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Review Article

Ceftaroline fosamil in the treatment of methicillin-resistant *Staphylococcus aureus*

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ABSTRACT

Ceftaroline fosamil, a cephalosporin approved by the FDA for treating infections caused by methicillin-resistant *Staphylococcus aureus* (MRSA). *Staphylococcus aureus*, particularly MRSA strains, poses a significant health risk due to antibiotic resistance. Ceftaroline fosamil is unique in its ability to bind to penicillin-binding protein 2a (PBP2a) found in MRSA, inhibiting bacterial cell wall synthesis and causing bacterial death. The pharmacokinetics of ceftaroline involve rapid conversion to its active form, primarily excretion through the kidneys, and a plasma protein binding rate of approximately 20%. Ceftaroline is effective against complex skin and soft tissue infections (cSSTIs) and community-acquired pneumonia (CAP), especially when MRSA is suspected. However, its efficacy against gram-negative bacteria is limited. The safety profile of ceftaroline fosamil is generally good, with reported adverse events comparable to other comparator agents in clinical trials. It is contraindicated in individuals with hypersensitivity to cephalosporins. Comparative efficacy with other antibiotics like vancomycin and daptomycin is discussed, emphasizing the importance of considering individual patient characteristics and local prevalence of resistant bacteria. The use of ceftaroline fosamil in special populations, such as pediatric and adult patients. While its efficacy in pediatric MRSA infections is explored, the lack of large-scale clinical trials for certain conditions like MRSA bacteremia is acknowledged. Clinical outcomes, including successful treatment of MRSA bacteremia, infective endocarditis, central nervous system infections, and nosocomial pneumonia, are discussed, suggesting ceftaroline fosamil's potential as a valuable therapeutic option. The conclusion underscores its breakthrough status, offering hope in addressing MRSA infections and improving patient outcomes.

Keywords: Ceftaroline fosamil, MRSA, MRSA, Antibiotic, Pneumonia, Antibacterial spectrum, Mechanism of action, Clinical trials, Efficacy, Safety, Tolerability, Treatment options

INTRODUCTION

Gram-positive, spherical-shaped, non-motile, non-spore-forming bacteria called *Staphylococcus aureus*, some strains of which are capsule-like. Due to the release of the penicillinase enzyme, the majority of the strains of *Staphylococcus aureus* (*S. aureus*) (94%) exhibit pronounced resistance to penicillin and its derivatives. MRSA, sometimes known as MRSA, is one kind of *S. aureus*. By using PCR to detect the mecA gene and cefoxitin resistance, it is possible to diagnose methicillin resistance clinically. The penicillin-binding protein (PBP-2A), which causes this kind of antimicrobial resistance, is mostly encoded by the mecA gene.[1] MRSA is a historically emerging zoonotic pathogen of public and veterinary relevance. *Staphylococcus aureus* is a severe health risk to human beings as well as animals and is able to withstand harsh environmental factors including direct sunlight and desiccation.[2] MRSA is invariably multidrug-resistant, not only to penicillin but also to a variety of

other antibiotic classes such as macrolides, fluoroquinolones, aminoglycosides, tetracyclines, and lincosamides. MRSA has the potential to cause serious infectious disorders in humans, such as pyogenic heart disease, suppurative pneumonia, acute otitis media osteomyelitis and infection of the skin and soft tissue, and septic arthritis. A notable public health issue is the spread of MRSA strains that are drug-resistant and virulent.[3]

The US food and drug administration (FDA) approved ceftaroline, an intravenous bactericidal cephalosporin, in 2010 to be used in the management of acute skin and skin-structure infections (ABSSSI) spurred on by susceptible microorganisms such as MRSA. It is also licensed for the treatment of community-acquired bacterial pneumonia (CABP), which includes patients with concomitant bacteremia caused by susceptible microbes other than MRSA.[4] MRSA is a major public health problem that causes severe community and health-care-associated illnesses each year. Bloodstream infections (BSI) caused by MRSA can result in mortality rates of up to 57%.[5]

