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

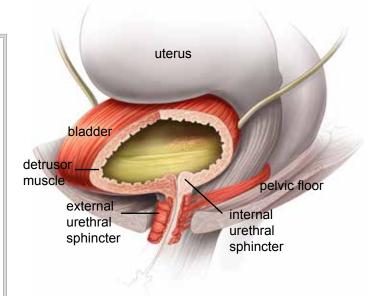
A Guide for Women

Botulinum Toxin A Is a treatment for 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.

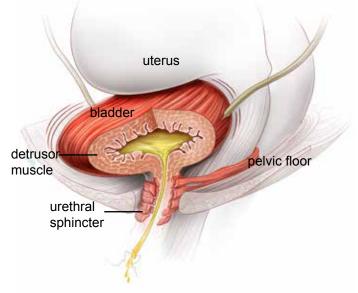
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How Does a normal bladder work?

The bladder is similar to a balloon. As urine is produced and fills the bladder up, the walls stretch to accommodate the extra fluid. Urine is kept inside the bladder by a valve-like mechanism ("urethral sphincter") that stays shut until you feel the need to empty and have reached a toilet. The valve mechanism is assisted by the pelvic floor muscles below the bladder, which tense up when you cough or sneeze and keep the urine in. As the bladder fills up, you start to be aware of the feeling that you need to pass urine, but are able to hold on. 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 bladder valve and pelvic floor muscles relax to allow the urine to flow out. The



Overactive bladder half full and contracting and leaking



bladder usually needs to be emptied about 4-7 times per day, and once at night.

What is an overactive bladder (OAB)

OAB symptoms are caused by the bladder muscle squeezing to empty out urine inappropriately even when the bladder isn't full. This often happens without warning, and when you do not want it to, for example when hearing the sound of running water, 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 feeling you need to pass urine urgently.

The bladder leaking at times when you have an urgent desire to pass urine..

The need to go to the toilet often even if the bladder isn't full.

The need to get up to the toilet at night.

Patients with neurological conditions may have urge incontinence but may also experience difficulty emptying the bladder due to failure of the urethral sphincter muscle to relax and so release urine from the bladder.

What is Botulinum Toxin A and how does it work?

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

BOTA works for the bladder by relaxing the muscle of the bladder wall (the detrusor muscle) reducing 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 <u>urodynamics</u> to confirm your diagnosis and a urine test to check that you do not have a urinary tract infection.

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

Who should not have BOTA

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

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

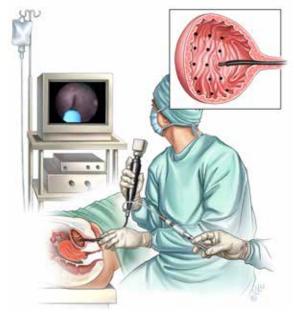
What does BOTA treatment involve?

The treatment is very simple and is usually performed as a day stay 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.

To put Botulinum Toxin A into the bladder your doctor will use a cystoscope. This is a fine tube with a camera on the end that is passed into the bladder that enables the doctor to see inside the bladder. Through the cystoscope your doctor will inject tiny amounts of diluted Botulinum Toxin A in the bladder muscle. Typically, 10 to 30 injections sites are used. If the procedure is performed under local anaesthetic 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 urine 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 while passing urine for the first few times 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 stop 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 of these once the Botox treatment begins to take effect, and 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 will return.

How long does the treatment effect last? Eventually, the effect of the Botox 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 months 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 to 10% of patients may require temporary self-catheterization to help the bladder empty.

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?

The clinical experience with Botulinum toxin for urinary incontinence at present is relatively limited. It is safe to say, however, that there is a 60 to 90% chance of achieving significant improvement in urinary urgency and urge leakage following Botox injections and a reduction in urinary frequency. Most women require repeat doses of BOTA whilst others find significant long term improvement after a single dose.



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.