin, gentamicin	No change
25	Blood (peripheral)	*Staphylococcus simulans*	1	Vancomycin, linezolid, daptomycin, rifampicin	Cloxacillin, gentamicin	No change
27	Blood (peripheral)	*S simulans*	1	Vancomycin, linezolid, daptomycin, rifampicin	Cloxacillin, gentamicin	No change
29	Blood (peripheral)	*S epidermidis*	1	Vancomycin, linezolid, daptomycin, rifampicin	Cloxacillin, gentamicin	No change
31	Blood (peripheral)	*S capris*	2	Vancomycin, linezolid, daptomycin, rifampicin	Cloxacillin, gentamicin	No change
34	Blood (peripheral)	*S epidermidis*	1	Vancomycin, daptomycin, rifampicin	Cloxacillin, gentamicin, linezolid	No change

(*Table cont. on page 511*)

Table 1. Clinical Course of Neonate Described in Case 1 *(cont.)*

Day of Life	Culture	Organism	Vancomycin MIC, mg/L	Antimicrobial Sensitivity	Antimicrobial Resistance	Antibiotic
37	Blood (peripheral)	*S epidermidis*	1	Vancomycin, linezolid, daptomycin, rifampicin	Cloxacillin, gentamicin	Daptomycin and linezolid for 3 days
40	Blood (peripheral)	*S epidermidis* *Staphylococcus lentus*	1	Vancomycin, linezolid, daptomycin, rifampicin	Cloxacillin, gentamicin	Daptomycin and linezolid and rifampicin for 6 days
44	Blood (peripheral)	*S lentus*	1	Vancomycin, linezolid, daptomycin, rifampicin	Cloxacillin, gentamicin	No change
46	Blood (peripheral)	No growth				Ceftaroline and linezolid for 2 days

CSF, cerebrospinal fluid; ESBL, extended-spectrum beta-lactamase; MIC, minimum inhibitory concentration

was switched to daptomycin (10 mg/kg/dose IV every 24 hours) owing to persistent *S epidermidis* infection. The laboratory results were as follows: WBC and PLT counts, 9.75 × 10^9/L and 257 × 10^9/L, respectively; neutrophils, 72.6%; and lymphocytes, 17.1%. On DOL 20, rifampicin was started (10 mg/kg/dose IV every 12 hours) owing to a high antimicrobial MIC (*S epidemidis* MIC of 2) and a persistent positive blood culture result. Daptomycin and rifampicin were continued for an additional 3 days. However, vancomycin (15 mg/kg/dose IV every 6 hours) was started with rifampicin on DOL 23 owing to the unavailability of daptomycin. The serum vancomycin trough concentration was 16 mcg/mL (therapeutic goal: 10–20 mcg/mL). In spite of this, the repeated culture was positive for *S epidermidis*; the CBC showed WBC and PLT counts of 11.38 × 10^9/L and 43 × 10^9/L, respectively; 65.4% neutrophils; and 20.4% lymphocytes. On DOL 26 and after 3 days of vancomycin initiation, ceftaroline (6 mg/kg/dose IV every 8 hours) was added to the treatment regimen. The CBC showed a WBC count of 2.6 × 10^9/L and a PLT count of 22 × 10^9/L. Repeated cultures on DOL 28 and 31 remained positive for *S epidermidis*. On DOL 36, the baby was shifted to nasal cannula. Repeated blood culture tests showed no bacterial growth, and the WBC and PLT counts were 7.48 × 10^9/L and 72 × 10^9/L, respectively. Table 2 shows the responsible organisms with susceptibilities and concurrent antibiotic regimens. No impairment in renal or liver functions were noticed during therapy. Figure 2 presents the trend of WBC, PLT, and creatinine from admission until discharge. On DOL 48, the nasal cannula was removed. The infant was discharged at the corrected age of 39 weeks, weighing 1790 g.

Discussion

This report describes 2 unique cases of infants who were treated with ceftaroline (6 mg/kg/dose IV every 8 hours) for persistent CoNS infections in extremely premature neonates.