THE EMERGENCE OF CEFTAROLINE FOSAMIL

Ceftaroline fosamil is a prodrug form of a new semi-synthetic broad-spectrum cephalosporin. It exhibits bactericidal activity against MRSA, multidrug-resistant Streptococcus pneumoniae, and some Gram-negative organisms. What sets ceftaroline fosamil apart from other cephalosporins is its ability to bind to a specific protein called penicillin-binding protein 2a (PBP2a), which is found in MRSA strains. This unique mechanism of action makes it highly effective against MRSA infections.[2]

In vitro studies have demonstrated the activity of ceftaroline against both methicillin-susceptible and methicillin-resistant isolates of *S. aureus*, including strains with reduced susceptibility to vancomycin or linezolid. It has also shown potent activity against *Streptococcus pyogenes*, *Streptococcus agalactiae*, and *Streptococcus pneumoniae*. However, its activity against Gram-negative pathogens is limited, with no efficacy against extended-spectrum β-lactamase (ESBL)-producing or the AmpC-overexpressing *Enterobacteriaceae*.[6]

PHARMACOKINETIC

When administered intravenously, it is rapidly metabolized to the active form of ceftarine. Plasma protein binding~20%, plasma elimination half-life ~2.5 hours. Ceftaroline is primarily excreted via the kidneys ~88% is excreted in the urine. Dose adjustment required in patients with CrCl ≤ 50 mL/min. The pharmacokinetics of ceftaroline were similar in healthy older adults (65 years and older) and healthy young adults (18-45 years).[7]

The prodrug ceftaroline fosamil is rapidly converted to the active form ceftarine after intravenous administration. Ceftaroline exhibits consistent pharmacokinetics with increasing doses between 50 and 1000 mg, resulting in proportional increases in max plasma concentration (Cmax) and area under concentration-time curve (AUC).In healthy adult men, single intravenous dose of 600 mg of radiolabelled ceftaroline fosamil resulted in a mean steady-state volume of distribution of ceftaroline of 20.3 L. Ceftaroline has plasma protein binding rate of approximately 20%, an elimination half-life of 2.5 h and is primarily excreted from body through kidneys. Portion is converted to inactive metabolite ceftaroline-M1.[7]

Antimicrobial activity

Ceftaroline has broad-spectrum antibacterial activity, making it effective against many types of bacteria. Important points regarding antibacterial activity are Ceftaroline is particularly effective against Gram-positive bacteria such as MRSA, *Streptococcus pneumoniae*, and *Streptococcus pyogenes*.[8]

Its unique ability to bind to PBP2a of MRSA makes it valuable in the treatment of MRSA infections. Ceftaroline is also active against some gram-negative bacteria, such as *Escherichia coli*, *Haemophilus influenzae*, and *Klebsiella pneumoniae*. However, they are generally more effective against gram-positive bacteria. Used to treat complex skin and soft tissue infections and CAP that may involve a combination of gram-positive and gram-negative pathogens.[9]

Mechanism of action

Ceftaroline, potent bactericide, stands out among cephalosporins due to its unique mechanism of action, which targets a wide range of gram-positive and some gram-negative bacteria.[2] By binding to penicillin-binding proteins (PBPs), such as PBP2a, found in MRSA, it inhibits bacterial cell wall synthesis, disrupting its structural integrity and causing bacterial death. Its effectiveness extends to a variety of pathogens, including *Streptococcus pneumoniae*, *Streptococcus pyogenes*, MRSA, *E. coli*, *Haemophilus influenzae*, and *Klebsiella pneumoniae*. Ceftaroline's primary uses include complex skin and soft tissue infections and CAP. Despite its effectiveness, modification of the PBP binding site can cause resistance, which may limit its usefulness.[10,11]

Structure and chemistry

Ceftaroline has an additional 1,3-thiazole ring in its structure, which increases its effectiveness against Gram-positive bacteria such as MRSA. Its bactericidal action is based on inhibition of bacterial cell wall synthesis by binding to penicillin-binding proteins (PBPs), particularly PBP2a (associated with MRSA resistance) and PBP2x (associated with penicillin-resistant *Streptococcus pneumoniae*).[10] The unique structure of ceftaroline, particularly the oxime of the 1,3-thiazole ring at the 3-

position and the acyl group at the 7-position, contributes to the efficacy of ceftaroline against MRSA.

