

## **BOTOX TREATMENT FOR SPASMODIC DYSPHONIA**

The following information is summarized from the consensus statement of NIH Consensus Development Conference, November 12-14, 1990. A copy this statement can be obtained from the Office of Medical Applications of Research, National Institute of Health, Building One, Room 260, Bethesda, Maryland, 20892. At present the injections of Botox are not approved by the FDA for use in voice and speech disorders. However, since there is no uniformly effective therapy for treatment of spasmodic dysphonias, Botox has become the widest and one of the most effective forms of therapy for this condition.

### **INTRODUCTION**

Botulinum toxin therapy for voice and speech disorders requires the involvement of an interdisciplinary team, including an otolaryngologist, a speech-language pathologist, a neurologist, and a physician skilled in regional electromyography. A psychiatrist and/or psychologist, voice scientist, and neuroradiologist should be available. Voice laboratory facilities should be available to assure valid diagnosis and to document and quantify voice and speech function before and following treatment. In addition, the team should make available to the patient other treatment such as voice and speech therapy.

### **ADDUCTOR SPASMODIC DYSPHONIA:**

Predominantly adductor spasmodic dysphonia is characterized by forceful, involuntary approximation of the vocal folds. This interrupts the airstream and produces a strained, hoarse, choppy voice. Botulinum toxin therapy is effective in ameliorating the symptoms and restoring fluency. Because the effect is temporary, repeated injections are required.

### **ABDUCTOR SPASMODIC DYSPHONIA:**

Predominantly abductor spasmodic dysphonias is a condition characterized by forceful, involuntary separation of the vocal folds. This causes breathy interruptions in speech. Botulinum toxin therapy has been reported to be effective in selected cases, but it carries a risk of bilateral abductor paralysis with airway obstruction if the posterior cricoarytenoid muscles are injected.

### **STUTTERING AND VOCAL TREMOR:**

Stuttering is characterized by repetitions of sounds and words, prolongations of sounds, and interruptions of the fluent flow of speech. Vocal tremor is characterized by quavering because of adductor and abductor oscillations of the vocal folds. Preliminary reports of botulinum toxin therapy for each of these conditions warrant further research.

## **WHAT ARE ITS SIDE EFFECTS AND COMPLICATIONS?**

Botulinum toxin is a safe therapy when administered in the appropriate doses by experienced physicians. Side effects are generally transitory, well tolerated, and amenable to treatment. Persistent complications are distinctly rare, and serious side effects are uncommon. Generalized weakness, mimicking botulism, is rare, but electromyographic abnormalities may occur in muscles distant to the site of injection without clinical signs of muscle weakness. Systemic complications are uncommon, but several studies report a flu-like syndrome, particularly after the first injection. A similar syndrome has been reported following placebo injection. Most complications are related to diffusion or, rarely, inadvertent injection of the toxin into nearby muscle groups. Some complications may be dose dependent.

Some patients develop antibodies to the toxin. It is unclear exactly what factors predispose to development of antibodies, but some studies suggest that risk is increased by the administration of more than 300 MU within a 30-day period and by low body weight of the patient. Antibodies may be one factor associated with therapeutic failure. The long-term (>5 years) effects of chronic botulinum toxin injections are unknown. Complications of therapy for specific disorders have been reported in large clinical studies and in a few, small, placebo-controlled studies. Although the types of complications are consistent from study to study, the rates vary, reflecting differences in technique and methods of data collection. Complications are described according to site of injection and clinical disorder.

## **CONCLUSIONS AND RECOMMENDATIONS:**

- Botulinum toxin therapy is safe and effective in the treatment of strabismus and in the symptomatic treatment of essential blepharospasm, hemifacial spasm, predominantly adductor spasmodic dysphonia, jaw-closing oromandibular dystonia and cervical dystonia.
- Botulinum toxin therapy appears promising in other conditions described in this report, but additional investigations, including controlled clinical trials, are needed.
- Botulinum toxin therapy is not curative in chronic neurological disorders
- Further study of the mechanism of action of botulinum toxin and its pharmacotherapeutics is needed.
- International standardization of measures of biological activity of botulinum toxin is needed.
- For most indications, botulinum toxin should be used by committed interdisciplinary teams of physicians and related health care professionals with appropriate instrumentation.
- The safety of botulinum therapy during pregnancy, breast feeding, and chronic use

in childhood is unknown.

- The long-term effects of chronic treatment with botulinum toxin remain unknown. Prolonged follow-up is necessary in patients on maintenance therapy. An independent national database should be established.
- The health care community needs additional education for the availability, benefits, risks and special health care provider skills associated with botulinum toxin therapy.
- Further clinical and basic research should be encouraged to address the many unanswered questions about botulinum toxin and its therapeutic uses.

