

Patient Use of Cannabis in Epilepsy Featured in Three New Studies

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SEATTLE, December 8, 2014 – There may have been many anecdotal reports about cannabis and its derivative cannabidiol (CBD) in the treatment of people with epilepsy, especially in very young children who have catastrophic forms of epilepsy such as Lennox Gastaut Syndrome (LGS) or Dravet Syndrome (DS). Despite all the media and legislative attention, there is little scientific evidence about its effectiveness. Three studies presented at the American Epilepsy Society's (AES) 68th Annual Meeting offer new insights into diverse patient experiences with CBD.

The first of three studies (Poster 1.326) is from Colorado, where much of the nation's attention has been captured by issues surrounding cannabis. The physicians and researchers at Children's Hospital Colorado and the University of Colorado have a unique perspective on CBD given the large number of cases they have treated. In addition to the many children already in their care, these professionals are now caring for many of the patients who have ventured to Colorado in search of cannabis treatment.

Dr. Kevin Chapman, associate professor of pediatrics and neurology at the University of Colorado, and his colleagues conducted a retrospective review of the 58 children and adolescents (average age of 7) with catastrophic forms of epilepsy who were receiving artisanal oral cannabis extracts when they came under the care of the hospital-based team. Chapman's team found that in only one-third of patients did the parents report a seizure reduction of 50% or more, and this did not correlate with an improvement in their electroencephalograms (EEGs). Of the sixteen patients who had baseline EEGs prior to and during treatment with cannabis, only two showed any signs of improvement. The researchers also noted that the response rate did not change with various strains of cannabis. Notably, families who moved to Colorado for CBD treatment were three times as likely to report a reduction greater than 50% than families who were already in Colorado.

Adverse effects occurred in 47% of patients, with increased seizures or new seizures in 21%, somnolence/fatigue in 14%, and rare adverse events of developmental regression in 10% with one patient needing intubation, and one death.

"This substantial gap between the clinical observations and various anecdotal reports highlighted in popular media underscores the desperate need shared by the entire epilepsy community for robust scientific evidence regarding the potential benefit and risks of marijuana in people with epilepsy," said Dr. Chapman.

A second study (Poster 2.372) documents the experiences reported by parents of children with infantile spasms (IS) or LGS who were treated with artisanal CBD-enriched cannabis preparations. Through a survey of 53 parents whose children had IS and/or LGS (n = 53), the UCLA based researchers found that 92% of parents reported a reduction in seizures and 13% reported complete seizure-freedom. The majority of respondents reported using a CBD preparation with a CBD:THC ratio of at least 15:1. Prior to starting CBD, the parents reported that their children (median age for 3.6 years) had typically tried and failed 8 medications prior to CBD. Most patients with IS had failed both hormonal therapy (prednisolone and/or ACTH) and vagabtrin. The median length of other therapies was 6.9 months. The survey

participants reported that side effects of treatment were also less than those with other medications. Benefits reported included improvements in sleep, alertness and mood during the CBD treatment.

"Although this study suggests a potential role for CBD in the treatment of IS and LGS, it is important to note that this study does not represent compelling evidence of efficacy or safety," said Raymond Zhou, research associate, UCLA Infantile Spasms Project. "From a methodological standpoint, this study is extraordinarily vulnerable to participation bias and placebo effect as our data is self-reported by parents and did not use objective measures such as EEG. Our hope in presenting this data is to emphasize the need for controlled clinical trials to establish safety and efficacy."

A third study (Poster 2.104) is a single case of a child with Doose Syndrome whose family initiated independent CBD treatment. A child aged 4 experiencing multiple seizure types tried several medications with various and limited benefits. Baseline video EEG showed that the child had at least 10 seizures per day while awake and asleep. Immediately after starting on CBD the child continued to have seizures and Valproic acid levels increased substantially. When the dosage of Valproic acid was reduced the blood level returned to the previous range, and over 4 months seizures disappeared clinically and a repeat EEG was normal in both awake and asleep periods.

"We cannot recommend CBD treatment based on the limited evidence at this time, but do hope that families who independently seek CBD treatment will continue conventional therapies and remain in close contact with their healthcare providers," said Jeffery Gold, MD, Ph.D., Rady Children's Hospital of San Diego. "Establishing EEG measures before and after CBD treatment will provide the best possible insight into the benefits of the treatment. Further, since the effect of CBD treatment on other medications is undetermined, we recommend that physicians work with families to determine if adjustments to other medications are necessary."

All three research studies will be provided in full at the American Epilepsy Society Annual Meeting in Seattle, December 5-9. Abstracts referenced above can be found on the American Epilepsy Society's <u>Annual Meeting Page</u>.

Editor's Note: The authors of the second study will be available at a press briefing on December 8, 2014 at 11:00 AM (PT)/ 2:00 PM (ET), and the authors of the other studies will be available on December 8, 2014 at 1:30 PM (PT)/ 4:30 PM (ET) in the onsite press room, Room 304, Level 3 of the Washington State Convention Center. The call-in number for off-site journalists is 1-605-475-4000, passcode 521653#.

About the American Epilepsy Society

The American Epilepsy Society (AES) is a non-profit medical and scientific society. Our individual members are professionals engaged in both research and clinical care for people with epilepsy from private practice, academia and government. For more than 75 years, AES has been unlocking the potential of the clinical and research community by creating a dynamic global forum where professionals can share, learn and grow. AES champions the use of sound science and clinical care through the exchange of knowledge, by providing education and by furthering the advancement of the profession.

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