DEBATE: THE BEST TREATMENT FOR CHRONIC MIGRAINE IS ONABOTULINUMTOXINA (BOTOX) - YES

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Migraine is the most common neurologic disorder. In a significant percentage, it may progress to chronic migraine (CM). The latter is common, affecting from 1½ to 2½% of the general population around the world. CM is recognized as a complication of migraine, distinct from episodic migraine (EM), characterized by headache frequency of at least 15 days per month. It is associated with greater disability and care costs than episodic migraine. 20% of chronic migraine sufferers are occupationally disabled, and many have difficulty attending social functions or performing household work. HIT-6 score has been validated as a reliable instrument for chronic migraine characterization by the American Migraine Prevalence and Prevention Study, and is elevated more in CM than EM.

There are many challenges in the care of individuals with CM. As part of helping them control headache frequency and severity, psychosocial factors, medication use patterns and prevention therapies are all important.

Preventive therapy is used to try to reduce the frequency, duration, or severity of attacks. Optimal preventive therapy should have good safety, tolerability, and effectiveness as well as ideally, infrequent need for treatment.

Few preventive medications have been studied for chronic migraine and currently only onabotulinumtoxinA has regulatory approval. Preventive oral medications for episodic migraine generally have responder rates of approximately 50% in reducing headaches by 50%, and studies of these generally have excluded chronic migraine sufferers. Of various medicines currently approved for episodic migraine, only topiramate has been studied to some degree for chronic migraine. Studies of this medication for chronic migraine have shown effectiveness, even in individuals who overuse acute abortive medicines. However, systemic side effects with this medication, as with other oral medications are common. Dropout rates due to side effects in the pivotal topiramate approval trials average about 30%, reflecting tolerability issues. No large well-designed, blind placebo controlled, pivotal trials for the management of chronic migraine with this medication have been performed.

Studies of onabotulinumtoxinA (Botox) have been performed evaluating its effectiveness in headache prophylaxis. Prior studies of episodic migraine showed no evidence of definitive benefits, and likewise a study of chronic tension type headache did not show a significant benefit favoring Botox in the number of headache free days per month.

Two pivotal trials have been performed of onabotulinumtoxinA for chronic migraine. These two studies included a total of 1384 patients randomized and treated. A variety of safety and effectiveness measures were captured and analyzed. The demographic baseline data of these studies was representative of the usual chronic migraine population. Approximately 2/3 were overusing acute headache pain medicines, which is common amongst chronic migraine sufferers.

Analysis of the studies by headache days and headache hours showed statistical benefit compared to placebo. Compared to baseline, Botox treated patients had a marked reduction in headache frequency and headache hours. The reduction of headache days compared to placebo was greater than in pivotal trials of divalproex or topiramate.

Side effects in the onabotulinumtoxinA pivotal trials were generally mild and transient, including headache, neck pain, or lid droop. Discontinuation in onabotulinumtoxinA treated patients due to adverse effects was seen in 4%, vs 1% in placebo treated patients.

Summary:
Chronic migraine is a disruptive and complex condition, which has significant costs and consequences, and for which more effective management strategies are needed. OnabotulinumtoxinA has been studied for the management of chronic migraine, and has been shown to be safe, generally well tolerated, and with good effectiveness. Other preventive medications have not shown this same balanced profile. Thus, onabotulinumtoxinA is the best preventive treatment currently available for chronic migraine.