Gram-positive organisms, including CoNS, remain the leading causative organisms of late-onset sepsis in premature infants.[5] The incidence of CoNS in the NICU is around 30% to 45%, and *S epidermidis* is reported as the most common causative organism.[6,7] Increasing antibiotic resistance during the treatment of invasive Gram-positive bacteria will accelerate the chances of antibiotic treatment failures.[8–10] Thus the management of these infections, especially in extremely premature infants, may be challenging for health care providers owing to the limited therapeutic options. While vancomycin remains the drug of choice for the treatment of severe CoNS infections, its use in neonates remains limited owing to fluctuations in the pharmacokinetics, the need for therapeutic drug monitoring, and reported treatment failures.[11] Hence, identifying alternative medications for the treatment of CoNS is critical. Linezolid and daptomycin are the currently available options.[9,10,12] The safety and efficacy of daptomycin in neonates and infants are limited, and linezolid is not recommended for endocarditis infections because of its bacteriostatic effects.[9,10,12,13] Therefore, ceftaroline may be a promising option owing to its bactericidal effects. Ceftaroline is the

Table 2. Clinical Course of Neonate Described in Case 2

Day of Life	Culture	Organism	Vancomycin MIC, mg/L	Antimicrobial Sensitivity	Antimicrobial Resistance	Antibiotic
1	Blood (central)	No growth				Ampicillin and gentamicin for 3 days
6	Blood (central)	*Staphylococcus epidermidis*	2	Vancomycin, linezolid, daptomycin	Gentamicin, cloxacillin	Amikacin and cloxacillin for 2 days
8	Blood (central)	*S epidermidis*	1	Vancomycin, linezolid, daptomycin, rifampicin	Gentamicin, cloxacillin	Linezolid and piperacillin-tazobactam for 6 days
10	Blood (peripheral)	*S epidermidis*	1	Vancomycin, linezolid, daptomycin, rifampicin, gentamicin	Cloxacillin	No change
14	Blood (peripheral)	*S epidermidis*	2	Vancomycin, linezolid, daptomycin, rifampicin, gentamicin	Cloxacillin, clindamycin	Linezolid for 2 days
16	Blood (peripheral)	*S epidermidis*	2	Vancomycin, linezolid, daptomycin, rifampicin, gentamicin	Cloxacillin, clindamycin	Daptomycin for 4 days
18	Blood (peripheral)	No growth				No change
20	Blood (peripheral)	*S epidermidis*	1	Vancomycin, linezolid, daptomycin, rifampicin, gentamicin	Cloxacillin, clindamycin	Daptomycin and rifampicin for 3 days
23	Blood (peripheral)	*S epidermidis*	1	Vancomycin, linezolid, daptomycin, rifampicin, gentamicin	Cloxacillin, clindamycin	Vancomycin and rifampicin for 3 days
26	Blood (peripheral)	*Staphylococcus hominis*	1	Vancomycin, linezolid, daptomycin, rifampicin, gentamicin	Cloxacillin, clindamycin	Vancomycin and ceftaroline for 28 days
28	Blood (peripheral)	*S epidermidis*	1	Vancomycin, linezolid, daptomycin, rifampicin, gentamicin	Cloxacillin,	No change

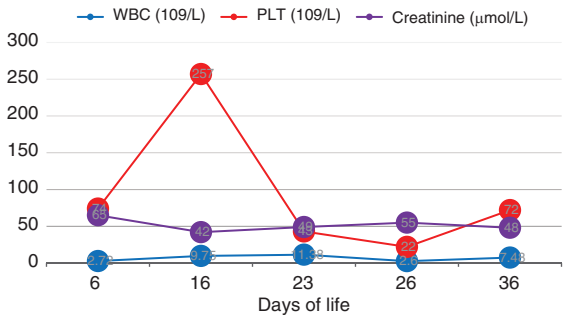
(*Table cont. on page 513*)

Table 2. Clinical Course of Neonate Described in Case 2 *(cont.)*

Day of Life	Culture	Organism	Vancomycin MIC, mg/L	Antimicrobial Sensitivity	Antimicrobial Resistance	Antibiotic
31	Blood (peripheral)	*S epidermidis*	1	Vancomycin, linezolid, daptomycin, rifampicin, gentamicin	Cloxacillin,	No change
36	Blood (peripheral)	No growth				No change
38	Blood (peripheral)	No growth				No change

MIC, minimum inhibitory concentration

Figure 2. Trends of WBC, PLT, and creatinine from admission until discharge.



