ABSTRACT

Assessment of Antibody Development in Patients Treated With Type A Botulinum Toxin

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The development of neutralizing antibodies in response to botulinum treatment of dystonic conditions is of significant concern in the long-term management of patients. This is particularly the case for patients with cervical dystonia, who receive larger doses of the products. Present estimates indicate up to 15% of patients may develop antibodies, becoming secondary non-responders to toxin therapy.

A series of 42 patients with cervical dystonia have been assessed for the development of antibodies to Botox® after varying treatment regimens and doses, including booster injections. A mouse *in vivo* antibody determination method was employed. Eleven (26%) demonstrated positive antibody response to varying degrees, with only three patients at the highest level of antibody titer. Seven antibody-positive patients were secondary nonresponders, whereas the other four were either previously poor responders or exhibited a decline in response to therapy. One patient was shown to have seroconverted to antibody-positive status between administration of toxin doses.

Of the entire group, 21 patients were classed as secondary non-responders by assessment of clinical efficacy of toxin administration. Therefore only approximately one-half of these were shown to have developed an antibody response, in line with reports from other studies where secondary non-response could not be entirely attributed to antibody development. These data underline the need to understand, in detail, the mechanism of secondary non-response before concluding that antibody development has prevented further therapy.

Some patient samples were also assessed by a commercial antibody *in vitro* determination using a Western blot technique. Two patients positive in the *in vivo* determination were found to be negative by the *in vitro* method. The Western blot method therefore may not register the presence of all neutralizing antibody levels in patient samples.

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