Retrospective Multi-Centre Experience of the Effectiveness and Safety with Ceftaroline Fosamil Therapy in Patients with Acute Bacterial Skin and Skin Structure Infections

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ECCMID 2014
eP422

Introduction

- Ceftaroline fosamil (CPT), is an advanced generation cephalosporin with bactericidal activity against Gram-positive and Gram-negative bacteria, including methicillin-resistant *Staphylococcus aureus* (MRSA)
- There is limited data regarding the use of CPT outside of FDA approved indications of acute bacterial skin and skin structure infections (ABSSSI)
- Objective of this study was to describe the outcomes of patients treated with CPT and ABSSSI such as off-label dosing and various types of ABSSSI

Materials and Methods

- A multi-centre, retrospective observational analysis conducted from January 2011 to December 2013
- Included consecutive adult patients with a ABSSSI treated with CPT for ≥72h during hospitalization
- Clinical data was collected from medical records
- Outcome assessments of clinically evaluable patients included documentation at end of CPT therapy
- Clinical Success: resolution of all signs/symptoms of infection with no further need of antibiotic treatment while on CPT
- Additional outcomes assessed were adverse events, readmission, and mortality
- SPSS, version 22.0 (IBM, SPSS Inc., Chicago, IL) was used to performed descriptive statistics such as data frequencies and distributions

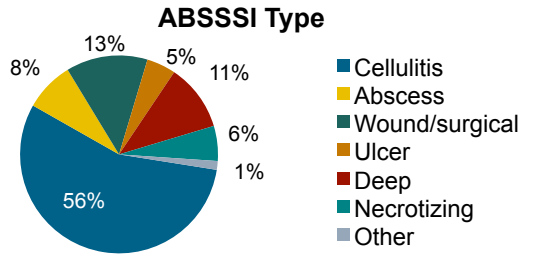
Patient Characteristics

- Over three years, 554 patients received CPT; 210 (40%) were for ABSSSI and were included for evaluation

Variable	Median (IQR) or n (%)
Age (years)	60 (49-72)
APACHE II score	10 (7-14)
Weight (kg)	85.6 (72.2-110.6)
ICU admission	45 (21%)
Diabetes	90 (43%)
Renal Disease	68 (32%)
Prior Hospitalization	112 (53%)

Disclosures: No Financial support was received for the conduct of this study.

Infection and Treatment Characteristics



- 13 (6%) had concomitant *S. aureus* bacteremia
- The most common reason for CPT use was clinical worsening on previous therapy (90, 43%), followed by risk for/evidence of adverse effects (64, 30%), and prescriber preference for simplification or empiric MRSA coverage (28, 13% each)

Antimicrobial Therapy

- 73% (164/210) were give another antibiotic prior to CPT
  - 76% (125/164) was vancomycin
- Median time to switch to CPT was 2 days IQR (0-4)
- Median duration of CPT therapy was 5 days IQR (3-7)
- 22% (46/210) received another agent in combination
- 8% (16/210) received CPT at doses higher than the FDA-labeled dose as adjusted for renal function

Microbiology

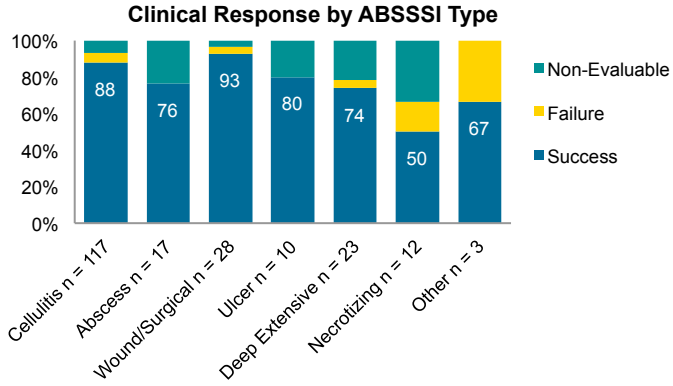
- Positive cultures were documented in 44% (92/210)

Pathogens	n = 92
Staphylococcus aureus	69 (75%)
Methicillin-resistant *S. aureus*	55/69 (80%)
Streptococcus spp.	16 (17%)
Coagulase-Negative *Staphylococcus* spp.	6 (7%)
Other Gram-positive organisms	5 (5%)
Klebsiella pneumoniae	9 (10%)
Escherichia coli	7 (8%)
Other Gram-negative organisms	7 (8%)

- 12% (25/210) were polymicrobial
- 18 *S. aureus* isolates had CPT MIC data available:
  - 0.38mg/L in 1 isolate, 0.5mg/L in 8, 0.75mg/L in 6 and 1mg/L in 3

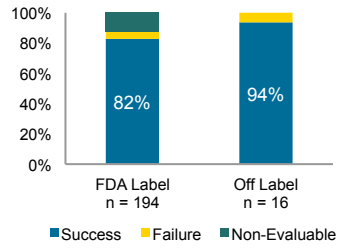
Patient Outcomes

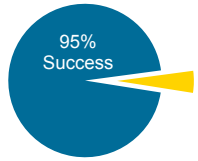
- Among 186 clinically evaluable patients, 175 (94%) achieved clinical success; clinical response varied by ABSSSI type.



- 5% (11/210) of patients experienced an adverse event
  - Renal insufficiency was commonly reported
- All cause hospital mortality was 3% (7/210)
- Overall, 30 day all cause mortality rate was 5% (10/210)
- 30-day readmission rate was 4% (7/200)

Subset Analyses





13/69 (19%) had concomitant bacteremia; clinical success observed in 12 of 13

Conclusions

- CPT is safe and effective for complicated ABSSSI including those with concomitant *S. aureus* bacteremia
- Further research is necessary in off-label dosing and difficult to treat infections

References: Product Information. Telfaro (ceftaroline fosamil). St. Louis MO: Forest Laboratories Inc. Dec 2013. Corey GR et al. CANVAS 1. J Antimicrob Chemother. 2010 Wilcox MH et al. CANVAS 2. J Antimicrob Chemother. 2010