Outcomes of Patients Receiving Bezlotoxumab for the Prevention of Recurrent *Clostridioides difficile* Infection – A Multicenter Study

Abdelkader Chaar, MD [1,2], John Damianos, MD [1], Rabia Rizwan, MD [1,2], Ahmad Nawaz, MD [1,2], Paul Feuerstadt, MD, FACG, AGAF [3, 4]

[1] Department of Internal Medicine, Yale School of Medicine, New Haven, CT. [2] Department of Medicine, Yale-New Haven Hospital, New Haven, CT.
[3] Section of Digestive Diseases, Yale School of Medicine, New Haven, CT. [4] PACT-Gastroenterology Center, Hamden, CT.

Introduction

Clostridioides difficile infection (CDI) is the most common healthcare-associated infection in the United States (US). Recurrent disease remains a major issue associated with significant morbidity despite best practices.

Bezlotoxumab (BEZ) is a fully humanized monoclonal antibody approved by FDA in 2017 for prevention of recurrent CDI (rCDI). Limited real-world data are available regarding BEZ usage outside of clinical trials.

In this multicenter study, we aim to report our experience with BEZ at a large healthcare system in northeast US.

Methods

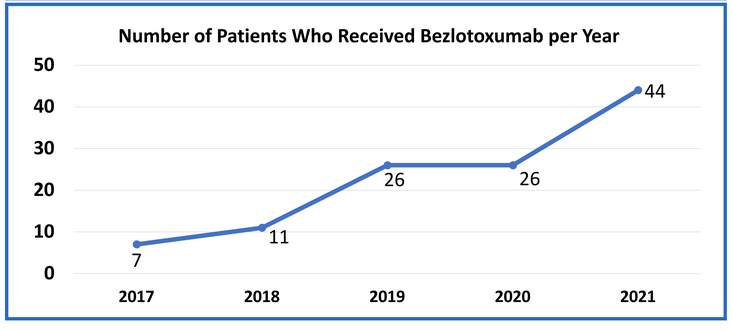
We retrospectively reviewed all consecutive adult patients who received BEZ from 1/2017 until 12/2021 at Yale-New Haven Health System and had at least 90 days of follow up. Data collected for each patient included demographics, medical co-morbidities, adverse events to BEZ and rates of rCDI following BEZ.

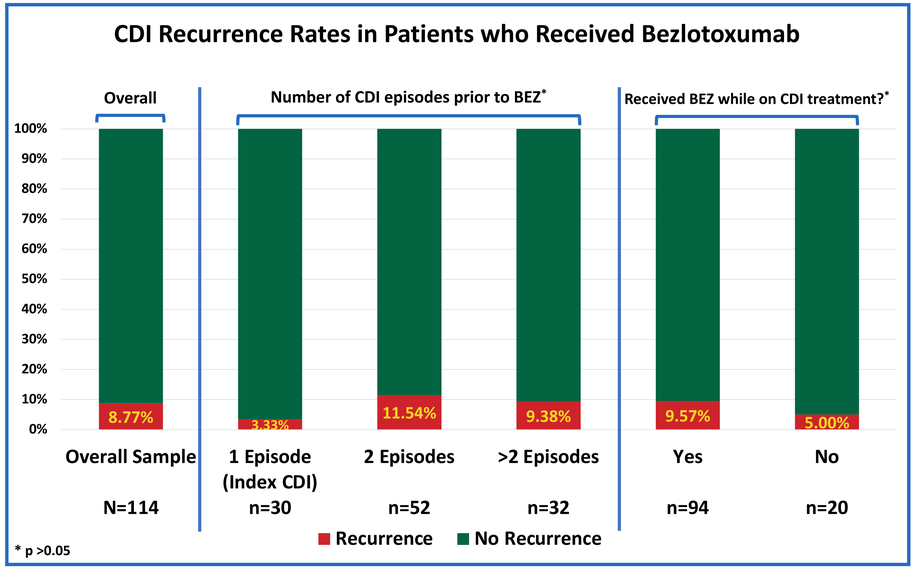
Results

A total of 114 patients were included with a mean age of 67.3 years (range 25-97); 74 (64.9%) were female. BEZ usage has increased in our health system with more than half of our sample (n=73, 64%) being since the beginning of COVID-19 pandemic and 38.6% in 2021 alone.

Results

Variable	All patients (N=114)	90-Day Recurrent CDI		p-value
		Yes (n=10)	No (n=104)	
Age (years), mean ± SD	67.3 ± 14.3	67.2 ± 13.2	67.3 ± 14.4	0.936
Age (years), median [range]	68.5 [25 – 97]	67.5 [42 – 86]	69 [25 – 97]	
Female, n (%)	74 (64.9)	7 (70.0)	67 (64.4)	0.724
Race, n (%)				0.048
White	96 (84.2)	7 (70)	89 (85.6)	
African American	9 (7.9)	3 (30.0)	6 (5.8)	
Asian	1 (0.9)	0 (0.0)	1 (1.0)	
Unknown	8 (7.0)	0 (0.0)	8 (7.7)	
Risk factors for recurrent CDI				
Age ≥ 65 years, n (%)	67 (58.8)	6 (60.0)	61 (58.65)	0.934
Co-morbidities / Immunosuppression, n (%)				
Active malignancy on chemotherapy	28 (24.6)	3 (30.0)	25 (24.0)	0.676
Organ transplant	27 (23.7)	3 (30.0)	24 (23.1)	0.623
On high dose steroids	4 (3.5)	1 (10.0)	3 (2.9)	0.243
Biologics/Immunomodulators	6 (5.3)	1 (10.0)	5 (4.8)	0.482
Hemodialysis	9 (7.9)	2 (20.0)	7 (6.7)	0.137
Charlson co-morbidity index, mean ± SD	4.9 ± 2.5	4.1 ± 2.0	4.9 ± 2.6	0.271
Charlson co-morbidity index ≥3, n (%)	91 (79.8)	8 (80.0)	83 (79.8)	0.988
Treatment of most recent CDI episode, n (%)				0.738
Vancomycin fixed dose	35 (31.0)	3 (30.0)	32 (31.1)	
Vancomycin taper	60 (53.1)	6 (60.0)	54 (52.4)	
Fidaxomicin	11 (9.73)	0 (0.0)	11 (10.7)	
Vancomycin taper + Nitazoxanide	4 (3.5)	1 (10.0)	3 (2.9)	
Vancomycin + Fidaxomicin	2 (1.8)	0 (0.0)	2 (1.9)	
Vancomycin chronic suppressive therapy	1 (.09)	0 (0.0)	1 (1.1)	
Days from most recent CDI to BEZ, median [range]	22.5 [4 – 426]	20 [7 – 69]	22 [4 – 426]	0.904
Days from starting SoC to BEZ median [range]	21 [3 – 211]	16 [7 – 67]	21.5 [3 – 211]	0.740





Conclusion

Our real-life data confirms that BEZ appears to be safe and effective in preventing rCDI in this population whether given during CDI treatment or after. BEZ represents an important treatment option in this highly morbid population. Further studies are needed to determine the benefit of early administration of BEZ after index CDI in those at risk and to consider utilization shifts following the 2021 ACG updated guideline recommendations[1].

[1]Kelly CR, Fischer M, Allegretti JR, LaPlante K, Stewart DB, Limketkai BN, Stollman NH. ACG clinical guidelines: prevention, diagnosis, and treatment of Clostridioides difficile infections. American Journal of Gastroenterology. 2021 Jun 1;116(6):1124-47.