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Citation

Authors' objectives
This Assessment will evaluate whether or not the addition of botulinum toxin (BTX) injections to patients usual regimens of prophylactic and/or abortive drug therapy improves outcomes in patients with primary chronic headache syndromes who have significant disability due to headaches in spite of conventional pharmacologic treatment.

Authors' conclusions
BTX for Headache Prophylaxis:

Migraine. Since the 2002 TEC Assessment, 1 new study meeting selection criteria has appeared. Published in 2004 (n=60), this trial randomized patients to saline placebo, low-dose BTX-A, or high-dose BTX-A. No significant differences were reported at 3 months for any of 7 pain-related outcomes. The low dose of BTX-A had a lower rate of accompanying symptoms (photophobia, phonophobia, nausea and vomiting), compared with the placebo and high-dose groups. A study from 2000 (n=123) provided mixed results for the use of BTX for migraine prophylaxis. This moderately sized trial reported only short-term outcomes, and questions remain regarding the variability of effect at different time points, as well as variability of dose and injection site. Isolated findings of statistical significance favoring BTX-A in these 2 studies could be explained by chance alone and evidence is judged insufficient for conclusions.

Tension Headaches. The 2002 TEC Assessment reviewed 4 trials providing data for 125 patients. Only 1 of these studies gave data suggesting better outcome for BTX-A over placebo. Four additional studies with data for 223 patients have appeared subsequently. Taking previously available and recent studies together, among 5 of 8 studies which identified a primary outcome, none found statistically significant differences favoring BTX-A over placebo for that outcome. In 2 studies, the primary outcome was area under the headache curve (AUC), computed as the sum of the product of headache duration and severity across days. The primary outcome was headache severity in 2 studies and headache frequency in 1 study.

Two of the 8 studies had fair quality ratings, while the other 6 were rated as poor. Neither of the two better-rated studies found significant differences between placebo and BTX-A groups. The largest study (n=107) found no differences between groups on 6 outcomes. The second study rated as fair in quality found inconsistent significant results. In 1 of these studies, there did not appear to be a statistically significant result on the primary outcome or 4 other outcomes, while 3 global rating scales significantly favored the BTX-A group. Groups differed greatly on the baseline mean frequency of headaches and the authors did not mention adjustment for confounding in the data analysis. Two other poor-quality studies finding selected significant differences between groups did not evaluate comparability of groups on any baseline characteristics or specify that analyses used adjustment techniques, so it is unclear whether findings were influenced by confounding.
The failure of 2 better-quality studies to find between-group differences calls into question the weakly positive findings of 3 poor quality studies. Overall, the evidence is not sufficient to support conclusions about the effects of BTX-A on tension headaches.

Cluster Headaches. Other than case reports, no studies of BTX-A treatment for the prevention of cluster headaches have been reported. Thus, no evidence of adequate quality exists to evaluate the effect of BTX-A injections on cluster headache.

BTX for Treatment of Acute Headaches:

There were no studies meeting inclusion criteria that tested BTX for the treatment of acute headache attacks. Thus, the evidence is insufficient to determine whether or not BTX-A is an effective treatment for acute migraine episodes.

3. The technology must improve the net health outcome; and
4. The technology must be as beneficial as any established alternatives.

The available evidence does not permit conclusions regarding the prophylactic or abortive effect of BTX-A or any other botulinum toxin type on chronic primary headache syndromes.

5. The improvement must be attainable outside the investigational settings.

It has not yet been demonstrated whether botulinum toxin improves health outcomes in the investigational setting. Therefore, it cannot be demonstrated whether improvement is attainable outside the investigational setting.

Based on the above, botulinum toxin therapy for primary chronic headache disorders does not meet the TEC criteria.

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