

Safety and Clinical Outcomes of an Equine-derived Heptavalent Botulinum Antitoxin Treatment for Confirmed or Suspected Botulism in the United States

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Abstract

Background

Botulism is a rare, life-threatening paralytic illness. Botulinum Antitoxin Heptavalent (A,B,C,D,E,F,G)–(Equine) (BAT) manufactured by Emergent BioSolutions Canada Inc is an equine-derived heptavalent botulinum antitoxin product indicated for the treatment of symptomatic botulism following documented or suspected exposure to botulinum neurotoxin serotypes A–G in adults and pediatric patients. BAT product was US-licensed in 2013.

Methods

In the United States, from October 2014 through July 2017, safety and clinical outcomes data were collected under a registry for patients treated with BAT product.

Results

Registry patients had a median age of 51 years (range, 32 days to 92 years). Among 162 patients, 7 (4.3%) experienced BAT product-related serious adverse events, including 1 (0.6%) report each of pneumonia, pneumonia aspiration, ventricular tachycardia, upper gastrointestinal hemorrhage, anaphylactic reaction, acute kidney injury, and acute myocardial infarction. Thirty-one (19.1%) patients had ≥1 BAT product-related adverse events. Six (3.7%) deaths were reported in the registry. All deaths were attributed to the underlying illness and were assessed as

unlikely related to BAT product. Among 113 (69.8%) patients with a final diagnosis of botulism, those treated early (≤ 2 days) spent fewer days in the hospital (5 vs 15.5 days), in the intensive care unit (ICU) (4 vs 12 days), and on mechanical ventilation (6 vs 14.5 days) than those treated late (> 2 days), respectively.

Conclusions

BAT product was well tolerated in patients. Treatment with BAT product at ≤ 2 days of symptom onset was associated with shorter hospital and ICU stays, and shorter duration and need for mechanical ventilation, showing clinical benefit associated with early treatment.

Keywords: [antitoxin](#), [BAT product](#), [botulism](#), [registry](#)

Topic: [botulism](#), [botulinum antitoxin](#), [equus caballus](#), [intensive care unit](#), [safety](#), [diagnosis](#), [treatment outcome](#)

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