

**Sensitivity of mouse bioassay in clinical wound botulism.**

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**BACKGROUND:** California has an ongoing epidemic of wound botulism (WB) among injection drug users (IDUs). We retrospectively studied a cohort of patients with WB and determined the sensitivity of the mouse bioassay-the gold standard laboratory test for confirmation of botulism-in verifying WB.

**METHODS:** We defined a clinical case of WB as an acute, bilateral, descending, flaccid paralysis starting with 1 cranial nerve palsies in an IDU with no other explainable diagnosis. We calculated the sensitivity of the mouse bioassay as the proportion of clinical WB cases that had positive serum toxin test results by mouse bioassay. We compared serum toxin-positive with serum toxin-negative patients.

**RESULTS:** Of 73 patients with WB, 50 tested serum toxin positive, yielding a sensitivity of 68%. Serum toxin-positive patients did not differ significantly from serum toxin-negative patients with respect to demographic characteristics or injection drug use practices or in days from patient symptom onset to collection of specimens for testing. Patients did not differ significantly by clinical characteristics, except that serum toxin-positive patients were more likely than serum toxin-negative patients to have required mechanical ventilation during their hospital courses (74% vs. 43%;  $P = .01$ ).

**CONCLUSIONS:** In this study, the mouse bioassay failed to detect botulinum toxin in the serum samples of nearly one-third of IDUs with characteristic WB. Such patients should be considered to have probable WB. Physicians should be aware of the test's limitations and base their final diagnosis of suspected WB on clinical criteria when the mouse bioassay produces negative results.

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