**BACKGROUND AND OBJECTIVE**

- Cannabidiol (CBD) is an orphan medicine recently approved in Europe for the treatment of Dravet (DS) and Lennox-Gastaut syndromes (LGS) in combination with clobazam, and for tuberous sclerosis. However, there is growing evidence that other types of refractory epilepsy could be treated with this drug.
- Objective: To evaluate the use of CBD in a paediatric hospital, as well as its effectiveness and safety.

**MATERIALS AND METHODS**

- A retrospective observational study including all patients treated with CBD in our paediatric hospital (January 2017-September 2021) was carried out.
- Variables collected from electronic medical records and pharmacy dispensing program were: age, sex, weight, concomitant antiepileptic drugs (AEDs), length of treatment, initial and maintenance dose, reasons for discontinuation and adverse events (AEs) related to CBD. Efficacy was assed following two criteria: reduction in number of seizures and opinion of caregivers.

**RESULTS**

- 31 patients included
  - Median age: 10 (2-16) years
  - Sex: 61.3% men (n=19)
  - Median weight: 28 (14-80) kg

- LGS 61.3% (n=19)
- Refractory epilepsy 13% (n=4)
- DS 6.5% (n=2)
- Epileptic encephalopathy 6.5% (n=2)
- West syndrome 6.5% (n=2)
- Rett syndrome 3.1% (n=1)
- Tuberous sclerosis 3.1% (n=1)

- Concomitant AEDs: Median 3 (0-4)
  - 64.5% in combination with clobazam

**EFFECTIVENESS RELATED TO CANNABIDIOL**

- Median initial dose: 3mg/kg/d (1-12)
- Median maintenance dose: 15mg/kg/d (5-44)

**DISCONTINUATIONS**

- 2 patients in the first two weeks: number of seizures increased
- 8 patients with maintenance dose: number of seizures not reduced

**Twenty-one patients continue on CBD:**

- 45.2%: number of seizures was significantly reduced and caregiver’s appreciation of effectiveness was good
- 22.5%: responded partially

**Median length of treatment was 7 months**

**Twenty-nine patients reached a maintenance dose**

**ADVERSE EFFECTS RELATED TO CANNABIDIOL**

<table>
<thead>
<tr>
<th>Effect</th>
<th>Frequency</th>
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<tbody>
<tr>
<td>Irritability</td>
<td>24.4% (n=7)</td>
</tr>
<tr>
<td>Diarrhoea</td>
<td>13.79% (n=4)</td>
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<tr>
<td>Anorexia</td>
<td>10.34% (n=3)</td>
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</tbody>
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Other AEs described were: Drooling 6.9% (n=2), somnolence (n=2); rash 3.4% (n=1), hepatobiliary disorders (n=1) and asthenia (n=1).

**CONCLUSIONS**

In our hospital, CBD was prescribed in numerous indications due to the lack of therapeutic alternatives in some seizures-refractory patients. It has been an effective option in most of our patients and its security profile is consistent with clinical trials.