

The role of BOTOX® in treating overactive bladder

This pamphlet is designed to help you understand how BOTOX®, also known as OnabotulinumtoxinA, is a well-tolerated and effective treatment option for overactive bladder when conservative measures and oral medications fail to effectively resolve symptoms. After reading this material, you will be more familiar with how BOTOX® works on the bladder, how this treatment can benefit you, what the procedure entails, and what potential side effects may arise.

What is overactive bladder?

- Overactive bladder (OAB) is a condition in which the bladder muscle has difficulty storing urine, and is associated with the sudden urge to urinate. Both men and women can have overactive bladder (OAB).
- This urge may be difficult to stop and can lead to urinating many times a day or at night, and can also cause urine leakage or urgency incontinence.
- You are not alone. In Canada, over 3 million patients have OAB, which is as common as diabetes. One-third of these patients have urgency incontinence.



Overactive bladder

What are my treatment options?

First-line treatment options usually consist of behavioural therapies, such as:

- Bladder training (training your bladder to hold larger volumes of urine by delaying urination when the urge comes on).
- Lifestyle strategies, such as fluid management, avoiding bladder irritants (especially caffeine and alcohol), and smoking cessation.
- Pelvic floor muscle training, such as Kegel exercises, pelvic floor physiotherapy, and biofeedback.

When behavioural therapies are not effective, second-line treatment involves medications. These medications are designed to promote relaxation of the bladder muscle for better control.

For some OAB patients, medications may not work well enough or their side effects are too difficult to tolerate. In these cases, third-line treatments, such as BOTOX®, may offer the most effective relief.

The two common types of incontinence are:

Urgency urinary incontinence (UUI), which refers to urine leakage caused by the strong urge to urinate, and is associated with OAB.

Stress urinary incontinence (SUI), which is caused by weak support structures in the pelvic floor, resulting in urine leakage with coughing, sneezing, exercise, and other activities that put physical pressure on the bladder.

Treatments for SUI are different from those for UUI.



1 Behavioural therapies

Lifestyle strategies, such as fluid management, avoiding bladder irritants (especially caffeine and alcohol), and smoking cessation

Pelvic floor muscle training, such as Kegel exercises, pelvic floor physiotherapy, and biofeedback



2 Pharmacologic treatments

Medications



3 Other treatment options

Such as BOTOX®

I thought BOTOX® was for wrinkles. How does it work for my overactive bladder?

- In Canada, BOTOX® has been approved for medical conditions since 1990 and has been approved for use in overactive bladder since 2013.
- BOTOX® provides a powerful and effective means of relaxing muscles, and it can be used anywhere in the body where muscles are found.

When injected into the bladder, BOTOX® works by blocking the nerve signals that trigger the overactive bladder muscle, helping to improve upon:

Urgency incontinence – leakage episodes associated with the urgent need to urinate

Urgency – the sudden and strong need to urinate right away

Frequency – the number of times you need to empty your bladder daily

Nocturia – waking from sleep to urinate

What are the are the benefits of BOTOX®?

- OAB can be embarrassing and uncomfortable. BOTOX® injections have been shown to significantly improve the quality of life of patients with OAB.
- BOTOX® treatment has been shown to reduce leakage of urine, improve symptoms of urgency, and reduce the frequency of daytime and nighttime urination.

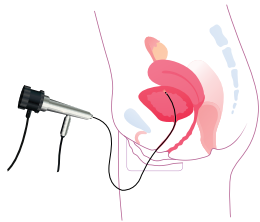
Is BOTOX® the right treatment for me?

- BOTOX® is recommended for patients who have tried first- and second-line therapies but are still bothered by frequency, urgency to urinate, and/or leakage associated with that urgency.
- Patients may consider BOTOX® when they are still experiencing urgency, frequency, or leakage despite being on medication, or when they cannot tolerate the side effects of that medication.
- If this sounds like you, you may be a good candidate for BOTOX® treatment.
- Inform your doctor if you have received BOTOX® for any other reasons.

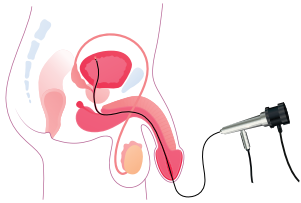
What happens during the procedure?

