DELAFLOXACIN (DLX) IS EFFECTIVE AND WELL-TOLERATED IN TREATMENT OF PATIENTS WITH RENAL IMPAIRMENT WITH ACUTE BACTERIAL SKIN AND SKIN STRUCTURE INFECTIONS (ABSSSI) VERSUS VANCOMYCIN/АЗТРЕОНАМ (VAN/AZ)

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ABSTRACT

INTRODUCTION

Background: DLX is an investigational new-generation fluoroquinolone with a classically extended spectrum of activity compared with VAN/AZ. The objective of this study was to evaluate the efficacy and safety of DLX in the treatment of patients with ABSSSI with renal impairment.

METHODS

Two multicenter, double-blind, double-dummy trials of adults with ABSSSI and renal impairment (NCT 01346025 and NCT 01479004) were conducted. Patients were randomized in US, Europe, Latin America and Asia. 42% were male with mean age 60 years. Of the 1510 patients randomized, 244 patients had renal impairment as calculated by Cockcroft-Gault. 11 of 58 pathogen pairs were resistant to one or both arms. DLX was well tolerated in this study; the most common TEAEs among DLX-treated patients were mild-to-moderate gastrointestinal events.

RESULTS

Overall, the incidence of TEAEs was comparable in the two treatment arms, with the most frequent TEAEs being gastrointestinal events. GI events were the most common TEAE in both treatment arms.

CONCLUSION


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