

# Botox Works Regardless of Medication History

BY DAMIAN McNAMARA

FROM THE INTERNATIONAL HEADACHE CONGRESS

BERLIN – People never treated for their chronic migraines and those who failed a previous first-line medication reported similar reductions in frequency of headache days after treatment with onabotulinumtoxinA in a post hoc comparison of the two phase III studies that Allergan used to gain approval for the new indication.

Some migraine medications work better in treatment-naive patients, compared with those with a past marred by partial responses or one or more failures to first-line prophylactic therapies.

For this reason, Dr. Sheena K. Aurora and her associates assessed data from the two phase III Research Evaluating Migraine Prophylaxis Therapy (PREEMPT) studies (Headache 2010;50:921-36) to determine if onabotulinumtoxinA treatment works the same way. They compared 575 participants with a history of migraine prophylaxis use to another 809 participants who never tried such a first-line medication, as defined by the British Association for the Study of Headache (BASH). Amitriptyline and propranolol were the most common previous medications.

There was no significant difference in the reduction of frequency of headache days with onabotulinumtoxinA be-



tween previously treated and untreated patients, Dr. Aurora said at the meeting, which was sponsored by the International Headache Society and the American Headache Society. A total 45% of patients with a history of first-line medication use versus 50% of those with no such history had a significant reduction in frequency of headache days.

“OnabotulinumtoxinA is an effective treatment of chronic migraine patients who previously failed BASH first-line migraine prophylactic meds and those naive to BASH first-line migraine prophylactic treatment,” said Dr. Aurora, a neurologist specializing in headache, migraine, and movement disorders at the Swedish Pain and Headache Center in Seattle.

Patients also experienced significant improvements in several secondary outcome measures that did not differ significantly between groups. These outcomes included frequency of migraine days, number of moderate to severe headache days, total cumulative hours of headache on headache days, and percentage of participants who reported severe migraines with a score of 60 or higher on the Headache Impact Test (HIT-6). Patient reports of improvements in health-related quality of life and disability did not differ significantly between groups, Dr. Aurora said.

The BASH guidelines assign medications to first-, second-, and third-line categories for prophylaxis against episodic

**Patients should undergo at least two treatment cycles. If they have absolutely no response, do not proceed.**

DR. DODICK

## VITALS

**Major Finding:** A total 45% of 575 first-line treatment-naive chronic migraine sufferers significantly responded to onabotulinumtoxinA treatment vs. 50% of 809 others with no such medication history.

**Data Source:** Post hoc analysis of the PREEMPT chronic migraine study.

**Disclosures:** The study was funded by Allergan. Dr. Aurora is on the Allergan medical advisory board. Dr. Blumenfeld and Dr. Dodick have received funding from Allergan.

migraines. However, many physicians use the same medicines to help chronic migraine sufferers, Dr. Aurora said, so the study answers a clinically relevant question.

Chronic migraine affects approximately 2% of the global population. Chronic migraine sufferers also report greater disability than patients with episodic migraine, according to Dr. Andrew Blumenfeld, who spoke during a separate session at the congress. “Chronic migraineurs experience a higher percentage of severe disability on more headache days than episodic migraineurs.”

The burden of illness could be an additional criterion to define chronic migraine beyond the traditional cutoff of 15 or more affected days per month, said Dr. Blumenfeld, who was the lead author on a study comparing disability status and migraine frequency (Cephalalgia 2011;31:301-15). He is a neurologist in private practice in Encinitas, Calif.

The PREEMPT studies included 1,384 highly disabled migraine patients who reported 15 or more days per month with a headache lasting at least 4 hours per day. In the 24-week, multi-

center, double-blind study, researchers randomized 688 of these men and women aged 18-65 years to onabotulinumtoxinA and another 696 to placebo. A 32-week, open-label phase followed the acute treatment study.

“There was a cumulative benefit over time – most patients continued to receive treatment benefit after five treatment cycles,” Dr. David Dodick, one of the PREEMPT investigators, said in a separate presentation at the congress. “In clinical practice, patients should be administered at least two treatment cycles. If they have absolutely no response, do not proceed.”

“You can tell patients that almost 70% of patients treated with [onabotulinumtoxinA] had 50% or more reduction in headache days at 56 weeks,” said Dr. Dodick, professor of neurology at the Mayo Clinic in Phoenix.

