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*Review*

# Cannabidiol in the treatment of status epilepticus

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**Abstract:** This is a systematic review to evaluate the efficacy of the treatment of status epilepticus with purified Cannabidiol. A search in the PubMed and Web of Science databases was conducted using the search item "status epilepticus" in combination with three other ones (i.e., Cannabidiol, Cannabis, THC). After excluding not relevant papers and duplicates, 11 papers with case reports remained, which described the successful therapy of refractory or super-refractory status epilepticus with purified Cannabidiol in 10 of 12 cases. Apart from one infantile patient, a 27-year-old male, and a 51-year-old female patient, all patients were children or adolescents. There is no reliable information about a proper loading dose in this situation. Apart from one case, the effective dose was at least 10 mg/kg/day. All results were be interpreted very cautiously; additionally, there are some reports about the provocation of status epilepticus using purified cannabidiol.

**Keywords:** Super-refractory status epilepticus; epileptic syndromes in childhood and adolescence; febrile infection-related epilepsy syndrome; loading dose; electroencephalographic seizures

**Abbreviations:** ASM: Antiseizure medication; CDB: Cannabidiol; DBS: Deep brain stimulation; EEG: Electroencephalography; FIRES: Febrile infection-related epilepsy syndrome; ILAE: International League against Epilepsy; IVIG: Intravenous immunoglobulin; NCSE: Nonconvulsive status epilepticus; NORSE: New onset status epilepticus; PRISMA: Preferred reporting items for systematic reviews and meta-analyses; RSE: Refractory status epilepticus; SPIDER: Sample, phenomenon of interest, design, evaluation, research type; SE: Status epilepticus; SRSE: Super-refractory status epilepticus; THC: $\Delta^9$-trans-Tetryhydrocannabinol; VNS: Vagus nerve stimulator

## 1. Introduction

This is a systematic review concerning the efficacy of the treatment of status epilepticus (SE) with cannabinoids. In 2015, SE was defined by the International League Against Epilepsy (ILAE) [1] as "a condition resulting either from the failure of the mechanisms responsible for seizure termination or from the initiation of mechanisms which lead to abnormally prolonged seizures." SE was further classified according to its semiology into SE with prominent motor symptoms and SE without prominent motor symptoms, which means nonconvulsive SE (NCSE). On another axis, SE was further classified according to the age of the patients and the related epilepsy syndromes. Most of the SE cases referred to in the papers relevant for our topic either belong to the group SE occurring in neonatal and infantile-onset epilepsy syndromes or SE occurring mainly in childhood and adolescence. Refractory status epilepticus (RSE) was recently defined as SE which persists despite the administration of at least 2 appropriately selected and dosed medications, including a benzodiazepine [2]. At minimum, anaesthetic drugs should be started for convulsive SE treatments. After the initiation of anaesthetic treatments, if seizures continue or recur for 24 hours or more, including cases in which seizure control is attained after induction of anaesthetic drugs but recurs on weaning the patient off the anaesthetic agent, then the situation is called super-refractory status epilepticus (SRSE) [2]. This is a situation in which cannaboids are sometimes used.

According to a review published in 2018 [3], cannabis was used with some success for treatment of epilepsy at the end of the nineteenth century. However, the plant contains many phytocannabinoids and terpenes, and the pharamcodynamic profile is not easy to estimate. Therefore, isolated cannabinoids were investigated for their effectiveness in treating epilepsy. Cannabidiol (CBD) was proven to be effective in very difficult to treat epilepsy syndromes such as Dravet-Syndrome and Lennox-Gastaut-Syndrome. This has probably encouraged using it in the treatment of SRSE.

## 2. Materials and methods

On August 2nd, a search in the PubMed and Web of Science databases was performed using three combinations of search items: "Cannabidiol" and "Status epilepticus"; "Cannabis" and "Status epilepticus"; and "THC" and "Status epilepticus". The SPIDER tool was used for the evaluation. The sample was people with SE, and the phenomenon of interest was treatment with any form of cannabinoid. After the exclusion of all papers not relevant to the phenomenon of interest and excluding all duplicates, only 11 papers remained (see Figure 1); thus, it was decided to not exclude any study because of its design and to include case reports. We solely excluded meeting abstracts. We evaluated how often and in which dosage CBD was successful in resolving SE. The method is qualitative due to the small number of cases. For this review, an ethical approval was not necessary.

