Botox Found to Reduce Frequency of Migraine

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PHILADELPHIA — OnabotulinumtoxinA appears to be a safe, effective, and well-tolerated headache prophylactic for patients with chronic migraine.

The PREEMPT 1 and 2 studies were conducted at centers in North America and Europe, and included 1,384 patients (average age 41 years). Each trial consisted of a 4-week baseline period, during which patients kept a headache diary, followed by 24 weeks of treatment during which patients received two injection cycles of either placebo or 155 U onabotulinumtoxinA (Botox), which has not been approved for migraine by the Food and Drug Administration. From 24 to 56 weeks, there was an open-label trial consisting of three injection cycles of the study drug, Dr. David W. Dodick of the Mayo Clinic Arizona, Phoenix, reported at the International Headache Congress.

At baseline, patients reported a mean of 20 headache-days a month, 19 of which were considered migraine days, with a mean of 290 cumulative headache-hours. The mean score on the Headache Impact Test-6 (HIT-6) survey was 65, indicating severe impact. Most of the patients (93%) also reported severe headache-related disability, and 65% were overusing acute pain medications. At 24 weeks, those in the active group had a significantly greater reduction in headache days and migraine days than those taking placebo (-8 vs. -6). The HIT-6 score also fell significantly more in the active group (–5 points vs. –2 points). The use of triptans did decrease significantly in the active group compared with the placebo group. The study was sponsored by Allergan Inc., maker of the study drug, and from which Dr. Dodick reported having received honoraria. ■