

Effectiveness of Cannabidiol in Patients With Rare Epilepsies Compared With External Placebo Control: A *Post Hoc* Analysis From the Expanded Access Program

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Objective

- To describe the baseline demographics and clinical characteristics, effectiveness, and safety of cannabidiol (CBD; Epidiolex® [US], 100 mg/mL oral solution) among Expanded Access Program (EAP) participants with rare epilepsy syndromes, including developmental and epileptic encephalopathies (DEEs) other than Lennox-Gastaut syndrome (LGS), Dravet syndrome (DS), and tuberous sclerosis complex (TSC)
- To compare the effectiveness of CBD treatment in participants with rare epilepsy syndromes with an external control arm (ECA)



Conclusions

- CBD treatment is associated with reductions in convulsive and total seizure frequencies in participants with DEEs and rare epilepsies beyond LGS, DS, and TSC
- The comparative effectiveness analysis confirms superiority of CBD compared with an ECA (placebo) in reducing seizure frequency from baseline
- This analysis supports investigation of CBD effectiveness for a broad range of DEEs and other rare epilepsies

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Epidiolex® is approved in the EU for the adjunctive treatment of seizures associated with Lennox-Gastaut syndrome or Dravet syndrome, in conjunction with clobazam, in patients 22 years of age. It is additionally approved in the EU for the adjunctive treatment of seizures associated with tuberous sclerosis complex in patients 32 years of age. Epidiolex® is approved in the US for the treatment of seizures associated with Lennox-Gastaut syndrome, Dravet syndrome, or tuberous sclerosis complex in patients 21 years of age.



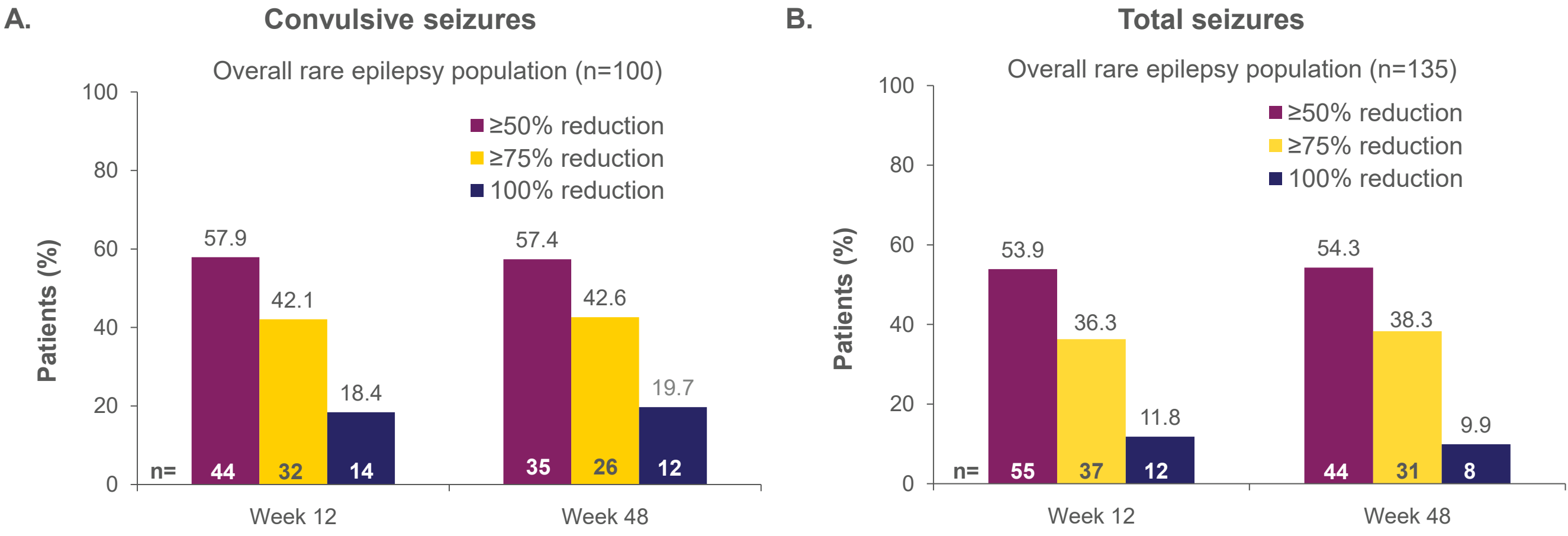
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Introduction

