



Botulinum Toxin A (BOTA) for Overactive Bladder and Neurogenic Detrusor Overactivity

A Guide for Women

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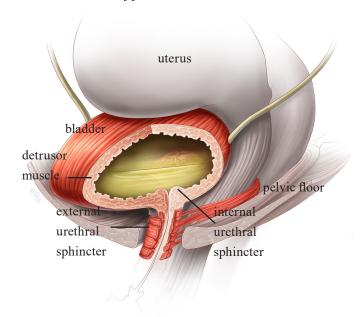
Introduction

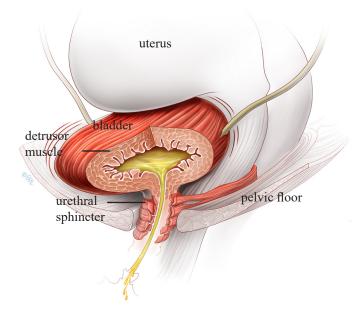
Botulinum Toxin A (BOTA) is used to treat urge urinary incontinence caused by neurological conditions such as multiple sclerosis and spinal cord damage, and in women with overactive bladder where no cause for the symptoms has been found.

How does a normal bladder work?

The bladder is like a balloon. As urine is produced by the kidneys and fills up the bladder, the bladder walls stretch to accommodate the extra fluid. Normally, as the bladder fills you become

Normal bladder half full and relaxed





aware of the feeling that you need to pass urine, but you can hold on. Urine is kept inside the bladder by a valve-like mechanism (urethral sphincter) that stays shut until you reach a toilet to empty your bladder. The valve mechanism (urethral sphincter) is assisted by the pelvic floor muscles below the bladder, which tense up when you cough or sneeze to keep the urine in the bladder and prevent any from leaking. Once you have decided to empty your bladder (i.e., in a toilet, at a convenient time), your brain signals the muscle of the bladder to squeeze and empty out the urine. At the same time, the urethral sphincter and pelvic floor muscles relax to allow the urine to flow out. The bladder usually needs to be emptied about 4-7 times per day, and once at night.

What is an overactive bladder (OAB)?

Overactive bladder (OAB) symptoms are caused by the bladder muscle squeezing to empty out urine inappropriately, even when the bladder is not full. This often happens without warning and when you do not want it to, for example, when hearing the sound of running water, or putting the key into the latch.

Neurogenic Detrusor Overactivity (NDO)

When the spinal cord is damaged, e.g., following spinal injury or as a result of multiple sclerosis, the signals between the brain and bladder no longer work as they should. The nerves may tell the bladder to contract too frequently, resulting in urinary urgency and frequency. Both OAB and NDO cause the following symptoms:

- A sudden, urgent feeling that you need to pass urine.
- The bladder leaking at times when you have an urgent desire to pass urine.
- Needing to go to the toilet often even if the bladder is not full.
- The need to get up to the toilet at night.

Patients with neurological conditions may have urge incontinence but may also experience difficulty fully emptying the bladder. This happens when the urethral sphincter muscle fails

to relax, thereby preventing the release of urine from the bladder.

What is Botulinum Toxin A (BOTA) and how does it work?

Many people have heard of Botox or Dysport for the treatment of frown lines or wrinkles. These are the drug company names for Botulinum Toxin Type A (BOTA). BOTA is a protein extracted from bacteria, under controlled laboratory conditions, in much the same way as penicillin is produced from mold.

BOTA is injected into the bladder and works by relaxing the muscle of the bladder wall (the detrusor muscle) to reduce urinary urgency and incontinence. Following treatment, the toxins' effects last for several months after which the muscles return to their normal strength (between 3 to 9 months, occasionally longer).

Am I a candidate for BOTA?

You may be a candidate for BOTA treatment if you have an overactive bladder and have tried treatments such as physical therapy and medications without success, or if you have Neurogenic Detrusor Overactivity. Prior to offering Botox, your doctor may perform investigations such as urodynamics to confirm your diagnosis, and a urine test to make sure you do not have a urinary tract infection. Your doctor will also discuss alternative treatments, such as nerve stimulation (posterior tibial nerve stimulation or sacral nerve stimulation). There are also surgical alternatives that are more invasive with increased risk of side effects.

