Scalp injection of botulinum toxin type A (BT-A) into the superficial musculature has evoked interest in the management of headache. In clinical trials, prevention of migraine attacks for 3 months or more has been seen in some patients following BT-A scalp injections. A direct or independent and prolonged analgesic action unrelated to skeletal muscle relaxation is believed to underlie the prophylactic efficacy of BT-A in migraine; peripheral and central modulation of pain impulses by BT-A has also been proposed. However, a direct peripheral antinociceptive effect was not seen in controlled studies of BT-A in normal human volunteers. Most of the initial reports on botulinum toxin in tension-type headache (TTH) and in migraine were positive. Unfortunately, these results were not reproduced in well-designed, randomized controlled trials. Researchers argued that current evidence does not support the use of botulinum toxin type A injections for migraine prophylaxis (1-4). So far, doses from 20 U (Botox) to 500 U (Dysport) have been studied in patients with chronic TTH, and doses from 16 to 200 U (Botox) in patients with migraine. Overall, there is no evidence for a beneficial effect of botulinum toxin, although trends favoring botulinum toxin were reported. The extended period for which migraine prophylaxis might be required, the antigenic and headache-provoking potential of BT-A, the inability of BT-A to affect central neuronal processes significantly, including the aura of migraine, the possible placebo effect of needling, and purely subjective outcome measures in headache studies are additional concerns in evaluating this treatment strategy. The clinical utility of BT-A has not been compared against established migraine prophylactic agents. Some have noted that some patient subpopulations may benefit from such treatment for some headache types, but identifying these patients will be difficult.

To summarize, the efficacy of BT-A in preventing migraine headache attacks remains controversial and the underlying scientific rationale is debatable. The mode of action by which botulinum toxin is effective in migraine prophylaxis is not fully understood and is under investigation. Currently, a number of other randomized, placebo-controlled, clinical trials are being conducted to evaluate the efficacy, optimal dosing, and side-effect profile of botulinum toxin type A in the prophylaxis of migraine and other headache entities.

Finally, and perhaps most notably, was the previously mentioned May 2008 recommendation of the American Academy of Neurology against the use of botulinum neurotoxin in the treatment of episodic migraine and chronic tension-type headache (4).

References: