Hospital General Universitario **Gregorio Marañón**

# BEZLOTOXUMAB FOR THE PREVENTION OF CLOSTRIDIOIDES DIFFICILE RECURRENCE: STUDY IN THE REAL WORLD

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OBJECTIVES

To determine the effectiveness of Bezlotoxumab in preventing recurrences of CDI in patients from a tertiary hospital in Spain.
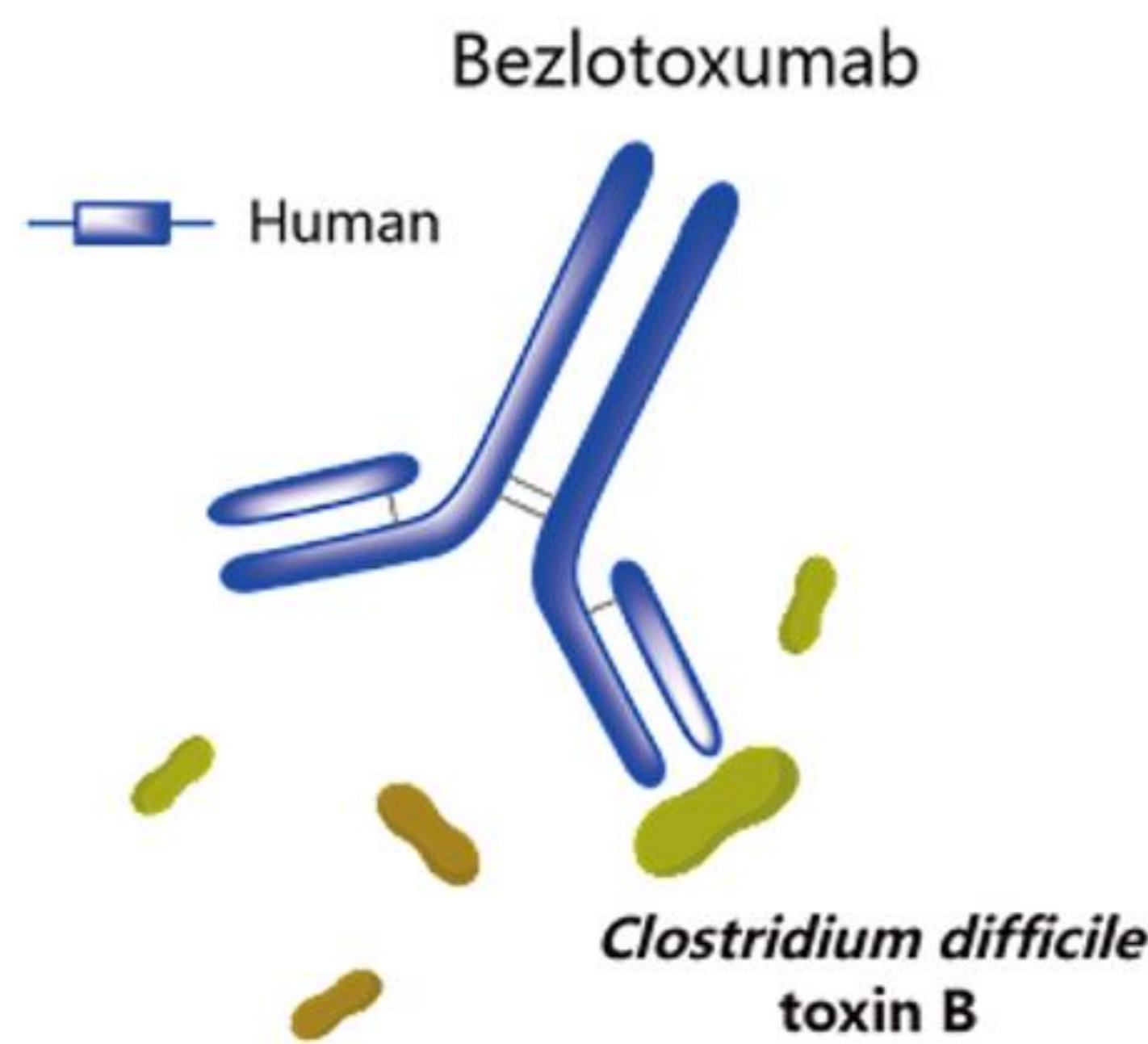
BACKGROUND AND IMPORTANCE

