

# Emerging Technologies

## **Botox**<sup>®</sup>

Botulinum toxin A, available in Canada under the trade name Botox<sup>®</sup>, has recently been applied for use in treating urinary incontinence (UI), as well as number of other urinary difficulties. This article will review this exciting new therapy, including when and how it is used to treat urinary incontinence.

The use of Botox<sup>®</sup> in treating UI is considered "off-label". Botox<sup>®</sup> has been given approval by Health Canada for use in treating a number of medical conditions, however at the present time urinary incontinence is not listed as one of these, so its use in this setting is not as yet approved by Health Canada. This treatment is therefore limited to a small number of specialists with an interest in these bladder conditions, and it is only offered to patients with specific types of incontinence, and only after other approved therapies have been tried. In some areas, Botox<sup>®</sup> treatment is limited to clinical research trials.

Having said this, Botox<sup>®</sup> is a rapidly growing treatment for UI, and hundreds of Canadians have been injected.

## WHAT IS BOTOX, AND HOW DOES IT WORK?

Botox is a purified form of Botulinum toxin type A, one of seven serotypes produced by the bacterium Clostridium botulinum. These toxins cause muscle relaxation by preventing the release of chemicals called neurotransmitters that normally are released from a nerve cell, travel across to a muscle cell, and signal it to contract. This action of the toxin lasts for a limited amount of time, eventually wearing off as the nerve cells regain their ability to release these molecules.

## **AM I A CANDIDATE FOR BOTOX?**

You may be a candidate for Botox treatment if you have a particular type of urinary incontinence called urge incontinence, and if you have tried other medications for this, called antimuscarinics, without success. Urge incontinence is also associated with frequent urination and night-time urination.

Botox is NOT effective for the treatment of another common type of urine leakage called stress incontinence. If this is the principle cause of your incontinence, your doctor will not likely discuss Botox treatments with you.



#### **HOW IS BOTOX TREATMENT PERFORMED?**

Botox is injected directly into the bladder muscle through an instrument placed into the bladder called a cystoscope *(see figure 1)*. After being appropriately positioned on an examining table, freezing jelly is passed into the urethra, then a catheter *(tube)* is passed into the bladder, and the urine is drained. Through this catheter, a local anesthetic *(freezing)* solution is placed into the bladder to numb its lining. A small flexible needle is then introduced through the cystoscope to perform the injections. Anywhere from 10 to 30 injections are made into the bladder, and at each site a small amount *(usually 1 milliliter)* of Botox solution is injected. *(You may feel small pokes or a pressure sensation)*. The bladder is then drained, and you will be discharged home after ensuring that you can urinate *(pee)*. If you are unable to do so, you may be taught to self-catheterize before going home. Depending on the preference of you doctor, you may or may not receive a prescription for an antibiotic to prevent infection afterward.

The procedure is usually performed on an outpatient basis, meaning that no overnight hospital stay is required. In most cases, only local anesthetic *(freezing)* is required; however, some doctors may also give sedative medication, and some prefer to perform the procedure with the patient under spinal or general anesthetic. Typically, the procedure takes only 10 to 30 minutes.

## WHAT SHOULD I EXPECT AFTER TREATMENT?

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You should not experience significant pain during or after the Botox treatment, although it may sting or burn when urinating the first few times. You may also see some blood in the urine initially after the treatments.

**Figure 1:** A small amount of Botox<sup>®</sup> solution is injected into muscle of bladder wall in multiple sites. (Illustration courtesy of mdconversation inc.)

It may take several days for the effect of Botox to be known. Initially, you may not notice any change in your urinary symptoms, but over several days to a week or so, you should begin to experience relief of sudden urges to urinate, and a lessening of the frequency and severity of leakage episodes. You will be able to hold your bladder for longer periods of time between urinations, and will wake up less frequently to empty your bladder. If you are taking medications by mouth to relax the bladder, you may 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 when urinating. This is because Botox works by relaxing the muscle of the bladder, which can weaken its ability to contract and empty. For some people, this change does not completely prevent them from emptying, but for others it can. In these cases, the bladder must be mechanically emptied by introducing a catheter into the bladder periodically.

## 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. You will begin to empty your bladder with greater ease again. 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 3 to 6 months, and sometimes up to 8 or 9 months.

## WHAT ARE THE RISKS?

- You may see some blood in the urine initially after the treatments. Significant bleeding is rare.
- Bladder infections occur in some patients. These may be caused by the procedure itself, or may be due to incomplete bladder emptying as the Botox takes effect. Notify your doctor if you are concerned about a possible infection.
- Up to 1 in 5 patients may require temporary self-catheterization to help the bladder empty.
- Other very rare potential adverse events, which have not been described following bladder injections may include:
  - Allergic reaction, including anaphylaxis;
  - Erythema multiforme (a severe skin rash); and,
  - Generalized weakness

## WHO SHOULD NOT HAVE BOTOX INJECTIONS?

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

- Myasthenia gravis of Eaton-Lambert Syndrome
- · Active bladder infection
- Pregnancy (effects on fetus are unknown)
- · Known allergy to Botox

## **HOW SUCCESSFUL IS IT?**

The clinical experience with Botox for urinary incontinence at present is relatively limited, and the research reports have studied only a small number of patients. It is safe to say, however, that there is a 60 to 90% chance of achieving significant improvement in urinary symptoms and leakage following Botox injections.

#### References

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#### **Sacral Nerve Modulation**



#### **Sacral Nerve Modulation is for:**

- Overactive bladder with or without incontinence (an urgent need to go to the bathroom and not being able to get there in time);
- Painful Bladder Syndrome/Interstitial cystitis (bladder pain associated with full bladder, frequent urination and nocturia);
- Voiding dysfunction (Urinary retention), (the bladder does not completely empty when you urinate, or you may not be able to urinate at all).

#### Procedure consists with two phases

#### Phase 1

The test phase (*Peripheral Nerve Evaluation = PNE*) is done to see if you are likely to respond to the treatment. This procedure will be carried out in an outpatient urology suite under local anesthesia. This procedure involves placing a needle electrode through the skin into existing holes in the sacrum. (*a bony plate near the end of your spine*). Recently so called "two stage procedure" of neuromodulation has been implemented. In this technique at the time of the first stage a permanent electrode is implanted with percutaneus techniques and if successful permanent stimulator is connected to this electrode and positioned under the skin in the buttock area at 2nd phase. With two stage procedure there is a better chance that you respond to stimulation.



#### Phase 2

The permanent implant. If a 1st Phase is successful you are a candidate for the second phase, which is the "Implant Phase". During the "Implant Phase", a wire electrode, an extension cable, and a stimulator, are implanted into the body. If you had a successful first stage implant, you do not need to have another electrode placement during the second phase. The neurostimulator and extension cord will be connected to the already implanted lead.

Overall success rate is @ 80%. There are also usual risks associated with any surgical procedure, and also with general anesthesia. Based on previous experience, about 33% of the patients experience adverse effects related directly to the implant. There is about 30% risk of secondary operation due to malfunction of the stimulator or lead movement, fracture, or that there is failure at the connection site.

Remember - this treatment should not be considered unless you have already tried without success, other available non-surgical treatments.

Speak to a few people who have undergone sacral nerve stimulation for a similar problem to yours. (The Canadian Continence Foundation and your doctor may be able to put you in touch with some individuals).

It is important to be confident that you have all the information needed to make an informed decision with your healthcare professional.

This fact sheet was made possible by an educational grant from Allergan Canada Inc.

For more information about incontinence contact

#### **The Canadian Continence Foundation**

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