- Developmental and epileptic encephalopathies (DEEs) are a group of rare and severe childhood-onset epilepsies, marked by high seizure burden, pharmacoresistance, and disabling comorbidities, presenting several unmet clinical needs¹
- Plant-derived, highly purified cannabidiol (CBD; Epidiolex® [US], 100 mg/mL oral solution) is approved in the US for the treatment of seizures associated with Lennox-Gastaut syndrome (LGS), Dravet syndrome (DS), or tuberous sclerosis complex (TSC) in patients ≥1 year of age²
- Real-world evidence suggests that CBD may also be useful in other DEEs, including Aicardi syndrome, *CDKL5* deficiency disorder, Dup15q syndrome, and epilepsy with myoclonic-atonic seizures (EPMs)¹
- The CBD Expanded Access Program (EAP) provided compassionate access for treatment-resistant epilepsies, including DEEs
- This *post hoc* analysis of the US CBD EAP evaluated seizure and safety outcomes in participants with rare and severe childhood-onset epilepsies, compared with an external placebo control arm (ECA)^{2–4}
- This study was conducted with Epidiolex®, and results of this *post hoc* analysis do not apply to other CBD-containing products

Figure 3. Treatment response rates



Baseline demographics and clinical characteristics

- The overall analysis set included 135 participants with rare epilepsies in the CBD EAP effectiveness analysis set (Table 1)
- The mean age across subgroups ranged from 5.0 to 14.4 years, and in the overall population the most commonly used ASMs at baseline were clobazam (40%), levetiracetam (33%), and valproate (30%)
- Median (Q1, Q3) total daily CBD dose was 25 mg/kg/day (15.0, 25.0) at Week 12 and 25 mg/kg/day (20.0, 27.2) at Week 48

Table 1. Participant demographics and baseline antiseizure medications (CBD EAP effectiveness analysis set)

	Overall	Aicardi syndrome	CDKL5	Dup15q syndrome	EIEE	EMAIS	FIRES	Myoclonic absence	SCN2A	SWS	Other genetic epilepsies*
N (%)	135	17 (12.6)	20 (14.8)	11 (8.1)	6 (4.4)	11 (8.1)	13 (9.6)	5 (3.7)	5 (3.7)	5 (3.7)	42 (31.1)
Age, years, mean (SD)	9.7 (6.0)	10.2 (5.8)	6.8 (4.2)	12.4 (4.9)	6.0 (6.1)	9.5 (3.4)	9.4 (5.6)	14.4 (4.4)	5.0 (2.6)	8.9 (6.1)	11.2 (7.1)
Sex, female, n (%)	87 (64.4)	17 (100)	19 (95.0)	5 (45.5)	6 (100)	3 (27.3)	7 (53.8)	2 (40.0)	3 (60.0)	4 (80.0)	21 (50.0)
Number of ASMs, mean (SD)	2.8 (1.2)	2.5 (1.0)	2.5 (0.8)	3.0 (0.5)	3.5 (1.1)	2.8 (0.9)	4.5 (1.7)	—	2.8 (0.8)	2.6 (1.3)	2.5 (1.2)
ASMs, n (%)											
Clobazam	54 (40)	9 (53)	6 (30)	5 (46)	2 (33)	5 (45)	7 (54)	—	1 (20)	1 (20)	18 (43)
Levetiracetam	45 (33)	5 (29)	6 (30)	4 (36)	3 (50)	2 (18)	10 (77)	—	2 (40)	2 (40)	11 (26)
Valproate	40 (30)	5 (29)	10 (50)	5 (46)	0	2 (18)	3 (23)	—	0	3 (60)	12 (29)
Topiramate	13 (10)	0	4 (20)	1 (9)	1 (17)	0	3 (23)	—	1 (20)	1 (20)	2 (5)
Lamotrigine	28 (21)	7 (41)	5 (25)	4 (36)	0	3 (27)	1 (8)	—	1 (20)	0	7 (17)
Rufinamide	24 (18)	4 (24)	2 (10)	6 (55)	1 (17)	4 (36)	2 (15)	—	1 (20)	1 (20)	3 (7)
Felbamate	9 (7)	0	0	0	0	3 (27)	3 (23)	—	0	1 (20)	2 (5)
Seizure frequency, median (Q1, Q3), [n]											
Convulsive seizures	42 (16, 104) [100]	47 (18, 74) [14]	52 (25, 100) [18]	58 (5, 209) [11]	170 (29, 2950) [4]	61 (32, 116) [9]	60 (24, 2840) [13]	4 (4, 4) [1]	25 (13, 112) [5]	1 (1, 1) [1]	40 (4, 98) [32]
Total seizures	80 (28, 294) [135]	57 (24, 109) [17]	95 (42, 231) [20]	89 (55, 272) [11]	205 (18, 384) [6]	86 (32, 404) [11]	216 (60, 4000) [13]	2800 (1750, 2800) [5]	112 (74, 138) [5]	2 (1, 6) [5]	72 (20, 217) [42]

