Botox injections to treat overactive bladder

Patient information leaflet



About this leaflet

You should use the information in this leaflet as a guide. The way each gynaecologist does the procedure may vary slightly. Care in the hospital after your procedure and the advice given to you when you get home will also vary in different hospitals. You should ask your gynaecologist about any concerns that you may have.

You should take your time to read this leaflet. There is a page at the end of the leaflet for you to write down any questions you may have. It is your right to know about your planned operation/procedure, why it has been recommended, what the alternatives are and what the risks and benefits are. These should be covered in this leaflet. You may also want to ask about your gynaecologist's personal experience and results of treating your condition.

Benefits and risks

There are not many studies about the success and the risks of most of the procedures carried out to treat incontinence, so it is often difficult to state them clearly. In this leaflet, we may refer to risks as common, rare and so on, or we may give an approximate level of risk. You can find more information about risk in the leaflet. 'Understanding how risk is discussed in healthcare', published by the Royal College of Obstetricians and Gynaecologists.

https://www.rcog.org.uk/globalassets/documents/patients/patient-information-leaflets/pi-understanding-risk.pdf

The following table is taken from that leaflet.

Verbal description ^a	Risk	Risk description ^b
Very common	I in I to I in I0	A person in family
Common	I in 10 to I in 100	A person in street
Uncommon	I in 100 to I in 1000	A person in village
Rare	I in 1000 to I in 10000	A person in small town
Very rare	Less than 1 in 10000	A person in large town

British Society of Urogynaecology (BSUG) database

To try to begin to understand the success and risks of surgery for prolapse and incontinence the British Society of Urogynaecology has set up a national database. We ask all members of the society to enter all procedures they carry out onto the database. They may ask you before your operation if you agree to them entering the details of your procedure. We then use this information to develop a picture of what procedures are being performed throughout the UK, as well as complications and results. Individual surgeons can also use it to see how they compare with others.

What bladder condition is Botox used to treat?

Botox (Botulinum Toxin A) injections are a treatment for overactive bladder.

They are not a treatment for stress urinary incontinence (urine leaking when you exercise, sneeze or strain).

What is overactive bladder?

Overactive bladder (OAB) is a condition where you have a sudden, desperate need to pass urine (known as urinary urgency). You may also leak urine. You may also need to empty your bladder frequently during the day, and at night (known as nocturia). OAB is common, affecting at least 1 in 10 (10%) of adults (men as well as women).

It is more common:

- in older people;
- in people who have had pelvic surgery (gynaecological or urological); and
- in people with neurological (nerve) disease, for example multiple sclerosis.

However, many people have no obvious cause for their overactive bladder symptoms.

Before considering Botox

- We recommend you try bladder training, fluid management and pelvic floor exercises (see page 6). Pelvic floor exercises sometimes help patients with OAB especially if you are supervised by a trained women's health physiotherapist, for at least three months.
- You should have tried at least two different tablets to treat overactive bladder, unless there have been reasons not to.
- Usually you will have had urodynamic tests, which check how your bladder is working and whether it is overactive.
- Your case should be discussed at a multidisciplinary team (MDT) meeting. This is considered good practice before treating a patient with Botox injections. The MDT includes urogynaecologists, specialist nurses and physiotherapists and, in many hospitals, urologists. At the meeting, they will review your medical notes and the results of any tests and make a note of the treatment you'd prefer. They then decide whether your proposed treatment is appropriate. If they do not think it is appropriate, your doctor will discuss this with you.

How are Botox injections done?

A thin tube (a cystoscope) connected to a camera is passed into your bladder, through your urethra (the tube through which urine leaves the bladder). A needle is threaded down the side of the tube to give several injections of Botox into the wall of your

bladder. This can be done, as an outpatient in clinic using local anaesthetic or you can be admitted to hospital for it to be done in an operating theatre with a sedative or under a general anaesthetic (where you will be asleep).

You will be given either 100 units or 200 units. The recommended starting dose if you do not have neurological disease is 100 units. If you have the higher dose you will have a slightly higher chance of not being able to empty your bladder after the procedure.

How does Botox work?

Botox works by blocking nerves which make a muscle tighten. When you have OAB the bladder muscle tightens too much. When Botox is injected in the bladder it stops the bladder muscle tightening as much. The effect is not permanent.

Benefits

Botox injections are effective for 7 out of 10 patients (70%), meaning that urinary urgency and incontinence are either significantly improved or cured. The effects of the injections last for around six to 12 months and then your symptoms may start to return. You can have more injections when this happens. There is no limit to how many times you can have Botox injections, and most people find that having repeat injections works well over many years. There is evidence that after 12 years of repeated injections there is no damage to the bladder but this is a relatively new treatment and we do not yet know what happens if you have Botox injections for more than 12 years

Risks

The possible after-effects of Botox injections and your risk of getting them are shown below. Most of these after-effects disappear on their own and some can be corrected, but the impact of these after-effects can vary a lot from patient to patient. Ask your surgeon's advice about the risks and how they may affect you.

