Deutetrabenazine is Promising Treatment for Tardive Dyskinesia

Deutetrabenazine, a vesicular monoamine transporter 2 drug, shows improvement of tardive dyskinesia symptoms in phase II/III clinical trial.

Jennifer Gray Tomilov, PhD

July 12, 2017 – Patients with the movement disorder tardive dyskinesia (TD) had improved symptoms when treated with deutetrabenazine compared with placebo, researchers discovered in a phase II/III clinical study.

Hubert H. Fernandez, MD, with the Cleveland Clinic Center for Neurological Restoration in Cleveland, OH, and colleagues published their findings in the May 23, 2017 issue of *Neurology.*

According to researchers, TD is a movement disorder that often results from treatment with dopamine receptor antagonists (DRAs). "Approximately 20 to 50% of patients receiving antipsychotics develop TD," the group added.

In this study, deutetrabenazine, a "novel, highly selective" vesicular monoamine transporter 2 (VMAT2) inhibitor that regulates synaptic dopamine, was evaluated for its efficacy to treat TD. The drug effectiveness was particularly assessed in the scope of concomitant DRA use.

A total of 117 patients were randomly assigned in a 1:1 ratio either deutetrabenazine or placebo for the 12-week study. The drug was titrated from a starting concentration of 6 mg/day up to the maximum dose of 48 mg/day as required or tolerated per patient. A majority (~80%) of patients were concurrently treated with a DRA throughout the course of the study.

The primary endpoint was TD symptom assessment by the Abnormal Involuntary Movement Scale (AIMS). Deutetrabenazine treatment yielded a significantly reduced AIMS score compared with placebo (-3.0 [0.45] vs. -1.6 [0.46], p = 0.019) (mean [SE]).

Secondary endpoints including the Clinical Global Impression of Change (CGIC) and Patient Global Impression of Change (PGIC) were also documented. Although patients had improved scores for CGIC (48.2% vs. 40.4%) and PGIC (42.9% vs. 29.8%) for deutetrabenazine vs. placebo, respectively, these results were not statistically significant.

The researchers noted that deutetrabenazine treatment was generally well-tolerated: adverse effects occurred in three patients (5.2%) treated with deutetrabenazine and five patients (8.5%) treated with placebo. Somnolence (13.8% vs. 10.2%), insomnia (6.9% vs. 1.7%), and akathisia (5.2% vs. 0.0%) occurred more often in the deutetrabenazine group vs. placebo. No deaths were reported in this study.

"Almost all patients… had an underlying psychiatric comorbidity for which they were receiving concomitant medications, making these results especially relevant to clinical practice for clinicians managing similar patients in a real-world setting," detailed Dr. Fernandez in the *Neurology* manuscript.

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