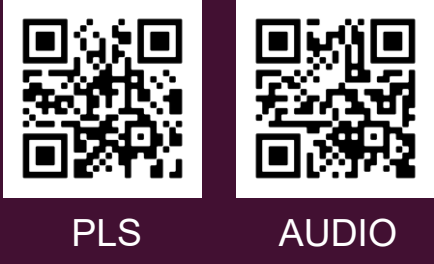
*Included rare epilepsies affecting <5 participants; had diagnostic terms: 15q11.2 deletion, 1p36 deletion, 22q11 duplication, ADNP/LEP/PCP5 mutation, Angelman syndrome, BRAF mutation, CACNA1E mutation, CLCN4 mutation, COL4A1 mutation, deletion 16 (p13, 11p13.1), Disomy X, Dup3q mutation, DYRK1A mutation, EPMF, EEOE, GLUT1 deficiency, GPR14 mutation, GRIN2A mutation, KCNV2 mutation, infantile spasms, Jeavons syndrome, KCNA1 mutation, KCNA2 mutation, KCNA3 mutation, KCNA4 mutation, KCNA5 mutation, KCNA6 mutation, KCNA7 mutation, KCNA8 mutation, KCNA9 mutation, KCNA10 mutation, KCNA11 mutation, KCNA12 mutation, KCNA13 mutation, KCNA14 mutation, KCNA15 mutation, KCNA16 mutation, KCNA17 mutation, KCNA18 mutation, KCNA19 mutation, KCNA20 mutation, KCNA21 mutation, KCNA22 mutation, KCNA23 mutation, KCNA24 mutation, KCNA25 mutation, KCNA26 mutation, KCNA27 mutation, KCNA28 mutation, KCNA29 mutation, KCNA30 mutation, KCNA31 mutation, KCNA32 mutation, KCNA33 mutation, KCNA34 mutation, KCNA35 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Effectiveness of Cannabidiol in Patients With Rare Epilepsies Compared With External Placebo Control: A *Post Hoc* Analysis From the Expanded Access Program

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Disclosures: All authors met the ICMJE authorship criteria and had full access to relevant data and information. Neither honoraria nor payments were made for authorship. YP and EAT have consulted for, conducted studies funded by, or received honoraria for services provided to Jazz Pharmaceuticals, Inc. TG, KCS, and TBS are employees of Jazz Pharmaceuticals, Inc., and hold stock and/or stock options in the company. Epidiolex® is approved in the EU for the adjunctive treatment of seizures associated with Lennox-Gastaut syndrome or Dravet syndrome, in conjunction with clobazam, in patients ≥2 years of age; it is additionally approved in the EU for the adjunctive treatment of seizures associated with tuberous sclerosis complex in patients ≥1 year of age. Epidiolex® is approved in the US for the treatment of seizures associated with Lennox-Gastaut syndrome, Dravet syndrome, or tuberous sclerosis complex in patients ≥1 year of age.