Who should not have BOTA?

BOTA is NOT effective for the treatment of another common type of urine leakage called stress incontinence (leakage with cough, sneeze, and exercise).

You should not receive BOTA treatments if you have any of the following:

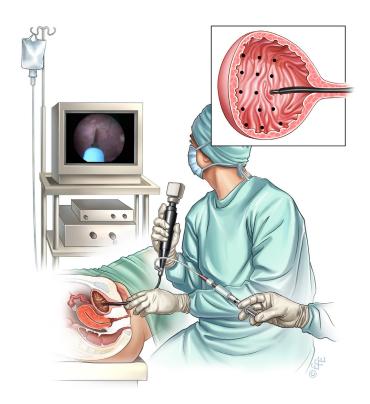
- Myasthenia gravis or Eaton-Lambert Syndrome
- An active or untreated bladder infection
- Pregnancy (effects on fetus are unknown)
- · Known allergy to Botulinum Toxin A

What does BOTA treatment involve?

The treatment is very simple and is usually performed as a day procedure at a hospital or clinic. BOTA injections can be performed under local, general, or spinal injections and your doctor will discuss which option is the most suitable for you.

Your doctor will use a cystoscope to inject Botulinum Toxin A into the bladder muscle. A cystoscope is a fine tube with a camera on the end that is passed into the bladder, enabling the doctor to see inside the bladder. Tiny amounts of diluted Botulinum Toxin A are injected through the cystoscope into the bladder muscle. Typically, 10 to 30 injection sites are used. If the procedure is performed under local anesthetic only, there may be a prickling sensation or minor discomfort during the procedure. It should not be painful.

Following the treatment your bladder is emptied and you will be discharged home. It is advisable to drink a little extra fluid for a couple of days to reduce the risk of a urinary tract infection. Your doctor may also give you a dose or short course of antibiotics to take following treatment.



What should I expect after treatment with BOTA?

You may experience some stinging or burning the first few times you pass urine following treatment. Your urine may also be a little blood-stained. This is normal and will clear over 24-48 hours.

Botulinum Toxin A *does not* work immediately, but over several days to 2 weeks you should begin to experience relief of sudden urges to urinate and a reduction in urine leakage or stoppage of leaking altogether. Your bladder should be able to hold more urine, thus reducing the number of times you go to the bathroom. If you are taking medications by mouth to relax the bladder, you should be able to wean yourself off these once the BOTA treatment begins to take effect. Your doctor will advise you about this.

Associated with this relief in symptoms, you may also notice that it becomes more difficult to empty your bladder. This is because BOTA works by relaxing the muscle of the bladder, which can reduce its ability to contract and empty. If you are unable to empty your bladder completely, your doctor or nurse will teach you clean intermittent self catheterization (CISC). This involves passing a tiny tube into the bladder up to 3 to 4 times a day to empty it. This is a simple and safe procedure. Don't worry; once the effect of the BOTA wears off, your bladder function should return.

How long does the treatment effect last?

Eventually, the effect of the BOTA will begin to wear off, and you may notice a gradual return of symptoms of frequent and urgent urination, as well as leakage episodes. As every situation is different, it is impossible to predict how long after your treatment this will happen. However, the treatment effect will commonly last 6 to 9 months. For some women, a single treatment is all that is required; others need repeated treatments.

What are the risks of BOTA treatment?

You may see some blood in the urine initially after the procedure. Significant bleeding is extremely rare. Urinary tract infection is reported in about 1 in 12 cases, but this can be easily treated with antibiotics. 3-10% of patients may require temporary self catheterization to help empty the bladder. Other very rare risks include allergic reaction including anaphylaxis, erythema multiforme (a severe skin rash), and generalized weakness. You should consult your doctor if you experience any of the above problems.

How successful is BOTA treatment?

There is a 60-90% chance of achieving significant improvement in urinary urgency and urge leakage following BOTA injections and a reduction in urinary frequency. Most women require repeat doses of BOTA while others find significant long-term improvement after a single dose.

For more information, visit www.YourPelvicFloor.org.



The information contained in this brochure is intended to be used for educational purposes only. It is not intended to be used for the diagnosis or treatment of any specific medical condition, which should only be done by a qualified physician or other health care professional.