**ABSTRACT**

**BACKGROUND**

Delafloxacin (DLX) is a broad-spectrum fluoroquinolone that has been approved by the US Food and Drug Administration (FDA) for the treatment of acute bacterial skin and skin structure infections (ABSSSI). CLSI guidelines for the treatment of ABSSSI were recently released and recommend fluoroquinolones as monotherapy first-line agents for the treatment of ABSSSI caused by susceptible Gram-negative organisms.

**AIM**

A comparison of the efficacy and safety of IV DLX monotherapy to that of IV vancomycin + aztreonam (VAN/AZ) combination therapy in patients with ABSSSI caused by designated susceptible bacteria.

**METHODS**

This was a randomized, double-blind, phase III clinical trial conducted in 34 countries. Following enrollment, patients were randomly assigned to receive IV DLX (10 mg/kg, 20 mg/kg, or 40 mg/kg) or IV VAN/AZ (vancomycin 40 mg/kg and aztreonam 2.25 mg/kg) for a minimum of 5 days. The primary efficacy endpoint was the proportion of patients with complete resolution of all signs and symptoms (S&S) at the end of treatment (EOT) or at the first follow-up visit. Secondary endpoints included time to 20% and 100% reduction in signs and symptoms (S&S), lesion size, and pain score. Baseline characteristics such as age, race/ethnicity, sex, and country were balanced among the treatment groups. Baseline demographics, signs, and symptoms were also comparable between treatment groups.

**RESULTS**

Efficacy was evaluated through assessments of the signs and symptoms of clinical response measurement, lesion size, and pain score. A global phase 3 study was conducted to compare the efficacy and safety of IV DLX monotherapy to that of IV VAN/AZ combination therapy in patients with ABSSSI. The primary efficacy endpoint was the proportion of patients with complete resolution of all S&S at the EOT visit. Secondary endpoints included time to 20% and 100% reduction in S&S, lesion size, and pain score. Baseline demographics, signs, and symptoms were also comparable between treatment groups. Baseline characteristics such as age, race/ethnicity, sex, and country were balanced among the treatment groups. Baseline demographics, signs, and symptoms were also comparable between treatment groups.

**CONCLUSION**

Results indicated that DLX monotherapy was as efficacious and safe as VAN/AZ combination therapy for the treatment of ABSSSI caused by specified susceptible bacteria. DLX may be an alternative treatment option for ABSSSI caused by susceptible Gram-negative organisms.

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**REFERENCES**