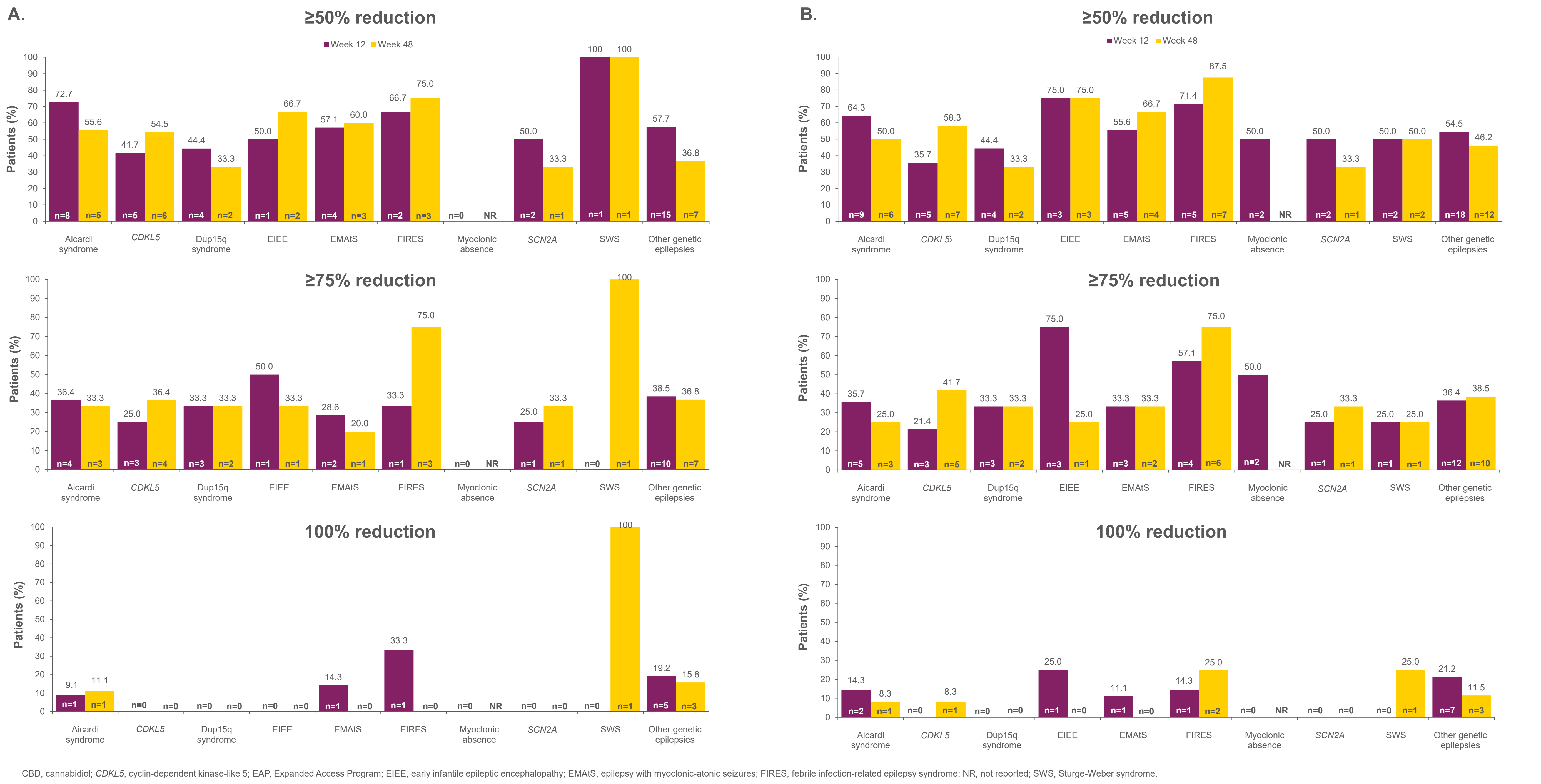
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Supplementary Material

Descriptive analysis: CBD EAP effectiveness analysis set

Figure S1. Subgroup treatment response rates for convulsive seizures and total seizures: (A) convulsive and (B) total seizures at ≥50%, ≥75%, and 100%



