

What are the side effects of BT?

- The main side effect is the pain that may occur with the injections. No local anesthesia is given in most cases, because the exact sites of injections are determined during the procedure.
- The muscles injected can be sore for a few days after the injections
- BT causes temporary partial weakening of the muscles injected. In most cases, the benefits of spasticity relief outweigh the effects of increased weakness. BT does not cause weakness in muscles that have not been injected.
- When BT is used for a long time, it may cause atrophy (thinning) of the muscles injected. This atrophy is reversible if the therapy is discontinued.
- There have been reports of temporary side effects such as flu-like symptoms, palpitations, tingling sensations, or nausea. These side effects are rare, and usually go away within 1 to 2 days
- The FDA has reported rare cases of more severe side effects in adults treated with BT, such as difficulty swallowing or breathing.

What happens if I develop antibodies to BT?

In our experience, it is rare that people develop antibodies to BT. If this happens, you may notice that the treatment does not help any more, but no harmful effects from the antibodies have been reported. In some cases,

switching from one type of BT to the other helps restore the treatment effect.

How do I know if I am a good candidate for BT therapy?

BT therapy is usually considered when spasticity needs to be relieved in only a few muscle groups. It can be used in addition to other treatments for spasticity. If your health care provider thinks that you may be a candidate for BT therapy, you will be scheduled for an evaluation. During this visit, you will also be given detailed information about the treatment, so you can make an informed decision.

Does insurance cover BT therapy?

BT therapy is not yet approved by the FDA for the treatment of spasticity, but it is covered by Medicare at this point. Since insurance coverage varies greatly, depending on individual insurance plans, we encourage you to check with your insurance ahead of time. The following codes can be helpful when calling your insurance:

- for the procedure: 64614 chemo-denervation of extremity(ies)
- for the medications: J0585 Botox®, J0587 Myobloc®

In summary:

- BT therapy can be helpful when relief of spasticity is needed in a few muscle groups

- The treatment is usually safe and well tolerated, but needs to be repeated every few months to maintain the therapeutic effect
- Daily stretching and exercise, and in some cases rehabilitation, are essential to maximize the potential benefits of treatment

This information is not intended to replace the medical advice of your health care provider. Please consult your health care provider for advice about a specific medical condition.



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Botulinum Toxin Therapy

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What is spasticity?

Spasticity is a movement disorder that can occur in conditions which affect the brain or the spinal cord, such as multiple sclerosis, stroke, cerebral palsy, spinal cord injury, or brain injury. Spasticity is caused by an imbalance between signals that inhibit or stimulate the spinal cord. This results in hyperexcitable stretch reflexes, increased muscle tone, and involuntary movements.

What are the symptoms of spasticity?

Spasticity causes muscle stiffness and tightness which interferes with voluntary movements. Spasticity can also cause *muscle spasms* (jerky involuntary movements) or *clonus* (repetitive involuntary movement).

Stiffness and spasms are often bothersome and sometimes painful, and they interfere with the ability to carry out daily activities. Spasms may also disrupt sleep and increase daytime fatigue. When spasticity is severe, *contractures* (fixed limitations of range of motion) may develop.

How can spasticity be treated?

Stretching, exercise, and rehabilitation are the first line of interventions for spasticity. Oral medications are often effective, but may cause side effects such as drowsiness. When spasticity affects only a few muscles, local injections of botulinum toxin

can be helpful. When spasticity is diffuse and severe, intrathecal baclofen (ITB) may be a good treatment option.

What is botulinum toxin (BT)?

Botulinum toxin is a medication derived from a neurotoxin produced by a bacteria (*Clostridium Botulinum*). In its natural form, this toxin causes botulism, a severe condition that can be fatal. The botulinum toxin (BT) medication is designed to be used safely without causing botulism. There are two commercially available forms of BT currently:

- botulinum toxin type A (Botox®)
- botulinum toxin type B (Myobloc®)

How does BT work?

Normally, the brain sends messages to the muscles so they can contract and move. These messages are transmitted via the nerves to the muscles by a substance called acetylcholine. BT blocks the release of acetylcholine from the nerve to the muscle, therefore the muscle relaxes.

How is BT given?

BT is given as an intramuscular injection (into the muscle). The injections are given during an outpatient visit, which lasts 1 hour. Your health care provider will determine beforehand which muscles need to be injected. Because BT does not

travel far from the injection site, several injections are performed during one visit. To ensure that BT is injected in the right place, short electrical impulses are sent through the needle used for the injection, to make the muscle contract. In some cases, electrical signals from the muscle are recorded via the needle, for the same purpose.

What can I expect after the injections?

There are no activity restrictions after the injections. The effect of BT is usually not felt until a few days, up to 2 weeks after the injections. We usually ask that you return for a follow-up visit or call with an update 2 to 3 weeks after the injections.

The effect of BT is expected to last between 2 and 6 months, then gradually wears off. Most often, the injections are repeated every 3 months. In many cases, physical or occupational therapy is needed after the injections to maximize the benefits of BT. In all cases, it is necessary to stretch and exercise daily at home.

What are the advantages of BT over other treatments for spasticity?

- BT is usually effective in relaxing the muscles injected, and provides a stable effect for several months.
- BT is preferred when only a few muscle groups are spastic, or

when spasticity relief is needed in only a few muscle groups, because it allows to treat only selected muscles.

- BT is usually very well tolerated, in part because only very small amounts of medication go into the bloodstream.

What are the disadvantages of BT?

- The benefits of BT are limited to the muscles injected. Therefore, it may not be a good treatment choice when many muscles are spastic.
- The effect of the injections is always temporary, therefore the injections need to be repeated at regular intervals to maintain the therapeutic benefits.
- There are limits to the amount of BT that can be injected during one session, and to the frequency at which BT can be injected, in part because the body can create antibodies against the medication. These antibodies are not dangerous, but may neutralize the effects of BT.
- BT is not yet approved by the FDA for the treatment of spasticity, even though it has been used worldwide for this indication for many years, and its benefits and risks are well-known. Therefore, insurance companies may not cover the treatment.