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

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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
  - 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:

\[ N = 30 \text{ patients} \]

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

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\% \text{ 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.