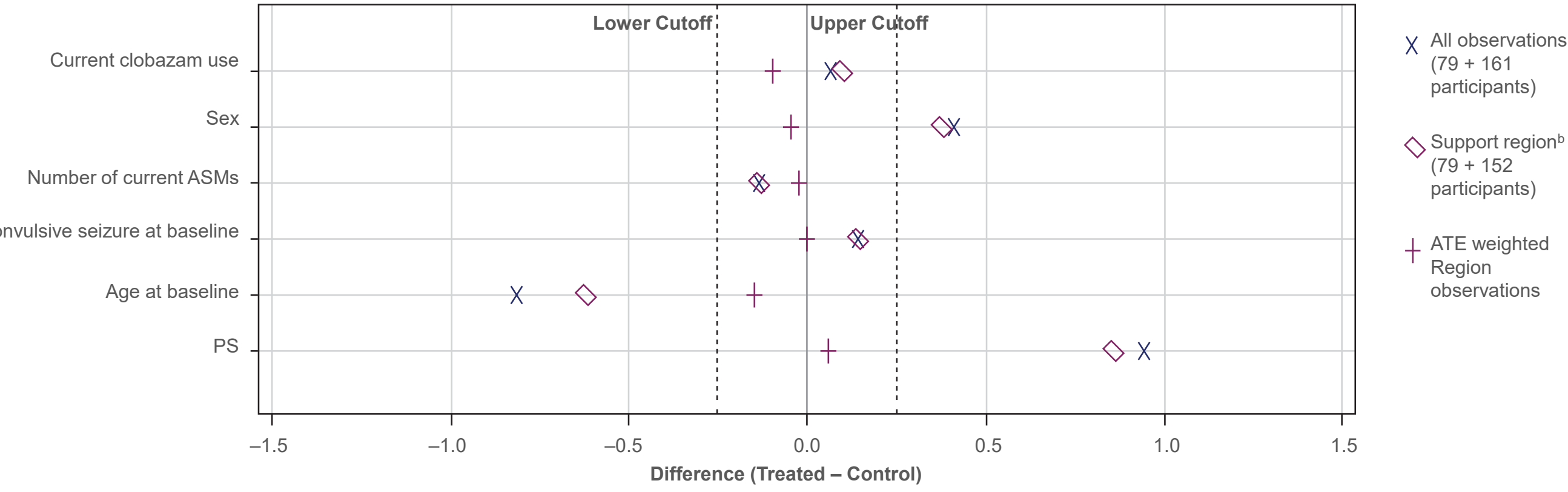
Comparative effectiveness analysis of CBD EAP versus ECA

Table S1. Baseline characteristics: Comparative effectiveness analysis set

	Unweighted		Weighted ^{a,b}	
	CBD EAP	ECA	CBD EAP	ECA
N, Effectiveness analysis set	79	161	79	152
Age, years, mean (SD)	9.2 (4.7)	15.3 (9.5)	11.1 (8.3)	12.2 (8.9)
Sex, female, n (%)	52 (65.8)	74 (46.0)	52 (51.2)	72 (53.3)
Number of ASMs, mean (SD)	2.8 (1.2)	2.9 (0.9)	2.9 (2.0)	2.9 (1.2)
ASMs, n (%)				
Clobazam	36 (45.6)	79 (49.1)	36 (55.0)	77 (50.3)
Levetiracetam	27 (34.2)	58 (36.0)	27 (30.1)	56 (37.2)
Valproate	23 (29.1)	63 (39.1)	23 (32.7)	60 (38.3)
Lamotrigine	18 (22.8)	56 (34.8)	18 (28.1)	53 (33.8)
Rufinamide	18 (22.8)	41 (25.5)	18 (27.9)	38 (23.5)
Convulsive seizure frequency, mean (SD)	328.1 (1002.1)	219.7 (409.4)	260.2 (1417.5)	260.3 (613.6)
Total seizure frequency, mean (SD)	626.9 (2187.7)	437.4 (713.5)	522.7 (3206.2)	519.1 (1003.8)

^aSummary statistics are weighted for propensity score derived by balancing the average distribution of age, sex, convulsive seizure frequency at baseline, number of concomitant ASMs, and current use of clobazam. ^bTo avoid large standard error for causal effect estimates, the analysis used a support region of all observations having a percentile from 2 to 98 of the propensity score distribution. The support region included 79 CBD EAP and 152 ECA participants with balanced baseline characteristics. ASM, antiseizure medication; CBD, cannabidiol; EAP, Expanded Access Program; ECA, external placebo control arm.