Furthermore, the presence of the 1,2,4-thiadiazole ring increases the affinity for transpeptidase enzymes, allowing entry of Gram-negative bacteria. Upon administration, ceftaroline fosamil, a prodrug form that contains a phosphono group to increase water solubility, is converted to the active metabolite ceftaroline, which lacks the phosphono group found in the prodrug.[8]

EFFICACY AND EFFECTIVENESS

Ceftaroline uniquely targets PBP2a in MRSA and therefore exhibits high activity against Gram-positive bacteria, particularly MRSA, *Streptococcus pneumoniae*, and *Streptococcus pyogenes*.[8]

Although it has some activity against certain Gram-negative bacteria such as *E. coli*, *Haemophilus influenzae*, and *Klebsiella pneumoniae*, its main strength lies in its fight against gram-positive bacteria. Therefore, it may not be the first choice for the treatment of gram-negative infections. Its effectiveness in complex skin and soft tissue infections (cSSTIs), particularly when MRSA is suspected, is well documented based on clinical studies and real-world use.[12]

In addition, ceftaroline is also used in CAP, including when MRSA is suspected. However, the efficacy of ceftaroline may be influenced by factors such as the local prevalence of resistant bacteria and individual patient characteristics. Healthcare, providers must evaluate the specific clinical scenario and potential pathogens to determine the most appropriate antibiotic treatment. As with other antibiotics, judicious use of ceftaroline is important to prevent antibiotic resistance. Before considering use, it is important to consult your doctor for a proper diagnosis and treatment plan.[9,13]

SAFETY AND TOLERABILITY OF CEFTAROLINE

In extensive phase 3 clinical trials, ceftaroline fosamil exhibited overall good tolerability with no unexpected safety issues.[14-16] Adverse events in patients aged ≥65 years and <65 years were similar, and ceftaroline fosamil demonstrated a safety profile comparable to the comparator agents, ceftriaxone, and vancomycin plus aztreonam in the trials.[15,17] Allergic reactions to cephalosporins, including rash, urticaria, serum sickness, and anaphylaxis, are commonly reported at frequencies ranging from 1% to 3% in large patient populations. In phase 3 studies of ceftaroline, rash occurred in 3% of patients, and urticaria and anaphylaxis were infrequently reported.[15,17] All cephalosporins, including ceftaroline, have been associated with a positive Coombs' test, with varying frequencies. In phase 3 trials, approximately 11% of patients treated with ceftaroline and 4.4% with comparators exhibited a positive Coombs' test, but none experienced hemolytic anemia.[15-17]

Ceftaroline fosamil is contraindicated in patients with a history of hypersensitivity to cephalosporins and those with a history of immediate and severe hypersensitivity, such as anaphylactic reactions, to other beta-lactam antibacterial agents like penicillins or carbapenems.[14]

The clinical safety of ceftaroline at doses higher than those recommended by the FDA is currently unknown. However, initial investigations in healthy subjects have not identified any serious adverse events.[15]

COMPARATIVE EFFICACY OF VAN-DAP AND CEFTAROLINE

Comparative efficacy of vancomycin-daptomycin (VAN-DAP) as well as ceftaroline summarized in the Table 1 below.

