
INTRODUCTION

Bezlotoxumab (BEZ, Zinplava™) was approved by the FDA in October 2016 for prevention of C. difficile infection (CDI) in adults receiving standard-of-care (SoC) therapy and are deemed at high risk for recurrence.

The MODIFY trials have demonstrated significantly lower rates of CDI in patients (pts) receiving BEZ plus SoC compared to those with SoC alone.

Presently, little is known about CDI recurrence rates and factors associated with recurrence in patients (pts) receiving BEZ in the real-world. This study describes characteristics of pts receiving a single dose of BEZ in U.S. outpatient infusion centers (OICs) and analyzes CDI recurrences.

OBJECTIVES

• To characterize study cohort and utilization of BEZ in OICs
• To evaluate CDI recurrence rate after 90 days following BEZ dose
• To determine potential risk factors associated with CDI recurrence

METHODS

• Study design: retrospective multicenter single-arm
• Data source: pharmacy and electronic health records from March 2017 through December 2017 for treated patients and through March 2018 for follow-up patients
• Index CDI definition: episode of CDI (ICD-10 code A04.7) resulting in referral to BEZ
• Patient population: CDI pts of 18 years from 24 OICs in the U.S.
• Study parameters: demographics, clinical characteristics, reasons for not receiving BEZ and CDI risk factors. Utilization characteristics include time from initiation of SoC to BEZ, laboratory test confirming toxigenic C. difficile, and type/duration of SoC antibiotic.
• CDI recurrence: assessed 90 days post BEZ by MD visit or phone call defined as:
  - recurrence of diarrhea lasting ≥2 days post BEZ
  - medical intervention (SoC antibiotic, FMT) with or without positive stool testing for toxigenic C. difficile

Statistical analysis: continuous data are reported as mean or median with SD or IQR, categorical data as counts and percentages. Risk factors for BEZ use were assessed using Pearson Chi-square test. Kaplan-Meier method was used to describe time to CDI recurrence stratified by previous number of CDI episodes and analyzed using the log-rank Chi-Square test. A p<0.05 was considered significant.

RESULTS

• Mean ± SD time to recurrence were 34±20 and 28 days, respectively
• Patients with >2 prior CDI episodes had a significantly higher risk of CDI recurrence (p=0.049).

CONCLUSIONS

• This study provides real-world data on pt characteristics and use of BEZ in the outpatient setting.
  - 65% of patients received BEZ in OICs.
  - The referral rate was 86% with primary reason for non-treatment: patient refusal.
  - BEZ administered as single infusion in OICs demonstrated 76.3% efficacy in the prevention of recurrent CDI at 90 days.

Patients with ≥2 prior CDI episodes had a significantly higher risk of CDI recurrence (p=0.049).

• Results were comparable with data reported for MODIFY trials, despite a highly comorbid patient population with multiple CDI risk factors and prior CDI episodes.

• BEZ during CDI therapy for pts provides an effective treatment option for adults, especially for patients at high risk recurrence.

Disclosures

References