OUTCOMES WITH IV/ORAL DELAFLOXACIN (DLX) COMPARED TO VANCOMYCIN/ATZREONAM (VAN/AZ) IN TREATMENT OF PATIENTS (PTS) WITH ACUTE BACTERIAL SKIN AND STRUCTURE INFECTIONS (ABSSISI) AND GRAM-POSITIVE (GP) PATHOGENS

S. Overcash1, W. O’Riordan2, L. Lawrence3, S. McCurdy4, C. Tsen5, S. Cammarata6
1eStudySite, La Mesa, CA, 2eStudySite, San Diego, CA, 3Melinta Therapeutics, Lincolnshire, IL, 4Firma Clinical LLC, Hunt Valley, MD

ABSTRACT

Background: Delafloxacin (DLX) is a novel class D fluoroquinolone developed for the treatment of skin and skin structure infections (ABSSIs). This is the first study to report outcomes with DLX compared to VAN/AZ in this indication.

Methods: Two double-blind trials of 248 patients (PTS) enrolled in the 77/78% study in 2015 and 2016 in North America, Europe, and Latin America were compared with the 140/142 patients enrolled in the 140/142 study in 2016-2017 in North America, Europe, Latin America, and Asia. The 77/78% study enrolled 22 to 140/142 and 21 to 140/142 patients per site. A summary of patient demographics and baseline characteristics are shown in Table 1. In the 77/78% study, the proportion of patients treated for lower extremity ABSSIs (14/21; 66.7%) was more than twice that of upper extremity (5/21; 23.8%) and facial (2/21; 9.5%) infections. The 140/142 study included a similar distribution of upper extremity (21/142; 14.8%), lower extremity (110/142; 77.3%), and facial (19/142; 13.4%) infections. The percentage of ABSSIs due to vancomycin-resistant enterococci (VRE; 23/142; 16.2%) was twice that of the 77/78% study (11/21; 52.4%).

Results: In the 77/78% study, the proportion of patients treated for lower extremity ABSSIs (14/21; 66.7%) was more than twice that of upper extremity (5/21; 23.8%) and facial (2/21; 9.5%) infections. In the 140/142 study, the distribution of upper extremity (21/142; 14.8%), lower extremity (110/142; 77.3%), and facial (19/142; 13.4%) infections was similar. The percentage of ABSSIs due to VRE (23/142; 16.2%) was twice that of the 77/78% study (11/21; 52.4%).

Conclusions: DLX appears effective in the treatment of ABSSIs infected with Gram-positive pathogens. DLX also demonstrated excellent microbiological response to treatment in the 77/78% study (77/78% study, 97.1% vs. 98.6% for VAN/AZ). The results of this study confirm the observations reported in the 140/142 study for DLX compared to VAN/AZ in the treatment of ABSSIs infected with Gram-positive pathogens.

REFERENCES


INTRODUCTION

ABSSIs are a common cause of morbidity and mortality and represent a growing public health concern. The incidence of ABSSIs has been estimated at 2.8 million annually in the United States, with an estimated medical cost of $2 billion per year. Many patients require hospitalization and prolonged antibiotic therapy. The 2018 CDC report of community-associated methicillin-resistant Staphylococcus aureus (CA-MRSA) estimates that 21% of CA-MRSA isolates are resistant to vancomycin (vancomycin-resistant Staphylococcus aureus [VRSA]) and 23% are resistant to daptomycin (Daptomycin-resistant Staphylococcus aureus [DARESA]). The clinical spectrum of ABSSIs is wide, and the pathogens responsible are diverse. The choice of antibiotic therapy is often guided by the results of susceptibility testing and the clinical course of the patient. The prevalence of ABSSIs caused by drug-resistant pathogens has increased, and the number of patients requiring hospitalization has increased in recent years. The development of agents active against these pathogens is critical to maintaining the ability to treat ABSSIs. The objectives of this study were to evaluate the efficacy and safety of DLX compared to VAN/AZ in the treatment of ABSSIs caused by Gram-positive pathogens.

MATERIALS AND METHODS

Study design: In the 77/78% study, 122 patients received DLX (intravenous [IV] doses: 150 mg for 1 day, 75 mg for 1 day, 50 mg for 1 day) in a 3:3:1 randomization compared to a 5:6:1 randomization for VAN/AZ, including VAN and AZ. The 140/142 study was a 3:3:1 randomization for DLX compared to VAN/AZ, including VAN and AZ. The 77/78% study included 22 to 140/142 patients per site. A summary of patient demographics and baseline characteristics is shown in Table 1. In the 77/78% study, the proportion of patients treated for lower extremity ABSSIs (14/21; 66.7%) was more than twice that of upper extremity (5/21; 23.8%) and facial (2/21; 9.5%) infections. In the 140/142 study, the distribution of upper extremity (21/142; 14.8%), lower extremity (110/142; 77.3%), and facial (19/142; 13.4%) infections was similar. The percentage of ABSSIs due to VRE (23/142; 16.2%) was twice that of the 77/78% study (11/21; 52.4%).

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