Table 1: Comparative efficacy of VAN-dap and ceftaroline

Criteria	VAN	DAP	Ceftaroline
Mechanism of action	Vancomycin (VAN) hinders microbial activity by impeding cell wall synthesis. It binds to the D-Ala-D-Ala residue of C-terminal, obstructing cross-bridging and leading to the inhibition of peptidoglycan formation.[10]	Daptomycin (DAP) swiftly kills bacteria by disrupting their cell envelope. Acting faster than other antibiotics, daptomycin attaches to the cell membrane through a calcium-dependent mechanism, causing membrane disruption, release of the intracellular ions, and the rapid cell death.[10]	Ceftaroline demonstrates broad-spectrum effectiveness against both gram-positive and gram-negative bacteria by binding to essential penicillin-binding proteins (PBPs), including PBP2 for *S. aureus* and PBP2x for *Streptococcus pneumoniae*[10,19]
Adverse effects	Acute kidney injury (AKI), agranulocytosis, anaphylaxis, ototoxicity, thrombocytopenia, neutropenia and the hypotension[10,20]	Rhabdomyolysis, renal failure, muscle pain, or weakness, pulmonary eosinophilia[10,20]	Hypersensitivity, anaphylaxis, eosinophilia, *Clostridium difficile* infections, agranulocytosis, and leukopenia.[10,20]

Continued.

Criteria	VAN	DAP	Ceftaroline
Pharmacokinetics	Vancomycin is recommended for intravenous administration, avoiding intramuscular injection due to associated pain. About 30% of vancomycin binds to plasma proteins. Approximately 90% of a vancomycin dose is excreted through glomerular filtration, with an elimination half-life of around 6 hours in individuals with normal renal function. Hemodialysis can effectively remove the drug from plasma.[21]	Daptomycin is recommended for intravenous administration due to poor oral absorption and muscle toxicity, precluding intramuscular injection. Its serum half-life allows for once-daily dosing, with approximately 80% of the dose excreted in urine. In cases of low creatinine clearance (<30 mL/min), dosing frequency is adjusted to every 48 hours. For patients undergoing hemodialysis, dose should be administered immediately after dialysis session.[21]	The main route of elimination for ceftaroline is through the kidneys, and it has a half-life of around 2 hours. Ceftaroline exhibits minimal protein binding, approximately 20%, and is known for extensive distribution throughout most tissues. However, its penetration into the cerebrospinal fluid (CSF) has not been thoroughly characterized at this point.[21]
Therapeutic uses	Cutaneous and subcutaneous infections, bloodstream infections and inflammation of the heart valves caused by gram-positive bacteria. Pneumonia meningitis colitis caused by *Clostridium difficile*, treated with an oral formulation. Prophylactic use for surgery in procedures at high risk of MRSA infection.[21]	Cutaneous and sub cutaneous infection Bacteremia caused by Staphylococcal and Streptococcal infections. Infections caused by enterococcal bacteria that are resistant to vancomycin[21]	Complicated skin and soft tissue infection, community-acquired pneumonia[14,15]

SPECIAL POPULATION

Pediatrics

Ceftaroline fosamil was introduced in 2016 in pediatric patients aged 2 months to 18 years, particularly for acute bacterial skin and skin structure infections (ABSSSI) caused by methicillin-susceptible *Staphylococcus aureus* (MSSA) and MRSA.[11]

It has been approved by the FDA as a treatment (MRSA). Additionally, it is approved by the MSSA for community-acquired bacterial pneumonia (CABP). Although community-acquired MRSA first emerged in children in the United States, clinical trials for pediatric MRSA infections are lacking. Despite the limited number of cases, several studies have investigated the efficacy of ceftaroline in pediatric MRSA infections. In particular, Korczowski et al and Bloomer et al conducted a study focusing on ABSSSI and complex CABP, respectively. Their results showed variable clinical success rates. Blumer et al report his 50% success and 89% reported. Case reports document bacterial clearance and significant clinical improvement when added to ceftaroline in pediatric patients with persistent MRSA-related infections unresponsive to vancomycin or daptomycin. These findings highlight the need for further randomized controlled trials with larger numbers of patients to better understand the efficacy of ceftaroline in pediatric MRSA infections.[8,11]

