Evidence-Based Practice
A Peer-Reviewed Journal of the Family Physicians Inquiries Network
VOLUME 19  NUMBER 5  MAY 2016

IN DEPTH

What are the complications and complication rates of cosmetic Botox injections?

Evidence-based answer
Complications from cosmetic Botox injections depend on the location of treatment; they include headache (2%–17%), brow ptosis (3.1%), blepharoptosis (2.5%), muscle imbalance (6.9%), muscle bulge (5.9%), and bruising (9.2%–25%). Complications may last from several hours (headache) up to 1 month (some nerve paralysis) (SOR: A, systematic review of RCTs and subsequent RCT). Treatment applied to the upper and periocular regions of the face have the highest complication rates (4%–8%) (SOR: C, case series).

Evidence summary
A systematic review of 35 randomized, double-blind and open-label trials (N=8,787) evaluated the safety of botulinum toxin from 2000 to 2012. Studies with safety as a primary or secondary endpoint and studies indicating treatment for aesthetic conditions were included. Formulations used included onabotulinumtoxinA, abobotulinumtoxinA, and incobotulinumtoxinA at doses of 2 to 199 units. Only some results were pooled; the rest were reported separately, and statistical testing between treatment and placebo was not reported.

The most common adverse events were documented based on treatment location. All events were temporary and resolved spontaneously, within hours (headache) or up to a month later (eyelid ptosis).

For treatment of glabellar lines, 2% to 16.8% experienced a transient mild to moderate headache, which was reportedly not significantly different from 0% to 20% for placebo (15 studies, n=6,183). For any site, blepharoptosis occurred in 2.5% compared with 0% in the placebo group (11 studies, n=5,689) while eyebrow ptosis occurred in 3.1% (9 studies, n=1,661). For treatment of crow’s feet, mild bruising was the most common adverse event in 9.2% to 25%, similar to the 12.5% rate in the control group (2 studies, n=212). Lower face treatments induced perioral and labial muscular imbalance in 6.9% (4 studies, n=203). In 1 study (n=82), treatment of hypertrophied masseter muscles produced a muscle bulge in 5.9% compared with 0% of controls.
A 2013 double-blind, multicenter RCT evaluated 276 patients to assess the safety and efficacy of botulinum injections for glabellar frown lines. Patients received 5 injections of 0.1 mL per site that contained either 4 units of incobotulinumtoxinA or placebo at each site and were observed for 120 days. Patients in the study were adults with moderate to severe glabellar frown lines based on a facial wrinkle scale (FWS) score of 2 or 3. The FWS measures the severity of glabellar frown lines as 0-none, 1-mild, 2-moderate, or 3-severe.

Adverse reactions occurred in 7.1% of the treated patients versus 2.2% in those receiving placebo injections (no statistical analysis reported). The most common reaction was headache, reported in 3.8% of the botulinum group versus 2.2% in the placebo group (no statistical analysis reported). Two cases of transient ptosis resulted from botulinum injection of the bilateral eyebrows and brow.

A retrospective case series of 1,819 patients (5,310 treatments) at a single medical center analyzed the adverse events of botulinum toxin treatments performed by several specialists (neurology, ophthalmology, dermatology, plastic surgery) for conditions including cervical dystonia, hemifacial spasm, jaw dyskinesia, masseter hyperplasia, and wrinkle correction. Patients who received at least 1 injection of botulinum toxin A (onabotulinumtoxinA or abobotulinumtoxinA) were included. Most patients were women (73%), with an average age of 54 years.

Side effects were categorized as either muscle-related adverse events (ptosis, drooling, neck discomfort, dysphagia, and facial paralysis) or muscle-unrelated adverse events (edema, bruising, injection pain, and dissatisfaction). Ptosis (0.8%) and dissatisfaction (0.4%) were the most common. Treatment of blepharospasm, upper facial wrinkles, and hemifacial spasm incurred the highest adverse event rates of 8%, 4%, and 4% respectively, with muscle-related and muscle-unrelated events occurring at similar rates. A periocular injection site carried the highest adverse event rates. All adverse events (not described) were considered tolerable and lasted less than 4 weeks.

Matthew Lomeli, MD
Michael Mercado, MD
Naval Hospital Camp Pendleton
Camp Pendleton, CA

The opinions and assertions contained herein are those of the authors and are not to be construed as official or as reflecting the views of the US Navy Medical Department, the US Navy at large, or the US Department of Defense.

REFERENCES