Results of a Phase 2 Study of Delafloxacin (DLX) Compared to Vancomycin (VAN) and Linezolid (LNZ) in Acute Bacterial Skin and Skin Structure Infections (ABSSSI)

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Abstract

A randomized, double-blind, Phase 2 study compared the clinical activity of DLX 15 mg/kg IV every 12 hours or 25 mg/kg every 24 hours with IV LNZ (15 mg/kg every 12 hours) or IV VAN (15 mg/kg every 12 hours). Subjects were randomized to DLX, LNZ, or VAN and were assessed for clinical success rate at 14 days following the start of study drug for treatment of ABSSSI in the intent to treat (ITT) population. Treatment arms were similar, with success rates of 71.4%, 81.0%, and 70.4%, respectively. Baseline characteristics were balanced with no statistically significant differences across treatment arms. Baseline pathogens identified were methicillin-resistant Staphylococcus aureus (MRSA) and other gram-positive pathogens. The study included 217 patients, with 71.1% of patients having >30% wound area at baseline. Clinical success rates were similar across treatment arms and there were no treatment-related serious adverse events. The study demonstrated that DLX is a safe and efficacious agent in the treatment of ABSSSI.

Methods

A randomized, multicenter, double-blind, Phase 2 study was conducted to evaluate the clinical efficacy and safety of DLX compared to VAN and LNZ in the treatment of ABSSSI. Subjects were randomized to each group and were assessed for clinical success at 14 days following the start of study drug for treatment of ABSSSI in the intent to treat (ITT) population. Treatment arms were similar with success rates of 71.4%, 81.0%, and 70.4%, respectively. Baseline characteristics were balanced with no statistically significant differences across treatment arms. Baseline pathogens identified were methicillin-resistant Staphylococcus aureus (MRSA) and other gram-positive pathogens. The study included 217 patients, with 71.1% of patients having >30% wound area at baseline. Clinical success rates were similar across treatment arms and there were no treatment-related serious adverse events. The study demonstrated that DLX is a safe and efficacious agent in the treatment of ABSSSI.

Results

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Conclusions

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References