WHAT'S NEW IN MIGRAINE RESEARCH?

Good News Concerning Botox

Results from the COMPEL and FORWARD studies recently were presented at the annual scientific meetings of the American Academy of Neurology, the European Academy of Neurology and the American Headache Society.

In COMPEL, patients with chronic migraine http://www.migraineurmagazine.com/migraine/winter/managing-your-migraine participated in a study intended to evaluate the long-term effect of ona botulinumtoxinA (BotoxA). The results confirmed the treatment's safety and continued effectiveness over a period of 108 weeks (9 treatment cycles).

Further analysis of the COMPEL results demonstrated that BotoxA was equally as safe and effective in patients overusing acute/symptomatic medication...

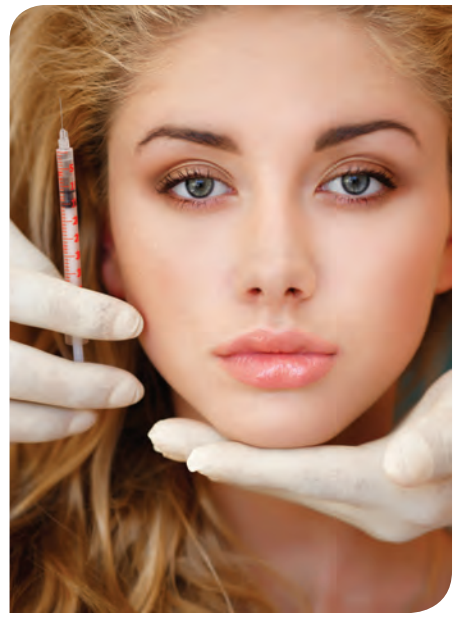
Further analysis of the COMPEL results demonstrated that BotoxA was equally as safe and effective in patients overusing acute/symptomatic medication (eg, acetaminophen) at the study's outset as it was in patients who were not overusing such medication. Given that overuse of acute/symptomatic medication is estimated to occur in 50-80% of patients with chronic migraine, these results come as welcome news.

FORWARD was a unique study for several reasons. First, it was an "active comparator" trial, involving two therapies widely used for chronic migraine, topiramate "immediate release" (IR) and BotoxA, rather than the usual comparison of a single active therapy to placebo. Second, the two therapies were investigated for their "usefulness", a blend of efficacy (does the treatment reduce chronic migraine... and if so, how much?) and tolerability (efficacy aside, do intolerable side effects arise and lead to treatment being discontinued?). Finally, after 12 weeks of therapy patients initially randomized to topiramate IR were given the option of "crossing over" to treatment with Botox.

When investigators evaluated treatment outcome, they found that only 12% of the patients initially randomized to treatment with topiramate IR achieved at least a 50% reduction in their headache burden compared to their pretreatment baseline. In the BotoxA group, over three times as many patients (40%) achieved that endpoint. The primary reason patients discontinued topiramate IR was poor tolerability; the drop-out rate was 14 times higher in the topiramate IR group than in the BotoxA group.

Conclusions from FORWARD Study

- For patients being treated for chronic migraine, serial BotoxA injection therapy is far better tolerated than is topiramate IR.
- In the relatively few chronic migraine patients who can tolerate topiramate IR, the drug may be at least as effective as BotoxA in suppressing headache. When the issue of tolerability is factored in, however, BotoxA is far more "useful" than topiramate IR. Whether more potentially tolerable formulations of topiramate (such as the extended release formulations) would be as useful as BotoxA remains unknown.
- In FORWARD patients who chose to discontinue topiramate IR and switch to BotoxA, BotoxA appeared to be no less effective than it was in patients who received BotoxA from the outset.



Menopause: Far From a Certain "Cure" for Migraine

Your mother's migraine ceased when she reached menopause? Don't count on the same happening to you. Data presented at the 2018 annual scientific meeting of the American Headache Society indicate that female migraineurs often experience an *increase* in headache burden as they pass through menopause.

In the core group of 60 female migraineurs studied, 25 had no change in their headache disorders during and through menopause...

In the core group of 60 female migraineurs studied, 25 had no change in their headache disorders during and through menopause, while 35 experienced changes in their migraine during menopause. Sixty percent of those 35 women reported an increase in the intensity of their migraine headache attacks or more frequent attacks.

A slight majority of the women in both groups were on estrogen hormone replacement therapy, and there were no significant differences in migraine frequency or intensity among those on versus not on estrogen replacement therapy.

The study's investigators hypothesized that fluctuations in sex hormone levels might be the mechanism that generates a change in migraine pattern, suggesting that a significant dip in estrogen level may stimulate migraine change during menopause transition,.

Commenting on the study, Vincent L. Martin, MD, professor of medicine and director of the Headache and Facial Pain Center at the University of Cincinnati, a widely acknowledged expert in hormonal influences in migraine, agreed that changes in hormone levels might well be the causative factor that leads to a menopause-related change in migraine pattern.

"A number of hormonal events occur during menopause," Dr. Martin said. "In early menopause, for example, the changes in the levels of estrogen are much more pronounced than they were during the pre-menopausal period. Levels of progesterone - considered a "protective' hormone - are decreased. These changes may favor clinical worsening of migraine."

In the later stages of menopause, Dr. Martin added, women have very low levels of estrogen, and those low levels may aggravate migraine. "Sometimes these changes in hormone levels can trigger new-onset migraines among women who never had them before," he suggested. "Or they could make migraine worse."

"The menopausal transition period is a time in when some of the worst migraine headaches can occur," he concluded.