After-effect	Risk
Symptoms return after 6 to 12 months, requiring repeat injections	Almost all patients
Mild burning on passing urine for 24 hours after the procedure	Almost all patients
Blood in the urine for 1 to 3 days after the procedure	Almost all patients
The treatment fails to improve overactive bladder symptoms	Around 3 in 10 patients (30%)
Infection in the bladder, needing antibiotic treatment	Between 1 in 6 and 1 in 7 patients (15%)

Difficulty passing urine after the procedure, which may require clean intermittent self-catheterisation (see page 5)	Around 1 in 10 patients (10%)
Recurrent urinary tract infections	Between 1 in 10 and 1 in 50 patients (2% - 10%)
Allergic reaction to Botox (with difficulty breathing, swallowing and speaking) requiring emergency treatment	Fewer than 1 in 250 patients (less than 0.4%)
Generalised weakness of the legs and arms due to the Botox (usually settles without treatment)	Fewer than 1 in 250 patients (less than 0.4%)

What can I do to reduce the risks?

- Please let your doctor know if you are taking a blood-thinning tablet such as warfarin, aspirin, clopidogrel or rivaroxaban, as you may be asked to stop them before your operation.
- Bring a urine sample with you to the clinic so it can be tested for signs of a urine infection before the procedure is done.
- Learn clean intermittent self-catheterisation before the procedure is done.

Clean intermittent self-catheterisation

- It is normal to leave a small bit of urine behind after going to the toilet. We call this the 'residual volume'. However, if too much is left behind it can lead to problems, such as having to go to the toilet too often or bladder infections.
- Some women have difficulty emptying their bladder after having Botox. This mostly gets better, but in a small number of women it can be long term.
- If the residual volume is too high or if you cannot empty your bladder at all, you may need to use clean intermittent self-catheterisation (CISC). In many clinics everyone is taught how to do this before being given Botox.
- CISC involves using a fine catheter tube to empty out the urine that has been left behind. The tube is passed along the urethra into the bladder so the urine can drain into the toilet. Once the urine is out, the catheter is removed and thrown away. You use a new catheter each time and they are available on prescription from your doctor.
- Although using a catheter might sound unpleasant, most women find it is easy to do
 and it gives more control and freedom than a permanent catheter. The normal
 feeling of wanting to pass urine is not altered, so you know when to empty your
 bladder. The catheters are very small and can easily be hidden in a handbag.

What happens on the day of the procedure?

Your surgeon will go through the plans for your procedure with you. If you are having a general anaesthetic, an anaesthetist will also see you. You will be asked to sign a consent form (if you have not done this already).

Alternative treatments

Your clinician will be happy to discuss any of these options with you.

Non-surgical

You can often make considerable differences to your symptoms by making simple changes, such as:

- drinking about 1.5 litres of fluid in a day;
- reducing your caffeine intake;
- reducing your alcohol intake;
- having fewer fizzy drinks; and
- giving up smoking.

Weight loss. Losing weight has been shown to reduce leakage of urine.

Bladder training. This is where the time between visits to the toilet is slowly increased.

Fluid management. It is important not to drink too little or too much fluid, as either can make OAB worse.

Pelvic floor exercises. The pelvic floor muscles support the pelvic organs. Strong muscles can help to prevent or reduce leakage of urine. A women's health physiotherapist can explain how to do these exercises correctly. These exercises have little or no risk.

Medication

This may be very effective. However, some patients do not respond to any medications or may suffer from unbearable side effects.

Nerve stimulation

Posterior tibial nerve stimulation (PTNS)

Type of treatment: A fine, acupuncture-like needle is inserted near a nerve above the inner side of your ankle and a sticky pad attached to the arch of your foot. The needle is connected to a battery-operated stimulator, which delivers a mild electric current along the needle into the tibial nerve (part of the sacral plexus of nerves which control bladder function) for 30 minutes. The treatment usually consists of 12 sessions lasting 30 minutes once a week over 3 months.

Success rate: Studies show that up to 55% of patients are cured of their symptoms and up to 90% are improved after a full course of treatment. However, it may take up to 6 weeks before seeing any change.

Complications: The most common side effects are minor irritation, redness and/or bleeding where the needle has been inserted. You might experience short-lived foot or toe numbness. These symptoms usually go away within a few hours.

Advantages: Outpatient procedure. No anaesthetic required. In patients who have topup treatments the beneficial effects are usually maintained.

Disadvantages: The effects wear off with time.

More information: <u>Percutaneous Tibial Nerve Stimulation for Overactive Bladder</u> Symptoms.

Sacral nerve stimulation

Type of treatment: This involves two separate minimally-invasive surgical procedures, usually done under general or spinal anaesthetic.

