EFFECTIVENESS AND SAFETY OF CENOBAMATE: EXPERIENCE IN A THIRD-LEVEL HOSPITAL

Ardizone Jiménez B[1]; Bécares Martínez FJ[1]; Hernández Segurado M[1], Tortajada Esteban E[1]; García Jiménez L[1]; Barreras Ruiz N[1]; Jiménez Navarro L[1]

[1] Pharmacy department, Fundación Jiménez Díaz University Hospital. Madrid. Spain

4CPS-028

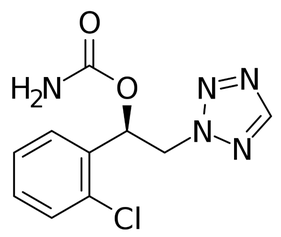
Background and importance

More than one third of patients with epilepsy have uncontrolled seizures despite being treated with two or more anti-seizure medications (ASM), this condition is known as **refractory or drug-resistant epilepsy**.

Cenobamate is a new ASM approved by the European Medicines Agency (EMA) for the adjunctive treatment of focal-onset seizures in adults with drug-resistant epilepsy. Real world data regarding Cenobamate use are currently very limited.

Aim and objectives

To evaluate the **effectiveness** and **safety** of Cenobamate in real world practice.



Materials and methods

- **Design**: a single-center retrospective study of patients who received Cenobamate, from September 2020 to September 2021.
- **Inclusion criteria:** patients should have been treated with Cenobamate for at least 3 months.
- **Efficacy outcomes:**
  - ✓ 50% responder rate → proportion of patients who exhibited a ≥ 50% reduction in the monthly seizure frequency from baseline
  - ✓ Reduction in the number of concomitant ASMs
- **Safety outcomes:** frequency of adverse events (AEs); rate of discontinuation of treatment due to AEs.

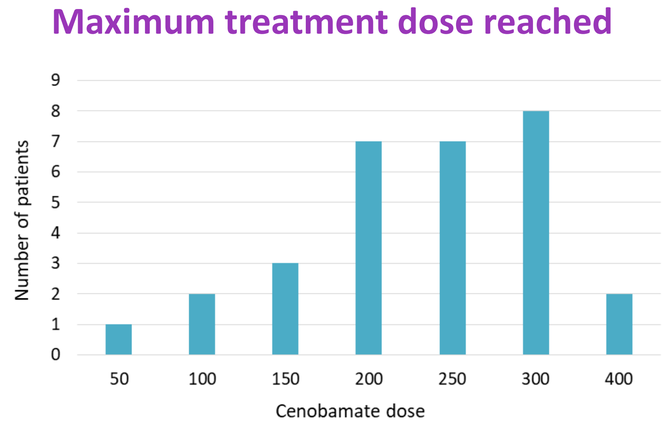
Results

Baseline characteristics:

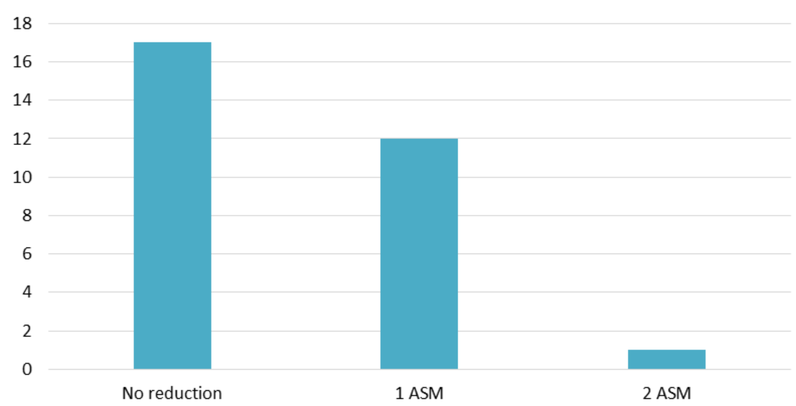
N = 30 patients

- Males 40%
- Average age: 46,9 years (SD = 15,06)
- Number of concomitant ASMs (median): 3 (IQR =2; 4)

Maximum treatment dose reached

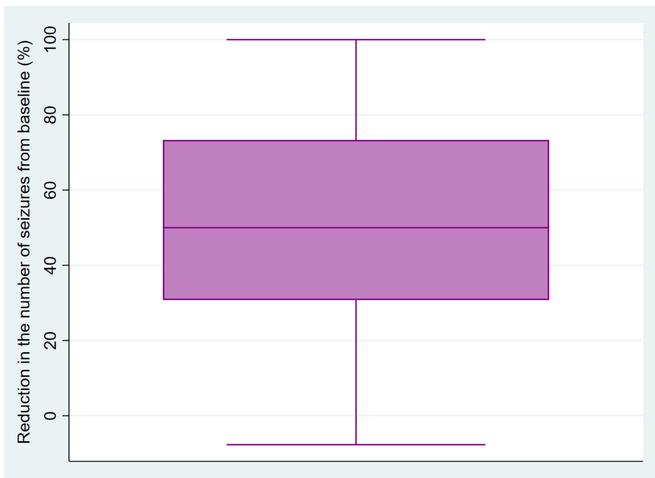


Reduction in the number of concomitant ASMs



43,3% of patients **reduced the number of ASMs in one or two**

Reduction in monthly frequency of seizures (%)

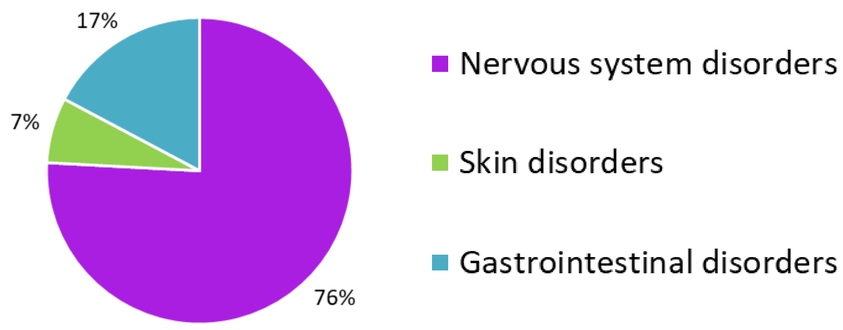


Median = 50 %
Q_1 = 31,2 %
Q_3 = 73,3 %

50% responder rate = 53,3%

Safety profile

- 73,3% of patients had one or more AEs (grade ≤ 2). One case of grade 3 AE.
- The most commonly reported AEs were somnolence, dizziness, fatigue and dysarthria.
- The discontinuation rate because of AEs was 13,3%.



Conclusion and Relevance

The effectiveness and safety data obtained in this study are similar to those of the pivotal clinical trial. We found that adjunctive treatment with Cenobamate allows a reduction in the number of concomitant ASMs in an important proportion of the patients.