Clostridioides difficile is the most common cause of infectious diarrhea in hospitalized patients and causes great morbidity due to the high percentage of recurrence. Bezlotoxumab is a monoclonal antibody against toxin B, intended to prevent relapse. Due to its high cost, it is used in a population and under conditions slightly different from those referred to in the MODIFY I and MODIFY II clinical trials. Due to the scarcity of real-life studies, it is necessary to collect data on their effectiveness in daily hospital practice.

MATERIALS AND METHODS

We conducted a longitudinal, retrospective study of a cohort of patients treated with Bezlotoxumab between 02/08/2018 and 31/03/2021. All patients received a single infusion of 10 mg/kg. The main variable is the percentage of recurrences in the 12 weeks following clinical cure. As secondary variable, this percentage was analyzed in terms of different risk factors.

RESULTS

We include 52 patients who received a 10 mg/Kg infusion of Bezlotoxumab. Of this 52 patients 6 died during the hospitalization and 3 patients did so during the 12-weeks follow up.

VARIABLE	N=52
Age (Md, IQR)	**74 (64 – 82)**
Age above 65 years old (n,%)	38 (73,1)
Female (n,%)	32 (61,5)
Comorbidities	
Charlson Comorbidity Index (Md,IQR)	5 (3 - 8)
Immunosuppression (n,%)	**31 (59,6)**
▪ Hematologic malignancy (n,%)	9 (17,3)
▪ Solid Organ Neoplasia (n,%)	14 (26,9)
▪ Solid Organ Transplant (n,%)	11 (21,1)
▪ VIH (n,%)	1 (1,9)
Inflammatory bowel disease (n,%)	19 (36,5)
Renal failure (n,%)	7 (13,5)
Broad spectrum antibiotic treatment in the previous 2 months (n,%)	37 (71,2)
Hospital admission in the previous 6 months (n,%)	28 (53,8)
Patient derived from a socio-sanitary centre with CDI (n,%)	5 (9,6)
Patients in their first CDI episode (n,%)	16 (30.8)
Patients with 1 prior CDI episode (n,%)	22 (42.9)
Patients with ≥ 2 prior CDI episodes (n,%)	14 (26.4)

Table 1. Description of the study population

Number of days from admission to Bezlotoxumab infusion (Md, IQR)	5 (2 – 9)
Number of days from diagnosis to Bezlotoxumab infusion (Md, IQR)	10 (7 – 27)
Severe CDI (n,%)	23 (44,2)
Diarrhea lasting >5 days (n,%)	19 (36,5)
Ribotipe 027 (hypervirulent) (n,%)	1 (1,9)
Concomitant antibiotic therapy (n, %)	
▪ Oral Vancomycin 10 days	34 (65,4)
▪ Vancomycin Tapering	15 (28,8)
▪ Fidaxomicin 10 days	4 (7,7)
▪ Fecal microbiota trasplantation	1 (1,9)

Table 2. Treatment variables

Clinical cure and hospital discharge (n,%)	46 (88,5)
Therapeutic failure of acute episode (n,%)	0 (0)
Exitus during admission (n,%)	6 (11,5)
Attributable to CDI	0 (0)
Exitus during the 12-weeks follow-up (n,%)	3
Recurrences in the 12 weeks following Bezlotoxumab infusion (n,%)	9 (18,4)
Time to recurrence (days) (Md, IQR)	43 (22 – 50)
Recurrences by risk factor (n, %)	
▪ >65 años	6 (66,7)
▪ Historia de ICD previa	5 (55,6)
▪ Inmunodepresión	4 (44,4)
▪ Infección grave	7 (77,8)

Table 3. Recurrence rate of the sample and by risk factors

CONCLUSION AND RELEVANCE

The recurrence rate at 3 months of Bezlotoxumab administration was 18.4%, similar to that found in the pivotal clinical trials (16.5%). The highest prevalence of recurrences was identified in the subgroup of patients with severe DCI, followed of the group of age above 65 years old.

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