Figure S2. Standardised weighted mean difference for covariate balance assessment^a



^aSummary statistics are weighted for PS derived by balancing the average distribution of age, sex, convulsive seizure frequency at baseline, number of concomitant ASMs, and current use of clobazam. Differences (SWMD) were calculated to show the difference in means of covariates between treated and control groups, standardised by the pooled SD, for each balancing covariate. A value SWMD <0.1 is acceptable; SWMD between 0.1 and 0.25 is not alarming; SWMD >0.25 denotes a serious imbalance. ^bTo avoid large standard error for causal effect estimates, the analysis used a support region of all observations having a percentile from 2 to 98 of the propensity score distribution. The support region included 79 CBD EAP and 152 ECA participants with balanced baseline characteristics. ASMs, antiseizure medications; ATE, average treatment difference; PS, propensity score; SWMD, standardised weight mean difference.

Safety results (CBD EAP safety analysis set)

Table S2. Summary of TEAEs reported in ≥20% of participants (CBD EAP safety analysis set)

	Overall ^a	Aicardi syndrome	CDKL5	Dup15q syndrome	EIEE	EMAIS	FIRES	SCN2A	SWS	Other genetic epilepsies
TEAEs reported in ≥20% of participants in any group by preferred term, n (%)										
Diarrhoea, n (%)	44 (28.2)	7 (36.8)	7 (30.4)	2 (18.2)	3 (50.0)	3 (27.3)	5 (25.0)	0	1 (16.7)	16 (32.0)
Convulsion, n (%)	42 (26.9)	5 (26.3)	7 (30.4)	4 (36.4)	3 (50.0)	2 (18.2)	5 (25.0)	0	5 (83.3)	11 (22.0)
URTI, n (%)	29 (18.6)	3 (15.8)	6 (26.1)	0	2 (33.3)	3 (27.3)	0	0	5 (83.3)	10 (20.0)
Vomiting, n (%)	25 (16.0)	3 (15.8)	8 (34.8)	1 (9.1)	2 (33.3)	2 (18.2)	4 (20.0)	0	2 (33.3)	3 (6.0)
Pyrexia, n (%)	24 (15.4)	3 (15.8)	7 (30.4)	0	3 (50.0)	1 (9.1)	2 (10.0)	1 (20.0)	1 (16.7)	6 (12.0)
Fatigue, n (%)	22 (14.1)	4 (21.1)	6 (26.1)	3 (27.3)	1 (16.7)	2 (18.2)	1 (5.0)	0	1 (16.7)	4 (8.0)
Somnolence, n (%)	20 (12.8)	3 (15.8)	3 (13.0)	3 (27.3)	1 (16.7)	4 (36.4)	0	0	0	6 (12.0)
Pneumonia, n (%)	19 (12.2)	4 (21.1)	2 (8.7)	1 (9.1)	3 (50.0)	0	4 (20.0)	0	1 (16.7)	4 (8.0)
Status epilepticus, n (%)	17 (10.9)	3 (15.8)	1 (4.3)	1 (9.1)	1 (16.7)	1 (9.1)	1 (5.0)	1 (20.0)	1 (16.7)	7 (14.0)
Decreased appetite, n (%)	16 (10.3)	1 (5.3)	5 (21.7)	4 (36.4)	0	1 (9.1)	1 (5.0)	0	1 (16.7)	3 (6.0)
Gastroenteritis viral, n (%)	12 (7.7)	1 (5.3)	0	0	0	0	1 (5.0)	3 (60.0)	2 (33.3)	5 (10.0)
Abnormal behaviour, n (%)	12 (7.7)	2 (10.5)	2 (8.7)	1 (9.1)	0	1 (9.1)	0	1 (20.0)	4 (66.7)	1 (2.0)
Sedation, n (%)	12 (7.7)	3 (15.8)	0	0	1 (16.7)	0	0	1 (20.0)	0	7 (14.0)
Rash, n (%)	12 (7.7)	0	4 (17.4)	2 (18.2)	0	1 (9.1)	0	0	2 (33.3)	3 (6.0)
Weight decreased, n (%)	9 (5.8)	3 (15.8)	2 (8.7)	1 (9.1)	0	0	1 (5.0)	1 (20.0)	0	1 (2.0)
Hypoxia, n (%)	6 (3.8)	0	1 (4.3)	0	1 (16.7)	0	1 (5.0)	1 (20.0)	0	2 (4.0)
Weight increased, n (%)	5 (3.2)	2 (10.5)	0	0	0	0	0	1 (20.0)	1 (16.7)	1 (2.0)
Ataxia, n (%)	4 (2.6)	0	0	3 (27.3)	0	0	0	0	0	1 (2.0)
Secretion discharge, n (%)	4 (2.6)	1 (5.3)	0	0	2 (33.3)	0	1 (5.0)	0	0	0
Headache, n (%)	4 (2.6)	0	0	0	0	0	0	0	2 (33.3)	2 (4.0)
Leukocytosis, n (%)	2 (1.3)	0	0	0	0	0	0	1 (20.0)	0	1 (2.0)
Pneumonia streptococcal, n (%)	1 (0.6)	0	0	0	0	0	0	1 (20.0)	0	0
Infectious mononucleosis, n (%)	1 (0.6)	0	0	0	0	0	0	1 (20.0)	0	0
Dermatitis allergic, n (%)	1 (0.6)	0	0	0	0	0	0	1 (20.0)	0	0
Pneumothorax spontaneous, n (%)	1 (0.6)	0	0	0	0	0	0	1 (20.0)	0	0
Throat irritation, n (%)	1 (0.6)	0	0	0	0	0	0	1 (20.0)	0	0

