

Lamotrigine Effective Add-On for PGTC Seizures

BY DIANA MAHONEY
New England Bureau

LOS ANGELES — Adjunctive therapy with lamotrigine significantly reduced the number of primary generalized tonic-clonic seizures in children and adolescents in whom such seizures are inadequately controlled with other antiepileptic drugs alone, judging from findings reported by Edwin Trevathan, M.D.

The investigators, with funding by GlaxoSmithKline, conducted a subanalysis of a larger double-blind, placebo-controlled study looking at the safety and efficacy of lamotrigine (Lamictal) as an adjunctive therapy in both adults and children with primary generalized tonic-clonic (PGTC) seizures, Dr. Trevathan said at the annual meeting of the Child Neurology Society.

The approved pediatric indications of lamotrigine are management of simple or

There were no reports of drug-induced serious rashes. The most common adverse events reported during treatment were headache, nasopharyngitis, and convulsion.

complex partial seizures or Lennox-Gastaut syndrome, a devastating childhood epileptic encephalopathy. The drug is not approved for use in children under 2 years of age.

In the larger study, 117 children, adolescents, and adults with EEG-confirmed PGTC seizures who were taking one or two concurrent antiepileptic drugs who also experienced three or more PGTC seizures during an 8-week baseline phase were randomized to adjunctive treatment with lamotrigine (58) or placebo (59). In the majority of patients, epilepsy ideology was classified as idiopathic. Patients with evidence of partial seizures were excluded from the study.

Data were collected at baseline, during the 7-12-week dose-escalation phase, and during the 12-week maintenance phase, when the dosage of the study drug and concurrent antiepileptics was held constant.

The results showed that lamotrigine reduced PGTC seizures significantly relative to baseline during both the dose-escalation and maintenance phases individually and during the entire combined treatment period, said Dr. Trevathan, director of pediatric and developmental neurology at Washington University, St. Louis.

In the posthoc subgroup analysis looking at only the results for adolescents and children—21 of whom were randomized to lamotrigine and 24 who got placebo—lamotrigine reduced the number of PGTC seizures from baseline by 77% during the entire treatment period compared with 40% for placebo. “Although the analysis was not powered to evaluate this subset of patients, the reduction is statistically significant,” Dr. Trevathan noted.

In the dose-escalation and maintenance phases, lamotrigine therapy was associat-

ed with a seizure frequency reduction from baseline in children of 72% and 83%, respectively, compared with 30% and 42% in the placebo group.

There were no reports of drug-induced serious rashes—rare cases of toxic epidermal necrolysis or Stevens-Johnson syndrome have been reported with lamotrigine treatment—in either treatment group. The most common adverse events reported during treatment were headache (10% with lamotrigine vs. 25% with placebo),

nasopharyngitis (14% for lamotrigine vs. 4% for placebo), and convulsion (10% for lamotrigine vs. 13% for placebo). One patient from each treatment group dropped out of the study because of an adverse event.

“The magnitude of the effect that lamotrigine had on seizures in the subgroup analysis was approximately the same as was seen in the overall trial—basically a median percent reduction that was about twofold higher than placebo,” Dr. Tre-

vathan said. Because PGTC seizures are associated with a range of potentially injurious physiologic and behavioral changes before, during, and after they occur and can have life-threatening complications, “effective control of these seizures is especially critical in the vulnerable child and adolescent populations,” said Dr. Trevathan. “We hope the results of this analysis will encourage more clinical trials of children and adolescents who suffer from these seizures.” ■

In the treatment of patients with mild to moderate dementia of the Alzheimer's type...

Help him stay
INTERACTIVE
in his daily activities™