The mechanism of action of onabotulinumtoxinA in chronic migraine remains to be elucidated, he said.

A recommended injection method for chronic migraine based on the PREEMPT studies, including a diagram of injection sites, was published in 2010 (Headache 2010;50:1406-18). ■

A video interview with Dr. Aurora can be viewed by using the QR code, or by visiting [www.clinicalneurologynews.com](http://www.clinicalneurologynews.com).



## Migraine Auras Are as Unique as Each Migraine Patient

BY MICHELE G. SULLIVAN

FROM THE ANNUAL MEETING OF THE AMERICAN HEADACHE SOCIETY

WASHINGTON – Aura with migraine seems to be a heterogeneous phenomenon, with up to 40% of patients in a prospective cohort reporting color as a component of the visual manifestation.

Dr. Deborah Friedman, a professor of ophthalmology and neurology at the University of Rochester (N.Y.), discussed results of an observational study of 122 subjects with migraine and aura at the meeting. They were surveyed about the characteristics of their visual symptoms and asked to draw their aura. The surveys were carried out at the university and at a clinic in Florianópolis, Brazil, during 2009-2010. Most (102) were women.

A majority of the patients (83%) were diagnosed as having typical aura with migraine. Another 9% had typical aura with nonmigraine headache. Others had had aura without headache (5%) or aura with probable migraine (3%).

In addition to visual symptoms, about 33% of the group also had other types of aura, including sensory, speech disturbance, motor symptoms, dizziness, and olfactory sensations.

“About 40% reported that they always experience aura with all of their headaches,” Dr. Friedman said. Another 40% reported that aura occurred with fewer than half

of their headaches, and 20% said aura accompanied more than half of their headaches.

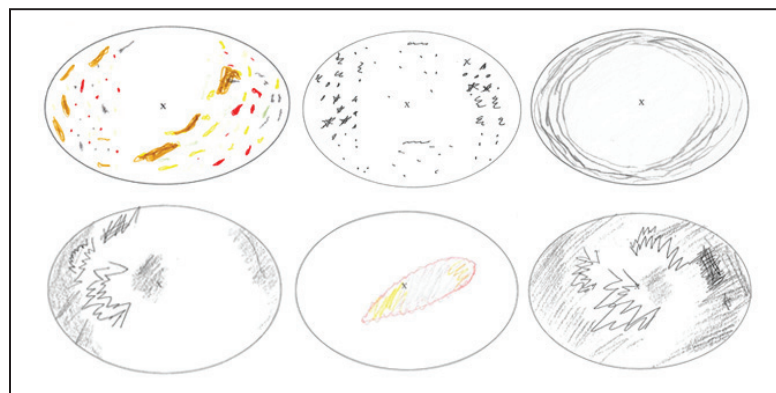
Auras started early in the headache history for most patients – 61% said the symptom appeared within the first year of having migraine.

The phenomenon begins in different fields of vision and different locations in relation to the region of pain.

“In about half, the aura starts in the peripheral visual field and in 45%, centrally. Only 5% said the aura clearly began in one hemifield of the vision.” Most auras were unilateral (75%). But 8% of patients said their aura always occurred on the contralateral side of a unilateral headache.

Motion was a common feature. “We tend to think about aura as moving across the visual field. In 57% of our group, this was true, with the aura moving from the center to the periphery in 48% and from the periphery to the center in the rest of the patients.” Most (67%) also reported a shimmering quality to the aura.

Timing was variable, Dr. Friedman said. “Most patients experienced aura before the onset of headache, with 65% reporting it less than 30 minutes before.” But



Patients' drawings of their aura show small bright dots, zigzag lines, crescent or C-shaped manifestations, mosaic patterns, round forms, and tunnel vision.

15% said it could occur up to 4 hours before a headache, and 20% said the two occurred simultaneously.

Color was a component of 40% of aura, with 18% of patients reporting their auras as always colorful. The majority also reported blurred vision as part of the phenomenon.

Other characteristics included small bright dots, zigzag lines, and crescent or C-shaped manifestations. Less often, patients reported bright flashes, blind spots, flickering lights, “heat wave” shimmer, partial loss of vision, colored or white spots, and corona. ■