Evaluation of Patients with Complicated Intra-abdominal Infections (cIAI) and Concomitant Bacteremia (CB) from IGNITE1: A Phase 3 study to Evaluate the Efficacy and Safety of Eravacycline (ERV) versus Ertapenem (ETP) in Complicated Intra-abdominal Infections (cIAI)

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Abstract

Introduction

Complicated intra-abdominal infection (cIAI) is a common problem, affecting 400,000 patients/year. The management of cIAI involves surgical removal of the focus and decontamination (decompression) with antimicrobial therapy. Empiric treatment of cIAI reflects a clinical challenge because of the polymicrobial infecting flora and the emergence of antibiotic resistance in multiple clinical situations. Furthermore, bacteria can occur in >30% of patients and management of this aspect is also a concern. Major pathogens are commonly acquired and include Escherichia coli, Klebsiella, Enterobacter spp., Proteus spp., Proteus vulgaris, Proteus mirabilis, and Pseudomonas aeruginosa. The flora varies (unrelated to the source of healthcare-associated cIAI). In previous studies that have monitored secondary bacteremia with these pathogens, regimens have been identified for antimicrobial actions in order to consider a combination; concurrent bacteremia can be associated with increased mortality.

Methods

Forty (40) subjects in IGNITE1 were coded with bacteremia in the micro-ITT population. Five bacteremia patients were removed from the post-hoc analysis as the blood culture isolates in these subjects were determined to be contaminants.

Results: 294 patients were randomized and 281 were included in the micro-ITT population. The study met criteria for non-inferiority (n=191: 27.7% vs. 28.9%). Differences between the eravacycline and ertapenem groups were not statistically significant for clinical cure, defined as the resolution of the clinical signs and symptoms of infection in the absence of major complications. 54.8% of patients with bacteremia received the combination therapy. 54.6% of patients with bacteremia received antibiotic therapy and had similar outcomes compared to those patients without bacteremia. These data suggest that the presence of concomitant bacteremia in cIAI does not increase treatment failure nor require prolonged antibiotic therapy.

Conclusion: 

Clinical success was defined as the resolution of clinical signs and symptoms of infection in the absence of major complications. The objective of this current study is to report the characteristics, treatment failures, and outcomes of patients with cIAI and concomitant bacteremia from IGNITE1. The study met criteria for non-inferiority (n=191: 27.7% vs. 28.9%). Differences between the eravacycline and ertapenem groups were not statistically significant for clinical cure, defined as the resolution of the clinical signs and symptoms of infection in the absence of major complications. 54.8% of patients with bacteremia received the combination therapy. 54.6% of patients with bacteremia received antibiotic therapy and had similar outcomes compared to those patients without bacteremia. These data suggest that the presence of concomitant bacteremia in cIAI does not increase treatment failure nor require prolonged antibiotic therapy.

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