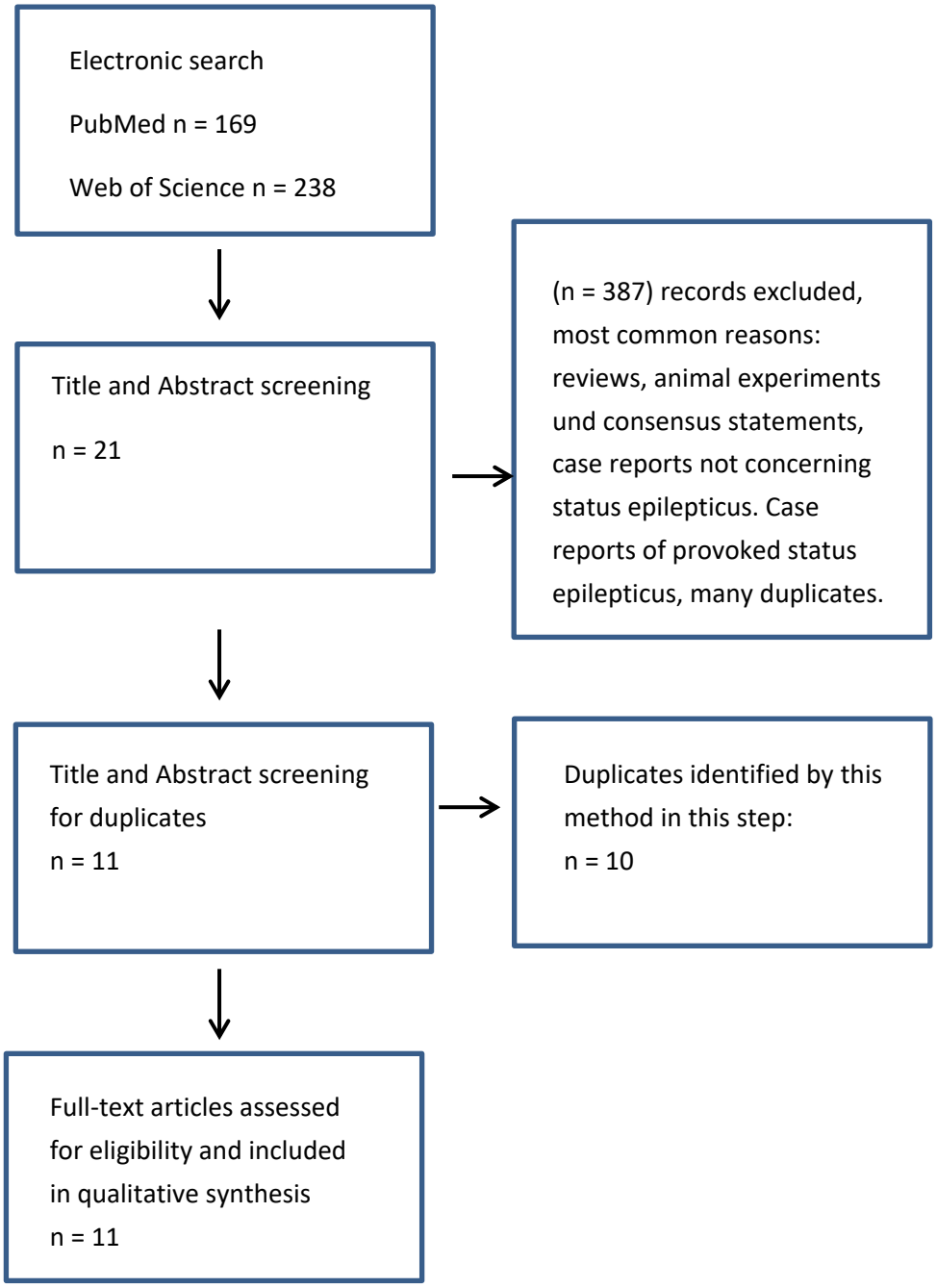


**Figure 1.** PRISMA Flow Diagram. Caption: PRISMA: preferred reporting items for systematic reviews and meta-analyses.

## 3. Results

The following papers will be referred to in order of the subgroups of SE to which the reported SE and patients belonged. Overall, 13 episodes of SE were treated with CDB, and one SE was treated with a hemp oil extract. One paper reported about 5 patients with a history of SE in a severe developmental epilepsy syndrome. Additionally, 19 reports will be summarized and discussed in the chapter discussion, and 5 case reports of SE provoked by the administration of cannabinoids are referred at the end of the chapter.

### *3.1. SE occurring in neonatal and infantile-onset epilepsy syndromes*

In a 24-month-old patient with West-Syndrome and refractory spasm status, CDB was obviously effective [4]. Unfortunately, the dose was not reported. In 20 other patients with refractory spasm status, the use of CBD was not attempted.

