Dalbavancin: A Nationwide Outpatient Experience in Physician Office Infusion Centers (POICs)

Lucinda J. Van Anglen, PharmD, Robin H. Drellet, MD, Luu Quyen, MD, Ramesh V. Nathan, MD, FIDSA, Barry Statner, MD CM, FRCP, FIDSA, Fernando S. Alvarado, MD

1Healix Infusion Therapy, Inc. Sugar Land, TX; Infectious Disease Specialists of Atlanta, Atlanta, GA; 2Quyen Luu, MD, Macon, GA; 3Mazur, Statner, Dutta, Nathan, PC, Thousand Oaks, CA; 4Infectious Disease Consultants, Altamonte Springs, FL

Abstract

Background: Dalbavancin (DAL), formerly known as telavancin, was recently approved for the treatment of acute bacterial skin and skin structure infections (ABSSSI) caused by susceptible gram-positive bacteria. The agent is not indicated for pediatric patients. A retrospective study was performed to assess the treatments and outcomes of patients treated in physician office infusion centers (POICs) with DAL.

Methods: A multicenter, retrospective database review was conducted of all patients (age ≥18 years) who received DAL for one of the following indications: ABSSSI, cellulitis, diabetic foot and/or prosthetic device infection. All patients treated with DAL for infections between July 1, 2014 and July 1, 2015 were included in this study. The primary outcome was the overall clinical success rate of patients treated with DAL at one or more POICs.

Results: A total of 105 patients were treated with DAL at 32 POICs. The clinical success rate was 84% (n=88). Among the 17 patients who failed therapy, 8 (47%) failed due to clinical cure, 6 (35%) had treatment-related adverse events (AEs), and 3 (18%) did not have culture data available.

Discussion: Overall, the clinical success rate seen in this study was similar to the clinical success rate reported in the DISCOVER 1 and 2 studies. In conclusion, DAL was well tolerated and demonstrated high clinical success rates in the outpatient setting.

Introduction

Dalbavancin (Dalvex®), a lipoglycopeptide approved for the treatment of acute bacterial skin and skin structure infections (ABSSSI) caused by susceptible gram-positive bacteria, has been shown to be enteric non-inferior to IV vancomycin when used as an alternative therapy in non-severe infections. Dalbavancin was recently approved for treatment of diabetic foot infections and intravenous antibiotic-naive patients. The purpose of this study is to report a nationwide clinical experience with DAL use in an OPAT setting.

Methods

A multicenter, retrospective database and chart review was conducted to identify pts who received DAL of 140 POICs from July 1, 2014 through July 1, 2015. The database was collected in database demographics, all treatment parameters including type of therapy, microbiology, regimen, clinical outcomes, and adverse events. descriptive statistics (mean, median) were used for demographics, microbiology, regimen, and outcome data. All APS were compared to clinical trial data using Chi-squared test to determine statistical significance with p < 0.05.

Clinical outcomes were calculated for all pts who completed therapy as follows:
- Clinical cure/overall success = improvement in signs/symptoms, confirmed by negative cultures or repeat cultures were negative or no clinical improvement.
- Clinical failure = worsened or no clinical improvement.
- Failure of therapy = failure after one dose of therapy.
- Discontinued therapy = therapy was interrupted due to adverse event(s).
- Adverse event = any untoward medical or surgical occurrence (serious or not serious).
- Adverse drug reaction = any untoward medical occurrence or event in a patient receiving therapy that was not already present and that results in death, is life-threatening, requires hospitalization, or is for a significant duration.

Results

Characteristics (n=105) No. (%)
- Gender, male 57 (54%)
- Age (years) Mean (range) 62 (19-92)
- ≥65 48 (46%)
- Pts with chronic kidney disease 35 (33%)
- History of diabetes 35 (33%)
- History of smoking 19 (18%)
- History of IVAB naïve 50 (48%)
- Home/POIC 49 (47%)
- Antibiotic Use Prior to DAL
- Antibiotic naïve 13 (12%)
- IVAB naïve 50 (48%)

Table 1: Demographics

Antibiotic Treatment Prior To DAL

Table 2: Antibiotic Use Prior To DAL

Adverse Events

Table 3: Adverse Drug Reactions

Conclusions

- Dalbavancin was tolerated with a high clinical success rate of 84% in the outpatient setting, similar to the DISCOVER 1 and 2 studies.
- Dalbavancin was safe and effective for the treatment of non-severe ABSSSI, cellulitis, and diabetic foot infections.
- Dalbavancin can be used as an alternative therapy in non-severe infections and can be administered in the outpatient setting.

References