CONFERENCE COVERAGE

OnabotulinumtoxinA Versus Topiramate for Prevention of Chronic Migraine: The FORWARD Study

A randomized trial examines discontinuations, efficacy, cognition, and depressive symptoms over 36 weeks of treatment.

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SAN FRANCISCO—For the prevention of chronic migraine, onabotulinumtoxinA has a superior tolerability profile versus topiramate based on treatment-related adverse events and overall discontinuations, according to data presented at the 60th Annual Scientific Meeting of the American Headache Society. In addition, “patient-reported outcomes data suggest that changes in cognition, an important adverse event leading to treatment discontinuation with topiramate, may be seen as early as week 12,” said Andrew M. Blumenfeld, MD, Director of the Headache Center of Southern California in Oceanside, and colleagues. Dr. Blumenfeld also reported that onabotulinumtoxinA has a more favorable effect on depressive symptoms than does topiramate.

According to Dr. Blumenfeld and colleagues, many adults with chronic migraine are not receiving appropriate preventive treatment and when prescribed, adherence to treatment is relatively low. To address this problem, he and his colleagues conducted a multicenter, prospective, randomized, parallel-group, open-label study to compare onabotulinumtoxinA and topiramate for headache prevention in adults with chronic migraine (the FORWARD study).

The study assessed the effectiveness of onabotulinumtoxinA 155 U administered to 31 sites across seven head and neck muscles, fixed-site, fixed-dose, every 12 weeks for three cycles versus topiramate 50 to 100 mg/day up to week 36. The primary efficacy measure was the proportion of
patients with a 50% or greater reduction in headache days versus baseline in the 28 days before week 32. Safety and tolerability were assessed; adverse events were monitored. Patient-reported outcomes collected from questionnaires at day 1 and weeks 12, 24, and 36 included the Controlled Oral Word Association Test (COWAT; a cognitive test assessing verbal fluency) and the nine-item Patient Health Questionnaire (PHQ-9; a measure of depressive symptoms). Baseline observation carried forward (BLOCF) was used to impute missing values at primary time points, followed by questionnaire guidelines for missing questionnaire data.

A total of 282 patients were enrolled—140 in the onabotulinumtoxinA arm and 142 in the topiramate arm. Mean baseline headache days (onabotulinumtoxinA, 22.1; topiramate, 21.8) were similar. Of the patients enrolled, 148 completed randomized treatment (onabotulinumtoxinA, 85.7%; topiramate, 19.7%). Primary reasons for withdrawal were ineffective treatment (onabotulinumtoxinA, 5.0%; topiramate, 19.0%) and adverse events (onabotulinumtoxinA, 3.6%; topiramate, 50.7%). Based on BLOCF, more patients on onabotulinumtoxinA had a 50% or greater reduction in headache frequency compared with baseline versus topiramate (40.0% vs 12.0%).

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