Success Rate: 70% of patients report improvement.

Complications: Infection of the implanted stimulator (very rare).

Advantages: Minimally-invasive and safe, with a good success rate.

Disadvantages: Requires two separate procedures under anaesthetic. Patients are currently unable to go in MRI scanner afterwards but new MRI safe technology is due to be released in 2020.

More information: <u>Sacral nerve stimulation (neuromodulation)</u>

Surgical

Augmentation Cystoplasty

Type of treatment: Major abdominal operation with several days in hospital in which the bladder is enlarged using a piece of the bowel.

Success rate: 70% of patients report improvement.

Complications: 70% risk of needing to self-catheterise. Patients suffer mucus plugs in the urine and repeated infections.

Advantages: May be successful where other treatments have failed.

Disadvantages: Major surgery with significant long-term side-effects including bladder cancer and risk of needing to self-catheterise. Long term follow-up is required.

More information: Enlargement of the bladder with piece of bowel (enterocystoplasty).

Urinary diversion

Type of treatment: Major operation where the urine is diverted away from the bladder and collects in a stoma bag on your tummy. The operation takes on over 4 hours with several days in hospital afterwards.

Success rate: 70% of patients report improvement.

Complications: Wound breakdown and hernias around the stoma, requiring reoperation, often occur.

Advantages: May be successful where other treatments have failed

Disadvantages: Major surgery with significant long-term side-effects, needing long term follow up and with a risk of needing further major surgery.

More information: Urinary diversion (into ileal conduit).

Frequently asked questions

I have been told that injection of Botox can stop me passing urine for ever?

No - around one in twenty women will need help to pass urine by using clean intermittent self catheterisation (see page 5) for a few days, but you must let the team know if you have any history of difficulty passing urine.

Is it true that local oestrogen in the vagina, can help prevent urine infections

Yes - several studies have shown this.

Does Botox have to be repeated every 9 months?

Possibly - The effect will wear off, most commonly after about 9 months, but after the second treatment the benefit often seems to last longer. About 5% of patients lose their response to Botox over time because they develop antibodies to the Botox. This is more likely if injections are given more frequently than every 2-3 months.

Is the Botox used in the bladder the same as used for cosmetic use?

Yes

Is the Botox used in the bladder, used for any other medical conditions?

Yes - for many years it has been used to help control muscles in spasm

Is it true that Botox damages the bladder muscle for ever?

No - the effect of Botox is temporary.

Is local anaesthetic an injection?

No – the local anaesthetic is actually a gel.

Are there any alternatives to local anaesthetic?

Yes – although most patients find that local anaesthetic gel works well, we can do the procedure with sedation, with a spinal anaesthetic or rarely with a general anaesthetic

More information

If you would like to know more about overactive bladder and the treatments available for it, you could do the following.

- Ask your GP.
- Ask the doctor or nurse at the hospital.
- Look at these websites.
 - NHS choices http://www.nhs.uk/pages/home.aspx
 - o Patient UK http://patient.info/health
 - Bladder & Bowel Community https://www.bladderandbowel.org/
 - International Urogynaecology Association (IUGA) patient information leaflets

Bladder training

https://www.yourpelvicfloor.org/media/Bladder Training RV1-3.pdf

Botulinum Toxin A for overactive bladder

https://www.yourpelvicfloor.org/media/Botulinum Toxin.pdf

Intermittent self-catheterisation

https://www.yourpelvicfloor.org/media/Intermittent Self Catheterization.pdf

Overactive bladder

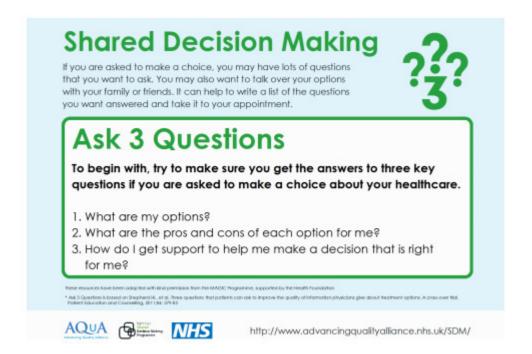
https://www.yourpelvicfloor.org/media/Overactive Bladder RV1.pdf

- The British Association of Urological Surgeons (BAUS) patient information leaflets
- National Institute for Health and Care Excellence (NICE). Urinary incontinence and pelvic organ prolapse in women: management. NG123
 April 2019 https://www.nice.org.uk/guidance/ng123/informationforpublic
- Patient information leaflets for your own hospital and others (usually available online)

Acknowledgements

Mrs Supriya Bulchandani, BSUG patient information committee project lead for this leaflet, on behalf of BSUG.

Making a decision - things I need to know before I have my operation



Please list below any questions you may have after reading this leaflet.

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