- The BOTOX® procedure may take place either in a cystoscopy room or in a surgical suite.
- The majority of BOTOX® treatments are done under local anesthesia only (freezing liquid and/ or jelly). In some cases, it may be appropriate to receive other types of anesthesia, such as sedation (to help you relax), general anesthetic (being put to sleep) or having a spinal anesthetic (an anesthetic that numbs you from the waist down only). Your doctor will discuss your options with you.
- A small, lighted instrument called a cystoscope (flexible or rigid) is then inserted into the urethra (urine channel) so the doctor can see your bladder.
- Lastly, a small needle is placed through the cystoscope and a number of injections are made to ensure BOTOX® is distributed throughout the bladder muscle.
- Discomfort during the procedure is minimal and the procedure is quick. After the BOTOX® treatment, you should not feel significant pain, although it may sting or burn when you urinate the first few times or you may experience some cramping. You may also notice some blood in your urine after treatment, which is common and usually resolves on its own.

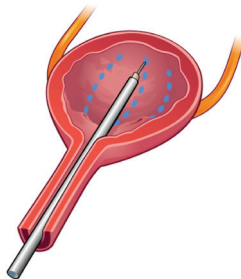
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Cystoscope into the female bladder



Cystoscope into the male bladder



Needle injecting BOTOX® into the bladder

- The entire treatment typically takes about 20 to 30 minutes; however, the injection procedure itself usually takes 5 minutes or less. Depending on the type of anesthetic you receive, you may be monitored for a short time afterward before being discharged.

What should I expect after my treatment?

- Most patients receiving BOTOX® treatment experience improvements in their symptoms within the first 2 weeks following the procedure, and the maximum effect is usually reached about 4 to 6 weeks after the treatment.
- BOTOX® is not permanent but one treatment usually provides up to 6 months or more of symptomatic improvement.
- Your doctor will schedule a follow-up visit to assess the results of treatment and to check that you are emptying your bladder well.
- After the first injection, your repeat treatments may be scheduled based on intervals guided by how you responded to the previous injection, while in other instances you may be required to book your

next injection once your symptoms return. Eventually, you will find a consistent injection interval that best suits your condition.

- In the event that you have an unsatisfactory response to the BOTOX® treatment, medications may need to be used in addition to the BOTOX®, or dose adjustments may be made for future injections.

Should I worry about the side effects?

- BOTOX® treatment is generally well-tolerated and possible side effects are usually short-lived.
- The most common side effects with BOTOX® treatment are urinary tract infection and difficulty urinating, also known as urinary retention.
- Clinical evidence suggests that approximately 20% of patients receiving BOTOX® treatment develop urinary tract infection as a side effect. Urinary tract infections can be managed by a healthcare provider, who will prescribe an antibiotic based on your symptoms and laboratory findings.
- While the majority of patients do not have trouble emptying their bladder after BOTOX® injections, there is a small chance you could experience temporary urinary retention afterwards. About 6% of patients may have to use a small flexible tube called a catheter to help empty their bladder while the BOTOX® generates its strongest effect.
- Self-catheterization only needs to be done until the BOTOX® effect wears off enough that the bladder is able to empty again on its own. Commonly, this lasts less than 6 weeks for the majority of patients.
- In the rare instance you do experience difficulty emptying your bladder, contact your doctor's office or go to your nearest hospital if you need after-hour assistance.

Is there insurance coverage for BOTOX® treatment?

- BOTOX® was approved by Health Canada for the treatment of overactive bladder in 2013.
- Private and provincial drug plans may cover the cost of BOTOX® treatments. Talk to your doctor about your coverage options.

Can I keep getting BOTOX for my bladder?

- BOTOX® wears off after 6 to 9 months so patients need to continue to get injections.
- Long-term studies have shown it is well-tolerated with no increase of side-effects.

Who shouldn't get BOTOX®?

- If you have urinary retention and are not catheterizing.
- If you are hypersensitive/allergic to any botulinum toxin type A or to any ingredients in the medication or in the container.
- If you have an infection at the injection site.
- If you have urinary tract infection or a recent history of urinary tract infections.
- If you have a severe bleeding disorder or take blood thinners, extra caution will be required.

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