

Background

CERVICAL DYSTONIA

What is cervical dystonia?

Cervical dystonia, also called spasmodic torticollis, is a chronic, often painful neurological disorder. Cervical dystonia is a type of movement disorder – conditions that are characterized by loss of control over one or more parts of the body – which is estimated to affect approximately 125,000 people in the United Statesⁱ, yet awareness of the condition is extremely limited.

Cervical dystonia is characterized by involuntary contractions of the neck muscles that cause twisting, repetitive movements, or abnormal postures of the head. These muscle contractions hinder normal movement and can cause severe, chronic neck pain. The mean age of symptom onset in patients with cervical dystonia is approximately 41 years – although it may occur in all ages – and women are twice as likely to be affected as menⁱⁱ.

The symptoms of cervical dystonia usually develop gradually over a period of time, with the severity of symptoms leveling off after five yearsⁱⁱⁱ. These symptoms can include painful contractions of the neck muscles that force the head to move forward (anterocollis), backward (retrocollis), sideways (laterocollis), or to twist to the left or right (torticollis). The neck spasms experienced by patients with this disorder may be constant or intermittent. This excessive muscle activity is often painful.

What causes cervical dystonia?

Until recently, cervical dystonia was often misunderstood and misdiagnosed as stress, scoliosis, arthritis, or a variety of other conditions. Although the exact cause of the disorder is unknown, cervical dystonia has been observed to develop in conjunction with an injury to the brain or neck muscles (e.g., whiplash), or after prolonged exposure to certain neuroleptic or antipsychotic drugs. Some forms of dystonia may also be genetic, as mutations in the *DYT-1* gene have been linked to an early-onset form of the disorder^{iv}. It is thought that each of these factors^{iv} may somehow

Indication

BOTOX[®] (onabotulinumtoxinA) is a prescription medicine that is injected into muscles and used to treat the abnormal head position and neck pain that happens with cervical dystonia (CD) in adults.

IMPORTANT SAFETY INFORMATION
BOTOX[®] may cause serious side effects that can be life threatening. Call your doctor or get medical help right away if you have any of these problems after treatment with **BOTOX**[®]:

- **Problems swallowing, speaking, or breathing. These problems can happen hours to weeks after an injection of BOTOX**[®] usually because the muscles that you use to breathe and swallow can become weak after the injection. Death can happen as a complication if you have severe problems with swallowing or breathing after treatment with **BOTOX**[®].
- Swallowing problems may last for several months. People who already have swallowing or breathing problems before receiving **BOTOX**[®] have the highest risk of getting these problems.
- **Spread of toxin effects.** In some cases, the effect of botulinum toxin may affect areas of the body away from the injection site and cause symptoms of a serious condition called botulism. The symptoms of botulism include: loss of strength and muscle weakness all over the body, double vision, blurred vision and drooping eyelids, hoarseness or change or loss of voice (dysphonia), trouble saying words clearly (dysarthria), loss of bladder control, trouble breathing, trouble swallowing.

Please see next page for additional Important Safety Information.

affect the basal ganglia of the brain, which is involved in the control and coordination of muscle activity, and cause the release of excessive and erratic signals to the neck muscles^v. Physicians use a variety of tools including function and movement scales, global assessment scales, and pain scales to assess the degree of disease progression and determine which treatment will provide the most benefit to the patient.

How is cervical dystonia treated?

Cervical dystonia is treated by various medical experts, including neurologists and movement disorder specialists, otolaryngologists (ear, nose and throat specialists), and physiatrists (doctors specializing in physical rehabilitation). While there is no cure for cervical dystonia, there are a number of treatment options that can help relieve the excessive muscle spasms of the neck and shoulder muscles and the associated neck pain.

Injection of therapeutic doses of BOTOX[®] (onabotulinumtoxinA) neurotoxin into the neck and shoulder muscles is the most commonly chosen treatment and is considered a first-line therapy for cervical dystonia^{vi} in adults to treat the abnormal head position and neck pain that happens with cervical dystonia. Derived from the bacterium *Clostridium botulinum*, BOTOX[®] therapy inhibits the release of a neurotransmitter, acetylcholine, from nerve cells, blocking the signals that promote involuntary muscle contraction. The effect is temporary and the treatment needs to be readministered approximately every three months depending on the individual patient.

Oral prescription drugs may also be used. In severe cases, surgeries in which either the nerve to the contracting muscle is cut or a section of the muscle itself is removed are recommended in patients who do not respond to less invasive therapy.

Finally, physical therapy is recommended in all patients with cervical dystonia as a complement to BOTOX[®] injections or other therapies to help ease the severity of contractions. Stretching exercises and neck braces have been shown to ease the severity

IMPORTANT SAFETY INFORMATION (continued)

These symptoms can happen hours to weeks after you receive an injection of BOTOX[®].

These problems could make it unsafe for you to drive a car or do other dangerous activities. See "What should I avoid while receiving BOTOX[®]" in Medication Guide.

There has not been a confirmed serious case of spread of toxin effect away from the injection site when BOTOX[®] has been used at the recommended dose to treat severe underarm sweating, blepharospasm, or strabismus, or when BOTOX[®] Cosmetic has been used at the recommended dose to treat frown lines.

Tell your doctor about all your medical conditions, including if you have: a disease that affects your muscles and nerves (such as amyotrophic lateral sclerosis [ALS or Lou Gehrig's disease], myasthenia gravis or Lambert-Eaton syndrome).

Tell your doctor about all the medicines you take, including prescription and nonprescription medicines, vitamins and herbal products.

BOTOX[®] can cause serious side effects. Other side effects of BOTOX[®] include: dry mouth, discomfort or pain at the injection site, tiredness, headache, neck pain, and eye problems: double vision, blurred vision, decreased eyesight, drooping eyelids, swelling of your eyelids, and dry eyes. Symptoms of an allergic reaction to BOTOX[®] may include: itching, rash, red itchy welts, wheezing, asthma symptoms, or dizziness or feeling faint. Tell your doctor or get medical help right away if you are wheezing or have asthma symptoms, or if you become dizzy or faint.

Tell your doctor if you have any side effect that bothers you or that does not go away.

Please see next page for additional Important Safety Information.

of contractions and are recommended in addition to medication and/or other therapies.

IMPORTANT SAFETY INFORMATION (continued)

These are not all the possible side effects of BOTOX[®]. For more information, ask your doctor or pharmacist.

For additional information refer to Medication Guide. This Medication Guide summarizes the most important information about BOTOX[®]. If you would like more information, talk with your doctor.

Please see the accompanying full Product Information, including Medication Guide, for BOTOX[®] (onabotulinumtoxinA).

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ⁱ Spasmodic Torticollis (ST) Dystonia Web site. Accessed March 2, 2009. Available at:

http://www.spasmodictorticollis.org/newsroom_QASheet.cfm

ⁱⁱ Jankovic, J; *Dystonia: Etiology, Clinical Features, and Treatment*, 2004: Chapter 13, Page 159.

ⁱⁱⁱ Pathak, M; *The Spasmodic Torticollis Handbook*, 2003: Page 5

^{iv} Ozelius LJ, Hewett JW, et al; The early-onset torsion dystonia gene (DYT1) encodes an ATP binding protein. *Nature Genetics*. 1997

^v Dystonia Medical Research Foundation. *Q&A about dystonia*. April 2000

^{vi} Jankovic J. Treatment of Cervical Dystonia With Botulinum Toxin. 2004;19(Suppl 8): pp S109-S115 *Movement Disorders* 2004;19: pp S109-S115