PLT, platelet; WBC, white blood cell.

active form of ceftaroline fosamil, a parenteral cephalosporin that exhibits time-dependent bactericidal effects. Initially, ceftaroline fosamil was approved by the FDA and the European Medicines Agency for treating CABP and ABSSSIs, including ABSSSIs caused by MRSA, in adults.[10,11] Since 2016, ceftaroline has been approved for treating ABSSSIs and CABP caused by MRSA in infants aged 2 months and older, as well as infections caused by penicillin-resistant and other cephalosporin-resistant *S pneumoniae* isolates, *Haemophilus influenzae*, and non–ESBL-producing Enterobacteriaceae species.[3] The safety, efficacy, and pharmacokinetics of multiple-dose ceftaroline in neonates and very young infants (7 to <60 days of age) with late-onset sepsis were recently reported by reported by Yim et al[14] Bradley et al[15] The authors found that ceftaroline (6 mg/kg every 8 hours) was well tolerated among this population with no safety concerns.[14,15] However, limited data are available on the safety, efficacy, and optimal dosage of ceftaroline in extremely premature (<28 weeks' gestational age) infants. Salerno et al[16] reported the pharmacokinetics of ceftaroline in the treatment of MRSA pneumonia in a premature infant born at <28 weeks' gestational age.[16] A dose of 8.5 mg/kg IV every 8 hours was adequate for achieving the pharmacodynamics endpoint associated with efficacy for MRSA. Recently, Heger and Al-Sayyad[4] reported the successful treatment of invasive MRSA, using a combination of daptomycin (6 mg/kg/dose IV every 12 hours) and ceftaroline (8 mg/kg/dose IV every 8 hours) in a premature neonate with a liver abscess.

In our NICU, the selection of optimal antibiotics for the treatment of empirical and proven sepsis (initiation, duration, and discontinuation) depends on an interprofessional team approach involving infectious disease experts, senior clinical pharmacists, and neonatologists. Several factors, such as the source of infection, antibiotics used, antimicrobial sensitivity results, bacterial outbreak, presence of persistent infections, hemodynamic stability of the patient, status of the laboratory tests before treatment, pharmacokinetic properties of the medication, and availability of the medication, are taken into consideration. According to our NICU guideline, ampicillin and gentamicin are provided as the first-line treatment for early-onset sepsis, whereas amikacin and cloxacillin are used for late-onset sepsis. The patient may develop new symptoms of sepsis even if the preliminary blood culture results are negative. Therefore, the physician initiates broad-spectrum antibiotics, such as cefotaxime, meropenem, and vancomycin. In addition, a stewardship program team reviews the patient's medications frequently and adjusts the treatment course according to the culture results, clinical conditions, and other laboratory results.

This report highlights 2 cases with brief follow-up periods until discharge or death, in which ceftaroline was administered alongside other antibiotics to enhance its effectiveness. It suggests that ceftaroline may show increased efficacy when used in combination with other antibiotics, although further studies are needed to investigate this potential. The level of the medication in the serum was not measured, so the need for dose adjustments based on the serum concentration remains unknown. To the best of our knowledge, this is the first

report describing the use of ceftaroline in premature neonates with persistent bloodstream infections.

Conclusion

Based on our findings, ceftaroline (6 mg/kg/dose IV every 8 hours) appears to be a potential treatment option for persistent CoNS infection with high antimicrobial MIC in the extremely premature neonatal population. However, large, well-designed, and prospective studies investigating the safety, efficacy, and pharmacokinetic characteristics of ceftaroline in premature infants are warranted.

Article Information

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