

Botulinum Toxin Use During Pregnancy: Analyzing Maternal-Fetal Outcomes

Shannon Y. Zhou, BS¹

¹University of Minnesota Medical School, Minneapolis, MN

Introduction

Botulinum toxin (BoNT), or Botox, is a neurotoxin produced by *Clostridium botulinum* that inhibits acetylcholine release at the neuromuscular junction, resulting in local muscle paralysis. Its uses are diverse, including treatment for chronic headaches, cervical dystonia, hyperhidrosis, achalasia, and aesthetic wrinkle reduction. With its rising popularity among individuals of reproductive age, questions about its safety during pregnancy have also emerged. Despite minimal systemic absorption, it is classified as a category C drug by the U.S. Food and Drug Administration. This signifies uncertainty about fetal safety and limited high-quality studies. One study in a murine model showed that a 500U dose of BoNT led to fetal body weight reduction and decreased skeletal ossification. Most clinical guidelines advise against use during pregnancy in the absence of robust human data. To better understand the maternal-fetal effects of pre- and intra-pregnancy BoNT exposure, a scoping review was conducted.

Methods

A systematic search of PubMed, Embase, Scopus, and Cochrane was conducted from inception through March 2025. Studies were included if they reported maternal or fetal outcomes following BoNT exposure before or during pregnancy. Case reports, case series, observational studies, and clinical trials were included. Extracted data included BoNT indication, timing, dosage, pregnancy outcomes, and maternal and fetal complications. Risk of bias was also assessed using the NIH Study Quality Assessment Tools.

Results

Of 222 studies, 8 met inclusion criteria. In total, there were 464 BoNT-exposed pregnancies. The most common indications were headache (32.1%) and aesthetic use (26.3%), followed by hyperhidrosis (5.8%), torticollis (5.2%), and dystonia (2.8%). BoNT was most often administered during the third trimester at a dose above 100U, though this was largely due to 1 outlier study. Dosages otherwise were more evenly dispersed in the 50-100U range. The spontaneous miscarriage rate was 15.3%—within the expected non-BoNT-exposed rate of 10–20%. Fetal complications were low and included preterm birth (1.1%), intrauterine death (0.9%), low birth weight (0.2%), and major congenital anomalies like cleft lip (0.2%). Across studies, there was no consistent pattern of adverse maternal or fetal outcomes. However, study quality was limited, with most data coming from case reports and case series with small sample sizes, minimal follow-up, and no controlled comparisons.

Conclusion

Literature suggests that Botox exposure during pregnancy is not consistently associated with adverse maternal or fetal outcomes, though the evidence base is limited. More rigorous studies are needed to support informed decision-making regarding BoNT use in pregnant patients.