### *3.2. SE occurring mainly in childhood and adolescence*

In a group of 26 children with either myoclonic atonic epilepsy (n = 22) or myoclonic atonic seizures due to Sturge-Weber-Syndrome (n = 4) [5], purified CBD was administered. They were given a mean of eight antiseizure medications (ASMs) before treatment with CBD was started; afterwards, they were still treated with a mean of four ASMs. At baseline, 8 patients had a history of NCSE that lasted from at least two hours to several days. Overall, 57.7% of the patients that received add-on CBD had a greater than 50% seizure decrease. Of the patients with a history of NCSE, 50% improved. The treatment was started with a purified CBD 100 mg/ml oral solution at a dosage of 2 mg/kg/day, which was gradually increased over two-weekly intervals until a maximum of 40 mg/kg/day; this could be indicative of the absence of an acute effect of CBD on an active NCSE, but rather a prophylactic effect.

For an 8-year-old boy with Angelman syndrome and refractory NCSE, a purified CBD solution 100 mg/ml was effective as an add-on to ethosuximide and clobazam within one week of treatment [6]. It was introduced with a dose of 10 mg/kg/day and increased to 20 mg/kg/day within 8 days. Angelman syndrome is a neurogenetic disorder mainly characterized by developmental delay, cognitive impairment, and epileptic seizures. About 20% of the patients with Angelman syndrome experience NCSE.

An 18-year-old man with Lennox-Gastaut-Syndrome suffered from a generalized tonic-clonic SE under the treatment with valproic acid and clobazam [7], which developed to a SRSE after therapy with diazepam, levetiracetam, valproic acid, lacosamide, and the anaesthetic drug propofol. Purified CBD was introduced into his therapy and titrated to 20 mg/kg/day within 24 hours. Another 48 hours later, he was able to execute simple one-step commands during an attempt to stop the sedation. Therefore, the sedative was tapered off and his neurological status continued to improve. Additionally, treatment with levetiracetam and lacosamide was halted, but the treatment with CBD 20 mg/kg/day was maintained. He remained seizure free for at least 6 months.

### *3.3. Febrile infection-related epilepsy syndrome (FIRES)*

Febrile infection-related epilepsy syndrome (FIRES) represents a subgroup of new-onset refractory status epilepticus (NORSE). NORSE was recently defined as a clinical presentation, not a specific diagnosis, in a patient without active epilepsy or other preexisting relevant neurological disorder, with new onset refractory SE without a clear acute or active structural, toxic, or metabolic cause [2]. FIRES was recently defined as being applicable to all ages. The diagnosis requires a prior febrile infection that started between two weeks and 24 hours prior to onset of RSE with or without fever at the onset of SE [2]. Despite FIRES being is applicable to all ages, the syndrome is mainly observed in children and adolescents. Despite this, a 27-year-old man with FIRES was reported, where the study utilized the word “NORSE” in the title [8]. About nine days after a febrile syndrome,

he developed a focal NCSE, which was resistant to five ASMs, including levetiracetam and lorazepam. Additionally, methylprednisolone was not effective. Several anaesthetic drugs and immunomodulating therapies were applied without success. After about three months, CBD was started with a dose of 15 mg/kg/day. The electroencephalogram (EEG) improved, and the patient started following simple one-step verbal commands after one week. Another week later, the CBD dose was increased to 20 mg/kg/day, and the patient was fully conversant. He was finally discharged with a CBD dosage of 7.5 mg/kg/day in combination with the five ASMS previously given.

