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Real-world utilization of eravacycline in the outpatient setting

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Background: Eravacycline (ERV) is a fully-synthetic, fluorocycline antibacterial with activity against Gram-negative, Gram-positive aerobic and anaerobic pathogens. ERV was FDA-approved in 2018 for the treatment of complicated intra-abdominal infections in patients ≥18 years of age. Outpatient Parental Antimicrobial Therapy (OPAT) services have been widely adopted across the United States and can offer potential benefits to patients and health-systems. In this study, we describe ERV real-world utilization and evaluate the clinical and safety outcomes in patients treated with ERV in the outpatient setting.

Methods: A multicenter retrospective study included patient treated at OPAT facilities across the United States between October 2018 and February 2020. Patients who received ≥1 dose(s) of ERV were included. Data captured patient demographics, comorbidities, risk factors, diagnosis, baseline pathogens, and ERV regimen. Outcomes and adverse events (AE) were collected. The primary objective was to describe the clinical utilization of ERV in the real-world outpatient setting. Secondary objectives were to evaluate clinical, microbiological and safety outcomes of patients treated with ERV using pre-defined criteria.

Results: 19 patient cases were collected from OPAT facilities. Patient demographics consisted of 57.9% (11/19) male, median age 56 (range, 31-80) years, mean weight 110.1 (range, 57-216) kg and mean Charlson Comorbidity Index of 3 (range, 0-8). 94.7% (18/19) of patients had comorbid conditions and 68.4% (13/19) had risk factors for resistant organisms attributed to recent hospitalization and antibiotic exposure. Sources of infection were intra-abdominal (10/19), skin and soft tissue (6/19) and other (3/19). 15 baseline pathogens were reported in 10 patients, most commonly *Enterococcus* spp. (n=3), methicillin-resistant *Staphylococcus aureus* (n=2), *Escherichia coli* (n=2) and *Acinetobacter baumannii*

(n=2). Mean ERV duration was 24 (range, 4-73) days and 89.5% (17/19) of patients received antimicrobial therapy prior to ERV. ERV was administered at 1 mg/kg q12hr or 1.5 mg/kg q24hr in 10/19 and 9/19 patients, respectively. Clinical cure, defined as complete resolution of signs and symptoms with no additional antibiotics required end of ERV therapy, was achieved in 12/19 (63.2%) cases; 1/19 (5.2%) had clinical improvement. There were 6/19 (31.6%) with clinical failure, including 3 who discontinued ERV due to AEs. Overall, 4/19 (21%) patients experienced AEs, most commonly were GI-related events and rash. Notably, no cases of *Clostridioides difficile* infection were reported.

Conclusions: Clinical cure was achieved in the majority of ERV treated patients and was generally well-tolerated. Additional investigation is warranted to fully determine the potential benefits of ERV in this treatment setting.

OR = Original Research