Characteristics and Outcomes of Complicated Intra-abdominal Infections Involving Pseudomonas aeruginosa

From a Phase 3 Ceftolozane/Tazobactam Study

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ABSTRACT

INTRODUCTION

- Ceftolozane/tazobactam, a novel β-lactam/beta-lactamase inhibitor (β-LA/BLI) combination (TOL/TAZ), was conducted during 2011-2013. (NCT01516899 and NCT01913445)
- Adult patients infected with Pseudomonas aeruginosa and confirmed to harbor a Pseudomonas aeruginosa extended-spectrum β-lactamase (ESBL) were randomized, double-blind, non-inferiority trial in hospitalized patients with cIAIs
- The efficacy and safety of TOL/TAZ in patients with cIAI with baseline P. aeruginosa infection were compared with meropenem (MEM) in the microbiologically evaluable (ME) population
- The primary efficacy endpoint was the clinical eradication of the pathogen, which was defined as a lack of clinical indication for subsequent culture and sensitivity testing is a validated microbiological correlate of clinical success
- The microbiological intent-to-treat (MITT) population included all randomized patients who had a baseline intra-abdominal culture

METHODS

- Ceftolozane was not in clinical development when this study was conducted
- Detailed clinical characteristics and outcomes of patients with cIAI who harbored P. aeruginosa were an analysis of the Phase 3 trial

OBJECTIVES

- To describe the characteristics and clinical outcomes of patients with cIAI who were infected with P. aeruginosa as an analysis of the Phase 3 trial

RESULTS

- The primary endpoint was clinical eradication of P. aeruginosa at baseline (n = 389)
- Patients were randomized to ceftolozane/tazobactam (TOL/TAZ) or meropenem (MEM) (n = 417)
- In the MITT population (n = 806), P. aeruginosa was isolated in 8.9% of patients
- Thirty-day clinical cure was achieved in 74.0% of patients infected with P. aeruginosa
- The clinical cure rate was 74.0% in the TOL/TAZ group and 65.8% in the MEM group

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- None

REFERENCES

4. APACHE II = Acute Physiology And Chronic Health Evaluation II; MITT = microbiological intent-to-treat; SD = standard deviation.

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