

Three Studies Shed New Light on the Effectiveness of Cannabis in Epilepsy

New Research from University of Colorado and Updates on Development of Epidiolex

West Hartford, Conn., October 14, 2014 – In advance of the American Epilepsy Society’s (AES) Annual Meeting in December, the organization has offered highlights of groundbreaking research being studied at a number of institutions regarding the effectiveness of cannabidiol (CBD) and its derivatives as a viable treatment for people with epilepsy.

The first of three studies (Abstract#1.326) to be presented in full at the Annual Meeting 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) who had catastrophic forms of epilepsy and 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.

Two additional studies that will be featured at the Annual Meeting provide updates on the development of Epidiolex (GW Pharmaceuticals), a purified and formulated form of CBD. The first study (Abstract #3.303) explores initial data from an efficacy and safety study, a precursor to a randomized clinical trial. Twenty-three patients with treatment-resistant epilepsies, especially Dravet Syndrome, with an average age of 10, were enrolled in two sites at New York University and the University of California San Francisco. After establishing a 4-week baseline of frequency, type of seizures and existing antiepileptic

drug (AED) regimes, patients received a purified 98% oil-based CBD extract, of known and constant composition at a dose of 5mg/kg/day in addition to their baseline AED regimen. The daily dose was gradually increased until intolerance occurred or a maximum dose of 25 mg/kg/day was achieved. After three months of therapy, 39% of patients had a greater than 50% reduction in seizures with a median reduction of 32%. Seizure freedom occurred in 3/9 Dravet patients and 1/14 patients with other forms of epilepsy. Adverse effects were mostly mild or moderate and included somnolence, fatigue, AED level increases, decreased appetite, weight gain, diarrhea, increased appetite and weight loss.

"These results are encouraging, especially since they involved a group of children and young adults with very treatment-resistant epilepsy. However, we await the planned double-blind study to truly assess the safety and efficacy of Epidiolex," said Orrin Devinsky, M.D., director of the NYU Comprehensive Epilepsy Center and professor of neurology, neurosurgery and psychiatry at the NYU School of Medicine.

The second abstract related to Epidiolex (Abstract #2.309) examined the drug interactions between existing AEDs and the CBD extract Epidiolex. In this study, 33 patients (with an average age of 10) were taking an average of three different AEDs including clobazam (54.5% of patients), valproate (36.4%) and levetiracetam (30.3%), felbamate (21.2%), Lamotrigine (18.2%) and zonisamide (18.2%). Baseline AED concentrations were established and then taken again after the addition of CBD. Patients were given a purified 98% CBD extract, of known and constant composition at a dose of 5mg/kg/day in addition to their baseline AEDs. The study found that in patients on multiple AEDs, the addition of CBD may be associated with changes in serum concentrations of some concomitant AEDs. A subset of patients experienced an increase in clobazam concentrations requiring a dose adjustment and suggesting CBD's effects on the major metabolic pathway of clobazam.

"These results support experimental findings that CBD can affect metabolism of some common anti-epileptic drugs though the effects may not be seen in all patients. More studies are needed to understand the potentially complex interactions between CBD and other drugs but in the meantime, frequent monitoring of drug levels is warranted in children taking CBD-containing products, including medicinal cannabis," Daniel Friedman, M.D., epileptologist and a clinical neurophysiologist at the NYU Comprehensive Epilepsy Center.

All three of these 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 [Annual Meeting Page](#).

Editor's Note: The authors of these studies will be available for comment during a press briefing at the Annual Meeting at the Washington Convention Center room 304, level 3. Press can also join by phone.

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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