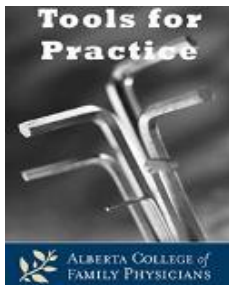


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## **Toxins for Health? Botulinum toxin for migraine.**

### **Clinical Question: What is the efficacy of botulinum toxin for migraine prophylaxis?**

**Bottom Line: Patients with chronic migraine who receive botulinum toxin (example Botox™) have 2 fewer migraine days per month compared to placebo (from 19 days to 11 days with treatment versus 13 days with placebo), with no benefit in episodic migraine. Adverse events include blepharoptosis, muscle weakness, neck/injection site pain and 3% stop treatment due to adverse events.**

#### **Evidence:**

- Systematic review of 28 double-blind, randomized, controlled trials (RCTs); 4190 patients with chronic or episodic migraine; mean age 42, 85% female, baseline number of headache days/month 19.<sup>1</sup> Follow-up 4 weeks (single treatment) to 9 months:
  - Versus placebo:
    - Number of headache days per month:
      - Chronic migraine (based on 2 largest RCTs):<sup>2,3</sup> from 19 days at baseline to 11 versus 13 (placebo), mean difference 1.9.
    - Headache severity lower with treatment by ~3 points on 10-point scale.
    - Other outcomes (migraine duration, migraine attacks per month, proportion with ≥50% reduction in migraine attacks or days): no difference.
    - Subgroup analysis of episodic migraines: no difference in migraine frequency or number of attacks.
    - Adverse events:
      - Blepharoptosis: 7.5% versus 0.5% placebo, number needed to harm (NNH)=14.
      - Muscle weakness: 13.4% versus 0.6% placebo, NNH=7.
      - Neck or injection site pain: NNH=11 or 40, respectively.
      - Stopping for adverse effects (4 RCTs): 3% versus 0.8%, NNH=45.
  - Versus topiramate or valproate:
    - Number of headache days per month: no difference.

- Withdrawal due to adverse effects: 6.7% versus 27.1% topiramate/valproate, NNT=5.
  - Limitations: Most RCTs industry sponsored, ~63-70% of patients in the 2 largest RCTs may have had medication overuse headache<sup>2,3</sup>, multiple outcomes reported.
- Other systematic reviews found similar.<sup>4,5</sup>

**Context:**

- Chronic migraine defined as  $\geq 15$  headache days/month (with at least 8 migraine days).<sup>1</sup>
- Botulinum toxin does not reduce number of chronic tension-type headaches.<sup>5</sup>
- Adverse effects generally transient but can last a few months.<sup>6</sup>
- Botox™ RCT dose 155-195 total units, delivered as 5-unit (0.1 ml) injections at 31-39 sites.<sup>2,3</sup>
  - Cost ~\$800 every 3 months.
- Guidelines suggest use<sup>7</sup> in chronic migraine after failure of 2-3 prophylactic agents.<sup>8</sup>

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**Disclosures:**

Authors do not have any conflicts of interest to declare

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