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Pediatric Drug-Resistant Epilepsies: Efficacy, Tolerability, and Safety of Add- On Cannabidiol.

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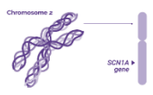
Background

Highly purified cannabidiol (CBD), a standardized formulation of the phytocannabinoid extracted from Cannabis sativa, was approved by the US Food and Drug Administration (FDA) and the European Medicines Agency (EMA) nearly 5years ago as an adjunctive treatment for seizures associated with Dravet syndrome (DS), Lennox–Gastaut syndrome (LGS) (in addition to clobazam), and tuberous sclerosis complex (TSC) in patients aged 2 years and older.

Dravet Syndrome *is a developmental and epileptic encephalopathy (DEE) with onset in the first year of life associated to pathogenic variants of SCN1A gene*



Lennox- Gastaut Syndrome *is a DEE, typically presenting with seizure in children 1 to 7 years old and has genetic or acquired etiology*

Tuberous Sclerosis Complex *is a multisystemic disorder with drug resistant seizures due to TSC1/TSC2 mutations*

Aims

This real world, retrospective and observational, study aims to evaluate the efficacy of add-on CBD on seizure frequency in DS, LGS, TSC and other drug resistant DEE and the overall effect of CBD on patient's quality of life (QoL).

Methods

Epidemiological, Clinical and treatment data where retrospectively collected from medical records; Cannabidiol (CBD) efficacy was defined as ≥50% reduction in seizure frequency. Adverse events (AEs) were classified as minor or major. Quality of life (QoL) was assessed through caregiver reports.

Results

Patient Demographics & Treatment	Value
Total Patients	36
Lennox-Gastaut Syndrome (LGS)	53% (n=19)
Tuberous Sclerosis Complex (TSC)	19% (n=7)
Syndrome Dravet (DS)	11%(n=4)
Other Drug-Resistant Epilepsy (DRE)	17% (n=6)
Mean Age at Onset	26 years 4 months
Pediatric Population (<18y)	50%
Mean Treatment Duration	15 months
Concomitant Antiseizure Drugs (mean)	3.25

Outcomes & Safety	Value
Clinically Relevant Seizure Reduction	53% (n=19)
Primary Responders (LGS)	36% (n=13)
Discontinuation Rate	47% (n=17)
*Lack of Efficacy n=12	33%(n=12)
*Adverse Events (AEs)	14% (n=5)
Adverse Events Reported	58%
Quality of Life Improvement	53%
Sleep Quality Improvement	30.5%

Conclusions

This study confirms the effectiveness of CBD in a real-world DEE population, including off-label use. Lennox Gastaut patients were the best responders with the higher percentage of subjects in whom CBD lead to a significant seizure frequency reduction. CBD improves quality of life in more than 50% of patients. Treatment is also safe and well tolerated, only a very small proportion discontinued treatment due to major adverse events. Future prospective studies are warranted to validate these observations and to investigate the mechanisms underlying differential responses based on etiology.