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MEDIA RELEASE

“SUBJECTIVE BENEFIT” TO CANNABIDIOL IN EPILEPSY

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A NEW trial of cannabidiol as a treatment for drug-resistant epilepsy in children has indicated “some subjective benefit for overall health, with a manageable adverse event profile”, according to the authors of the research, published online today by the *Medical Journal of Australia*.

The trial, a prospective, open label cohort study, involved 40 children enrolled in the NSW Compassionate Access Scheme for children with drug-resistant epilepsy and uncountable daily seizures. The children received cannabidiol as an adjunct anti-epileptic drug, titrated to a maximum of 25 mg/kg/day, for up to 12 weeks.

“Thirty-nine patients reported at least one adverse event; many were deemed unrelated to cannabidiol treatment,” reported the authors, led by Dr John Lawson, a paediatric neurologist at Sydney Children’s Hospital, Randwick.

“The most frequent treatment-related adverse event was somnolence (15 participants), which resolved spontaneously in ten patients; it was particularly frequent in patients taking higher clobazam doses. Gastrointestinal effects (nausea, vomiting, diarrhoea) were each reported by seven to nine participants. Four children were withdrawn from treatment, including one with elevated transaminase levels.

“The caregivers of 12 children felt the overall health of their children had much or very much improved; clinicians assessed seven children as being much or very much improved.”

The authors also reported that 17 patients were admitted to hospital or presented to the emergency department during the 12-week study period, not significantly different from the presentation rate for the preceding 12 months.

“There was no significant change in the number of rescue medication episodes or episodes of status epilepticus. No participants reported complete freedom from seizures.”

The authors cautioned against overstating their results.

“Our study had no objective outcome measure of efficacy, as the strict eligibility criteria (including uncountable seizures) for participation meant that changes in seizure frequency could not be quantified,” they wrote.

“The major limitation was the open-label design and lack of objective endpoints for assessing participants selected for compassionate access because of the severity of their disease; subjective assessment is liable to bias. Participants who reported a benefit could continue receiving cannabidiol, and this may have influenced self-reported improvement. Additionally, the cohort included children with a heterogeneous group of aetiologies.

“Finally, the treating clinician could change the doses of cannabidiol and other concurrent AEDs throughout the trial; it is therefore not possible to attribute any benefit to cannabidiol alone.”

They concluded with a call for more research.

“Randomised, controlled trials can help control for the biases that affected our study and provide data for informing further medical decisions about the patient population suitable for cannabidiol therapy, safety monitoring, and efficacy.”

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