Adult

An extensive literature review shows that there is a lack of randomized controlled trials evaluating ceftaroline for MRSA bacteremia (MRSAB). *In vitro* studies, particularly his 2010 AWARE study, have demonstrated efficacy of ceftaroline against MRSA isolates collected from various medical centers in US.[12] However, according to 2011 infectious diseases society of America (IDSA) MRSA guidelines, VAC/DAP remains main treatment for complicated and uncomplicated MRSAB. Additionally, studies of ceftaroline in gram-positive osteomyelitis, endocarditis, and *in vitro* synergy with daptomycin suggest promising clinical results, but further studies with larger sample sizes are needed. A report describes *in vitro* synergy between ceftaroline and daptomycin, indicating the potential for more rapid clearance of *Staphylococcal* bacteremia. Studies investigating combination therapy suggest that duration of bacteremia is shorter, especially when ceftaroline is used as 2nd line therapy, but mortality rates remain variable. Questions remain regarding the optimal combination, the role of ceftaroline in refractory cases, and its clinical and microbiological superiority, requiring further investigation and large-scale clinical trials.[8]

CLINICAL OUTCOMES OF CEFTAROLINE IN MRSA INFECTIONS

MRSA bacteremia and infective endocarditis

Multiple case series and retrospective reviews have demonstrated the effectiveness of ceftaroline in the treatment of MRSA bacteremia and infective endocarditis (IE). For instance, Ho et al reported a series of six patients with MRSA bacteremia or IE that were refractory to vancomycin or daptomycin therapy. Ceftaroline treatment resulted in complete sterilization of blood cultures in five patients and clinical cure in four patients.[22] Similarly, Lin et al described ten patients with MRSA IE, pneumonia, and bone and joint infections who were treated with ceftaroline. Six of these patients achieved complete clinical cure, while three died due to comorbidities.[23]

Central nervous system infections

In the treatment of MRSA infections of the central nervous system (CNS), ceftaroline has shown promising results. A case report by Kuriakose et al described the successful use of ceftaroline in the treatment of MRSA meningitis associated with a ventriculoperitoneal shunt. The patient showed clinical improvement after 24 days of ceftaroline therapy, and cerebrospinal fluid cultures were cleared upon shunt removal.[15] Another case report by Balouch et al documented the successful treatment of MRSA meningitis with ceftaroline and rifampin combination therapy.[24]

Nosocomial pneumonia

Ceftaroline has also been evaluated for treatment of nosocomial pneumonia caused by MRSA. In retrospective review of 12 patients with MRSA nosocomial pneumonia, Kaye et al reported a clinical cure rate of 58.3%.[25] Similarly, Pasquale et al described a case series of 10 patients with MRSA nosocomial pneumonia treated with ceftaroline, with a clinical cure rate of 60%.[26] These studies suggest that ceftaroline may be an effective alternative therapy for MRSA nosocomial pneumonia, particularly in cases where other antibiotics have failed.

Combination therapy with daptomycin

Combination therapy with daptomycin has been explored as a potential treatment strategy for difficult cases of MRSA infections. Several case reports have demonstrated the efficacy of ceftaroline-daptomycin combination therapy in the treatment of MRSA bacteremia and IE. In a case series of 26 patients with *Staphylococcal* bacteremia, Sakoulas et al reported a clinical success rate of 96% with the combination of ceftaroline and daptomycin.[27] Additionally, Rose et al described a case of MRSA IE treated with combination of ceftaroline and daptomycin, resulting in complete clearance of blood cultures and clinical cure.[28] These findings highlight the potential synergistic effects of ceftaroline and daptomycin in treatment of MRSA infections.

CONCLUSION

Ceftaroline fosamil represents a breakthrough in the treatment of MRSA infections, particularly in the context of limited treatment options and emerging resistance. Its unique mechanism of action, broad-spectrum activity, and favorable safety profile make it an attractive choice for the management of MRSA-related infections, including complicated skin and skin structure infections, community-acquired pneumonia, and potentially other severe MRSA infections. Further research and clinical trials will provide additional insights into the efficacy and optimal use of ceftaroline fosamil in the treatment of MRSA. With its promising potential, ceftaroline fosamil offers hope in the battle against MRSA and the improvement of patient outcomes.

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