FIRES can be divided into three phases: 1st, the fever; 2nd, highly recurrent seizures or refractory SE; and 3rd, a chronic phase with a drug-resistant epilepsy and neuropsychological impairments [9]. A 14-year-old girl with SRSE in FIRES was described [10]. 43 days after SRSE onset, a vagal nerve stimulator (VNS) was implanted, and the stimulation parameters were increased at least every day. Thus, they reached high therapeutic doses (e.g. 2.25 mA) after at least 10 days. However, the continuous EEG showed no immediate improvement. Therefore, 27 days after the implantation, CBD (galenic oil preparation derived from pure crystals) was started with a dose of 2.5 mg/kg/day, which increased every 5 days up to 12.5 mg/kg/day. Even with the starting dose, the SE weaned electroencephalographically after two days. Another 13 days later, the girl regained consciousness and started to recover. The authors discussed that the combination of neuromodulation by VNS stimulation and CBD suppressed the SRSE. In a case series of seven children with FIRES treated with purified CBD, only two of them were treated with CBD while still in SRSE [11]. The average age at onset of SE in the whole group was 7 years and 1 month. The start of the treatment with CBD in the two patients treated during their SRSE was 19 and 33 days after onset. Unfortunately, the starting dose was not described, but the two subjects treated during their SE were probably titrated to 25 mg/kg/day. Both were treated with at least five ASMs, including levetiracetam and valproic acid, before CBD was started alongside at least four anaesthetic drugs. One of them improved but died due to multiorgan failure thought to be related to the prolonged exposure to isoflurane. The other patient had a cessation of the SE, and was completely seizure free at 4 weeks and for some time afterwards. It was emphasized that he started a ketogenic diet two weeks before the CBD treatment. Two cases were published with a treatment of SRSE in FIRES and a good documentation of doses and effects [12]. The first patient was a four-year-old boy who developed SRSE two days after a pharyngitis with a high fever had resolved. After treatment with five ASMs, Intravenous Immunoglobulin (IVIG), methylprednisolone, anaesthetic drugs, and a ketogenic diet, purified CBD was started on day 26 after onset with a starting dose of 6 mg/kg/day, which rapidly increased up to 12 mg/kg/day in 4 days. The seizures disappeared another three days later, specifically on day 33 after onset. The patient was seizure free for one year. The second patient was a six-year-old boy who developed a fever probably as a side effect of the measles-mumps-rubella and diphtheria-tetanus-pertussis vaccinations. This was easily coped with ibuprofen and paracetamol administration. Two days later, he also developed an SRSE, which was treated with six ASMs, IVIG, methylprednisolone, anaesthetic drugs, and a ketogenic diet. Purified CBD was started together with clobazam on day 31 after seizure onset with a dosage of 4 mg/kg/day, which increased up to 20 mg/kg/day within 11 days. He reached complete seizure freedom three days after reaching the full dose, and has since remained seizure free. There are two reports of children with FIRES where CBD was given at a considerable dose but didn't produce substantial effects (i.e., 30 mg/kg/day and 20 mg/kg/day in the other one) [13]. In another 18-year-old male, the hemp plant extract Elixinol™, which according to the authors contains just 18% CBD, did not produce substantial effects [14].

### *3.4. RSE and SRSE in epilepsy syndromes not associated with a certain age*

A female patient with a history of epilepsy of an unknown cause and about one focal seizure since the age of 5 years developed an SRSE at age 12 [15]. It did not respond to nine ASMs, prednisone, and a ketogenic diet. After more than three months, purified CBD was added to the persisting medication with midazolam, clobazam, phenobarbital, and perampanel. She was started with a dosage of 5 mg/kg/day, which was titrated by 5 mg/kg/day every 3 days to a peak dose of 20 mg/kg/day. Three days later, clinical seizure freedom was achieved. The patient was discharged 9 days later, and another 43 days later, a 24-hour video-EEG documented complete seizure freedom.

A 51-year-old woman with focal epilepsy due to limbic seronegative encephalitis developed a generalized tonic-clonic SE despite a treatment with brivaracetam, phenobarbital, lacosamide, and clonazepam [7]. A bolus of diazepam had no effect, phenobarbital and lacosamide were applied intravenously, brivaracetam was changed to 3000 mg levetiracetam, and valproic acid was added. The status persisted for 24 hours, and a treatment with purified CBD 10 mg/kg/day was started, which increased to 20 mg/kg/day. The status resolved 12 hours later. The ASM regimen was confirmed, and CBD was maintained at a dosage of 20 mg/kg/day. A few days later, the patient was transferred to a rehabilitation centre.

### *3.5. SE provoked by the administration of cannabinoids*

There are at least 5 case reports regarding SE provoked by cannabinoids. Most relevant for the topic here is the report about a 63-year-old man with treatment-resistant epilepsy since his childhood, who had an episode of confusion over 30 minutes when a locally produced CBD product was added to his medication with tiagabine, perampanel, levetiracetam, lacosamide, and clonazepam [16]. The episode recurred with an increasing frequency, which was diagnosed as NCSE by an ictal EEG when the CBD product was changed to purified CBD. It resolved after the CBD treatment was stopped. Additionally, two studies that investigated the effect of purified CBD in patients with treatment-resistant epilepsy reported SE as serious side event in 6% [17] and 7.4% [18] of the patients, respectively. The other case reports described either SE or RSE in patients using synthetic cannabinoid [19–21], which mimics the effect of THC, and in a patient that used THC [22].

