OUTCOMES IN PATIENTS WITH HISTORY OF CARDIAC OR VASCULAR DISEASE (CV) DURING TREATMENT OF ACUTE BACTERIAL SKIN AND SKIN STRUCTURE INFECTION (ABSSI) WITH DELAFLOXACIN (DLX) VS VANCOMYCIN/AZTREONAM (VAN/AZ)

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INTRODUCTION

Delafloxacin (DLX) is an antibiotic-leukocyte permeability mediator (AMP) with potent in vitro activity against Gram-negative and Gram-positive bacteria. DLX has excelled in vitro activity against Gram-positive pathogens, such as methicillin-resistant Staphylococcus aureus (MRSA) and vancomycin-resistant Enterococcus (VRE) strains, and activity against Gram-negative pathogens. DLX shows broad-spectrum activity against vancomycin-resistant Gram-positive pathogens and is non-zwitterionic, which can improve tissue penetration compared with other fluoroquinolones. Delafloxacin and vancomycin-aztreonam (VAN/AZ) have unique mechanisms of action and are considered separately for the purposes of evaluating outcomes in patients with CV history. This study evaluates the efficacy and safety of DLX monotherapy compared to VAN/AZ in patients with CV history.

METHODS

STUDY DESIGN

Randomized, double-blind, Phase 3, multi-center, multinational, randomized, double-dummy trial comparing the efficacy and safety of IV/oral DLX monotherapy vs IV VAN/AZ in the treatment of ABSSSI patients. Patients were included if they were ≥18 years of age with an ABSSSI (cellulitis, abscess, or wound) complicating CV disease. The primary outcome was investigator-assessed response (≥20% decrease in lesion size) at 48-72 hours (FU) of DLX treatment after the end of therapy. Key secondary outcomes included all-cause mortality, safety, and tolerability.

RESULTS

This analysis assesses the efficacy and tolerability of delafloxacin in patients with ABSSSI caused by both Gram-positive and Gram-negative bacteria. We conducted two multicenter, double-blind, double-dummy trials (3024 and 3035) comparing the efficacy and safety of IV/oral DLX monotherapy vs IV VAN/AZ in patients with CV history. DLX patients had comparable per-pathogen microbiological response rates of success at FU. There were no treatment-related cardiac adverse events in either group. There were no study drug discontinuations due to adverse events. DLX patients had comparable per-pathogen microbiological response rates of success at FU. There were no treatment-related cardiac adverse events in either group. There were no study drug discontinuations due to adverse events.

CONCLUSION

In a population of patients with cardiac or vascular disease, delafloxacin monotherapy was as effective as the combination of IV VAN/AZ for the treatment of ABSSSI patients. Delafloxacin was tolerated well in this study, and the incidence of SAEs was slightly higher in the DLX group. There were no study drug discontinuations due to adverse events. DLX patients had comparable per-pathogen microbiological response rates of success at FU. There were no treatment-related cardiac adverse events in either group. There were no study drug discontinuations due to adverse events.

REFERENCES


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