^aAdverse event data were not available for the participants with myoclonic absence epilepsy (n=5; 3.2%).
CBD, cannabidiol; CDKL5, cyclin-dependent kinase-like 5; EAP, Expanded Access Program; EIEE, early infantile epileptic encephalopathy; EMAIS, epilepsy with myoclonic-atonic seizures; FIRES, febrile infection-related epilepsy syndrome; SWS, Sturge-Weber syndrome; TEAEs, treatment-emergent adverse events; URTI, upper respiratory tract infection.

Effectiveness of Cannabidiol in Patients With Rare Epilepsies Compared With External Placebo Control: A *Post Hoc* Analysis From the Expanded Access Program

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Plain Language Summary

What was this study about?

Developmental and epileptic encephalopathies (DEEs) are rare, severe epilepsies that usually begin in childhood and are often difficult to treat. Cannabidiol (CBD, also called Epidiolex® in the US) is approved in certain patients for seizures associated with three types of DEE: Lennox-Gastaut syndrome, Dravet syndrome, and tuberous sclerosis complex. This study looked at whether CBD could also help children and young people with other rare epilepsy syndromes.

What did the researchers do?

Researchers analysed information from 135 people with rare epilepsies who received CBD through a compassionate use programme. Examples of the types of rare epilepsies in this study included Aicardi syndrome, *CDKL5* deficiency disorder, *Dup15q* syndrome, early infantile epileptic encephalopathy (EIEE), epilepsy with myoclonic-atonic seizures (EMAtS), febrile infection-related epilepsy syndrome (FIRES), myoclonic absence epilepsy, *SCN2A*-DEE, Sturge-Weber syndrome (SWS), and other genetic epilepsies. Researchers measured changes in seizure frequency after 12 and 48 weeks of CBD treatment, and collected information from caregivers and doctors about overall improvement. Because there was no placebo group, the researchers compared the results with a matched group of patients who received placebo in earlier clinical trials of CBD.

What were the results?

After 12 weeks of CBD treatment, convulsive seizures were reduced by about 58% and total seizures were reduced by about 52%. These improvements continued for up to 48 weeks, with reductions of about 64% and 60%, respectively. More than half of participants had at least a 50% reduction in seizures. Most caregivers and doctors also reported that patients had improved. Compared with the matched placebo group, people taking CBD had fewer seizures than those taking placebo, suggesting that CBD helped reduce seizures.

What did the safety data show?

The most common side effects linked to CBD were diarrhoea, tiredness, sleepiness, reduced appetite, and sedation. Serious side effects related to CBD were uncommon, occurring in 3.2% of participants. A total of eleven deaths were reported during the study; none were considered related to CBD treatment.

What do these results mean?

Further research is needed; nonetheless, these results from a study that was nearly a year long suggest that CBD may help reduce seizures by about half in a range of rare epilepsies that are difficult to treat.

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Epidiolex® is approved in the EU for the adjunctive treatment of seizures associated with Lennox-Gastaut syndrome or Dravet syndrome, in conjunction with clobazam, in patients ≥2 years of age; it is additionally approved in the EU for the adjunctive treatment of seizures associated with tuberous sclerosis complex in patients ≥2 years of age. Epidiolex® is approved in the US for the treatment of seizures associated with Lennox-Gastaut syndrome, Dravet syndrome, or tuberous sclerosis complex in patients ≥1 year of age.



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