## 4. Discussion

After excluding papers not relevant for the subject and duplicates, 11 papers remained that described the administration of cannabinoids for the treatment of 19 patients. In one paper that focused on the treatment with deep brain stimulation (DBS) [13], a treatment with 30 mg/kg/day CBD in one case and 20 mg/kg/day in the other did not produce substantial effects. In another paper with used a hemp oil extract (i.e., not purified CBD) [14], the treatment did not produce substantial effects.

The other papers are summarized in Table 1.

The main limitation of this review is that it had to rely on case reports; thus, numerous questions remain. In one paper, no dosage was reported [4], and in another paper, 5 patients just had a history of NCSE, and it is not clear which dose prevented further NCSE. In a group of 7 patients with FIRES, only two of them were treated during SRSE, and it is not clear which dose was effective in resolving

SE [11]. In the other patients treated during episodes of RSE or SRSE, the starting dose was at least 2.5 mg/kg/day [10]. The highest starting dose was 15 mg/kg/day. Therefore, while for other ASMs such as levetiracetam, where there is extensive literature that discussed the proper loading dose (for a review see [23]), this cannot even be estimated for CBD. With one exception, the effective dose was at least 10 mg/kg/day, and four studies reported dosages of 20 mg/kg/day. The exception was the addition of a dosage of 2.5 mg/kg/day alongside VNS-stimulation with 2.25 mA [10], which may have been an add-on-effect. An add-on-effect to the established medication should be discussed in all cases, especially in combination with clobazam [24]. However, since the half-life of clobazam in adults is normally more than 24 hours, short term effects of the interaction are not probable. Since the effect of CBD on SE had a delay of at least 36 hours [7] and about a week in most other cases [6,8,12,15], the effect of interactions cannot be excluded. When restricting the analysis to treatments during episodes of RSE and SRSE with purified CBD, this was successful in 11 of 13 cases. However, it isn't known how many unsuccessful episodes have not been published.

**Table 1.** Cases with status epilepticus successfully treated with cannabidiol.

| Ref. | Epilepsy Syndrome | SE Type | N = | Initial dosage | Final dosage | Effect. Dosage |
|---|---|---|---|---|---|---|
| 4 | West-Syndrome | RSE | 1 | ? | ? | ? |
| 5 | Myoclonic astatic epilepsy | History of NCSE | 5 | 2 mg/kg/day | 40 mg/kg/day | ? |
| 6 | Angelman Syndrome | RSE | 1 | 10 mg/kg/day | 20 mg/kg/day | 10 mg/kg/day |
| 7 | Lennox-Gastaut-Syndrom | SRSE | 1 | ? | 20 mg/kg/day | 20 mg/kg/day |
| 7 | Post limbic encephalitis | RSE | 1 | 10 mg/kg/day | 20 mg/kg/day | 20 mg/kg/day |
| 8 | n.a. | FIRES | 1 | 15 mg/kg/day | 20 mg/kg/day | 15 mg/kg/day |
| 10 | n.a. | FIRES | 1 | 2.5 mg/kg/day | 12.5 mg/kg/day | 2.5 mg/kg/day |
| 11 | n.a. | FIRES | 2 | ? | 25 mg/kg/day | ? |
| 12 | n.a. | FIRES | 1 | 6 mg/kg/day | 12 mg/kg/day | 12 mg/kg/day |
| 12 | n.a. | FIRES | 1 | 4 mg/kg/day | 20 mg/kg/day | 20 mg/kg/day |
| 15 | Unknown cause | SRSE | 1 | 5 mg/kg/day | 20 mg/kg/day | 20 mg/kg/day |

Note: Caption: Effect.: Effective; FIRES: Febrile infection related epilepsy syndrome; n.a.: Not applicable; NCSE: Nonconvulsive status epilepticus; Ref.: Reference; RSE: Refractory status epilepticus; SRSE: Super-refractory status epilepticus.

## 5. Conclusions

Purified CBD was successful in the treatment of RSE or SRSE in 11 of 13 published cases. It is not clear what is the proper starting dose in this situation, though it should not be higher than 15 mg/kg/day. In most cases, the effective dose was at least 10 mg/kg/day, often 20 mg/kg/day. Since all these results solely rely on case reports, they were interpreted very cautiously.

For studies that investigated the effect of purified CBD in patients with treatment-resistant epilepsy, up to 7.4% of the patients experienced an episode of SE. It has to be emphasized that the level of evidence is very low because of the lack of any randomized clinical trials.

## Use of AI tools declaration

The authors declare they have not used artificial intelligence (AI) tools in the creation of this article.

## Conflict of interest

The author declares no conflict of interest.

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