DELAFLOXACIN (DLX) IS EFFECTIVE AND WELL-TOLERATED IN TREATMENT OF OBSESE PATIENTS WITH ACUTE BACTERIAL SKIN AND SKIN STRUCTURE INFECTIONS (ABSSI) VERSUS VANCOMYCIN/AZTREONAM (VAN/AZ)

**ABSTRACT**

Delafloxacin (DLX) is a fluoroquinolone antibiotic that is being studied in the treatment of acute bacterial skin and skin structure infections (ABSSIs), including Methicillin-resistant Staphylococcus aureus (MRSA) while retaining good activity against emerging Gram-negative pathogens. A randomized, double-blind phase 3 trial was conducted to evaluate the safety and efficacy of DLX compared with vancomycin/aztreonam (VAN/AZ) in obese patients with ABSSIs. A total of 306 patients were randomized to receive DLX 328 mg iv 8/8 (100%) or VAN/AZ (60/62 = 96.8%) for treatment of ABSSIs. Patients were eligible if they had ≥1 infected lesion due to the pathogen of interest. Clinical success (clinically improved or cured) was observed in 62 (18.7%) and 5 (1.7%) patients, respectively, for DLX and VAN/AZ. There were no deaths in the DLX group and 3 (0.9%) in the VAN/AZ group. Patients treated with DLX experienced fewer TEAEs (32/33; 97.9%) than those treated with VAN/AZ (60/62 = 96.8%). There were no deaths in the DLX group and 3 (0.9%) in the VAN/AZ group. Patients treated with DLX experienced fewer TEAEs (32/33; 97.9%) than those treated with VAN/AZ (60/62 = 96.8%). There were no deaths in the DLX group and 3 (0.9%) in the VAN/AZ group.

**INTRODUCTION**

Delafloxacin (DLX) is a fluoroquinolone antibiotic that is being studied in the treatment of acute bacterial skin and skin structure infections (ABSSIs), including Methicillin-resistant Staphylococcus aureus (MRSA) while retaining good activity against emerging Gram-negative pathogens. A randomized, double-blind phase 3 trial was conducted to evaluate the safety and efficacy of DLX compared with vancomycin/aztreonam (VAN/AZ) in obese patients with ABSSIs. A total of 306 patients were randomized to receive DLX 328 mg iv 8/8 (100%) or VAN/AZ (60/62 = 96.8%) for treatment of ABSSIs. Patients were eligible if they had ≥1 infected lesion due to the pathogen of interest. Clinical success (clinically improved or cured) was observed in 62 (18.7%) and 5 (1.7%) patients, respectively, for DLX and VAN/AZ. There were no deaths in the DLX group and 3 (0.9%) in the VAN/AZ group. Patients treated with DLX experienced fewer TEAEs (32/33; 97.9%) than those treated with VAN/AZ (60/62 = 96.8%). There were no deaths in the DLX group and 3 (0.9%) in the VAN/AZ group. Patients treated with DLX experienced fewer TEAEs (32/33; 97.9%) than those treated with VAN/AZ (60/62 = 96.8%). There were no deaths in the DLX group and 3 (0.9%) in the VAN/AZ group.

**MATERIALS AND METHODS**

Delafloxacin (DLX) is a fluoroquinolone antibiotic that is being studied in the treatment of acute bacterial skin and skin structure infections (ABSSIs), including Methicillin-resistant Staphylococcus aureus (MRSA) while retaining good activity against emerging Gram-negative pathogens. A randomized, double-blind phase 3 trial was conducted to evaluate the safety and efficacy of DLX compared with vancomycin/aztreonam (VAN/AZ) in obese patients with ABSSIs. A total of 306 patients were randomized to receive DLX 328 mg iv 8/8 (100%) or VAN/AZ (60/62 = 96.8%) for treatment of ABSSIs. Patients were eligible if they had ≥1 infected lesion due to the pathogen of interest. Clinical success (clinically improved or cured) was observed in 62 (18.7%) and 5 (1.7%) patients, respectively, for DLX and VAN/AZ. There were no deaths in the DLX group and 3 (0.9%) in the VAN/AZ group. Patients treated with DLX experienced fewer TEAEs (32/33; 97.9%) than those treated with VAN/AZ (60/62 = 96.8%). There were no deaths in the DLX group and 3 (0.9%) in the VAN/AZ group.

**RESULTS**

Delafloxacin (DLX) is a fluoroquinolone antibiotic that is being studied in the treatment of acute bacterial skin and skin structure infections (ABSSIs), including Methicillin-resistant Staphylococcus aureus (MRSA) while retaining good activity against emerging Gram-negative pathogens. A randomized, double-blind phase 3 trial was conducted to evaluate the safety and efficacy of DLX compared with vancomycin/aztreonam (VAN/AZ) in obese patients with ABSSIs. A total of 306 patients were randomized to receive DLX 328 mg iv 8/8 (100%) or VAN/AZ (60/62 = 96.8%) for treatment of ABSSIs. Patients were eligible if they had ≥1 infected lesion due to the pathogen of interest. Clinical success (clinically improved or cured) was observed in 62 (18.7%) and 5 (1.7%) patients, respectively, for DLX and VAN/AZ. There were no deaths in the DLX group and 3 (0.9%) in the VAN/AZ group. Patients treated with DLX experienced fewer TEAEs (32/33; 97.9%) than those treated with VAN/AZ (60/62 = 96.8%). There were no deaths in the DLX group and 3 (0.9%) in the VAN/AZ group. Patients treated with DLX experienced fewer TEAEs (32/33; 97.9%) than those treated with VAN/AZ (60/62 = 96.8%). There were no deaths in the DLX group and 3 (0.9%) in the VAN/AZ group.

**DISCUSSION**

Delafloxacin (DLX) is a fluoroquinolone antibiotic that is being studied in the treatment of acute bacterial skin and skin structure infections (ABSSIs), including Methicillin-resistant Staphylococcus aureus (MRSA) while retaining good activity against emerging Gram-negative pathogens. A randomized, double-blind phase 3 trial was conducted to evaluate the safety and efficacy of DLX compared with vancomycin/aztreonam (VAN/AZ) in obese patients with ABSSIs. A total of 306 patients were randomized to receive DLX 328 mg iv 8/8 (100%) or VAN/AZ (60/62 = 96.8%) for treatment of ABSSIs. Patients were eligible if they had ≥1 infected lesion due to the pathogen of interest. Clinical success (clinically improved or cured) was observed in 62 (18.7%) and 5 (1.7%) patients, respectively, for DLX and VAN/AZ. There were no deaths in the DLX group and 3 (0.9%) in the VAN/AZ group. Patients treated with DLX experienced fewer TEAEs (32/33; 97.9%) than those treated with VAN/AZ (60/62 = 96.8%). There were no deaths in the DLX group and 3 (0.9%) in the VAN/AZ group. Patients treated with DLX experienced fewer TEAEs (32/33; 97.9%) than those treated with VAN/AZ (60/62 = 96.8%). There were no deaths in the DLX group and 3 (0.9%) in the VAN/AZ group.