

Urethral Bulking to treat Stress Urinary Incontinence

Patient Information Leaflet



British Society of Urogynaecology
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About this leaflet

The information provided in this leaflet should be used as a guide. There may be some variation in how each gynaecologist performs the procedure, the care procedures on the ward immediately after your operation and the advice given to you when you get home. You should ask your gynaecologist about any concerns that you may have.

You should take your time to read this leaflet. A page is provided 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 wish to ask about your gynaecologist's personal experience and results of treating your condition.

Benefits and risks

The success and the risks of most operations carried out to treat prolapse and incontinence have been poorly studied and so it is often not possible to define them clearly. In this leaflet risks may be referred to as common, rare etc. or an approximate level of risk may be given. Further information about risk is explained in a leaflet published by the Royal College of Obstetricians and Gynaecologists "Understanding how risk is discussed in healthcare".

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

The following table is taken from that leaflet

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

^a EU-assigned frequency
^b Unit in which one adverse event would be expected

British Society of Urogynaecology (BSUG) database

In order to better understand the success and risks of surgery for prolapse and incontinence the British Society of Urogynaecology has established a national database. All members of the society are asked to enter all procedures that they carry out onto the database and you may be asked to consent to this for your operation. The data collected are being used to develop an overall picture of what procedures are being performed throughout the United Kingdom together with complications and outcomes. Individual surgeons can also use it to evaluate their own practice.

What is urethral bulking?

Urethral bulking involves the injection of a substance into the walls of the urethra (tube from your bladder through which your bladder empties) at 3 or 4 different sites around the urethra to improve the seal and prevent leakage of urine.

There are several varieties of bulking agent and you will need to ask your doctor which variety is used in your hospital and what are the specific benefits and risks of that product.

Some bulking agents contain particles which cause inflammation around the urethra and this reaction gives support around the urethra. As the inflammation is cleared by your body over time these agents often need repeat injections after a few years.

Other bulking agents are made of a fluid which is not absorbed by the body and it is pressure caused by the fluid itself that provides the bulking. As there is no inflammation the fluid does not disappear and may therefore be effective for longer reducing the need for repeat injections. There is as yet, however, not enough information about long-term success rates to be absolutely sure about this.

What condition does urethral bulking treat?

The procedure is designed to treat stress urinary incontinence which is often referred to just as stress incontinence. It has been approved by the National Institute for Health and Care Excellence (NICE).

There are a number of reasons for urinary incontinence (leakage of urine) and stress incontinence is one of these. It happens when there is a lack of support around the opening of the bladder allowing urine to leak out if any pressure (stress) is put on the bladder such as when coughing, lifting or exercising.

Urethral bulking is unlikely to improve any other type of urinary incontinence.

Before considering surgery

- It is recommended that you should have tried pelvic floor exercises for at least 3 months, supervised by a trained women's health physiotherapist, before considering surgery.
- Although urodynamic tests are not absolutely essential before the first surgery that is tried to treat stress incontinence they are often carried out to confirm that you do have stress incontinence. These tests should however be carried out before repeat surgery or if you also have symptoms of urgency.
- Discussion at a multidisciplinary team (MDT) meeting is considered good practice before carrying out surgery for stress incontinence. Your medical notes and the results of any tests are reviewed at the MDT meeting which is attended by urogynaecologists, specialist nurses and physiotherapists as well as urologists in

many hospitals. Taking into account any preferences you have expressed, a team decision is made as to whether your proposed treatment is appropriate.

How is urethral bulking done?

- The procedure can be done under local anaesthetic or general anaesthetic. A general anaesthetic will mean you will be asleep during the entire procedure.
- The procedure may be performed in an operating theatre or a treatment room within an outpatient department.
- A telescopic camera examination of your bladder and urethra is carried out initially.
- The bulking agent is injected into the tissues around the urethra either through the telescope or alongside the telescope.

Other operations which may be performed at the same time.

Surgery for prolapse of the uterus or vagina.

You should also refer to an information leaflet about any planned additional procedure.

Benefits of urethral bulking

- Cure or improvement in stress incontinence
- Minor procedure
- Treatment is often carried out with local anaesthetic
- May be performed in clinic without admission to hospital in some units
- Suitable for women who are not medically fit for a general anaesthetic

Risks

Specific risks of urethral bulking

Bulking agents are not as successful as other surgical procedures in curing stress incontinence. Occasionally the first treatment does not provide sufficient bulking and further bulking is required a few weeks later. Some of the bulking agents may provide a permanent cure and others may need to be repeated after some time.

Risks vary with the type of bulking agent used but the following apply to all.

- Small amounts of bleeding when you pass urine for up to a few days
- Discomfort around the bladder for a few days
- Urine infection immediately after the procedure. You may be given some antibiotics to try and prevent this.

- Difficulty emptying the bladder can occur. This generally settles quickly without any intervention but occasionally requires a catheter to help the bladder empty for one or two days. Rarely it can be more prolonged.
- Rarely infection at the bulking site causing an abscess

Other risks which do not apply to all bulking agents

- Migration (moving) of the bulking agent (particulate agents)
- Absorption of the bulking agent (particulate agents)
- Inflammation around the injection site

General Risks of Surgery and anaesthesia (if urethral bulking is done under general anaesthetic)

- **Anaesthetic risk.** This is very small unless you have specific medical conditions, such as a problem with your heart, or breathing. Smoking and being overweight also increase any risks.
 - **What can I do?** Make the anaesthetist aware of medical conditions such as problems with your heart or breathing. Bring a list of your medications. Try to stop smoking before your operation. Lose weight if you are overweight and increase your activity.
- **Bleeding.** There is a risk of bleeding with any procedure but this is minimal for urethral bulking
 - **What can I do?** 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 procedure.
- **Infection.** There is a small risk of infection with any operation (about 5 to 13 cases in 100 operations). If it occurs, an infection can be an infection at the site of the injections or a urinary infection, and is usually treated with antibiotics. The risk of infection is reduced by routinely giving you a dose of antibiotic during your operation. Chest infection may also occur as a result of a general anaesthetic.
 - **What can I do?** Treat any infections you are aware of before surgery. After surgery, regular deep breathing exercises can help prevent chest infections; the nurses will guide you how to do this.
- **Deep Vein Thrombosis (DVT).** This is a clot in the deep veins of the leg. Occasionally this clot can travel to the lungs (pulmonary embolism) which can be very serious and in rare circumstances it can be fatal (less than 1 in 100 of those who get a clot). The risk increases with obesity, severe varicose veins, infection, immobility and other medical problems. The risk is reduced for a short procedure such as urethral bulking and is minimal if the procedure is carried out in an

outpatient clinic. Any risk is significantly reduced by using special stockings and injections to thin the blood.

- **What can I do?** No action is needed if the procedure is carried out in an outpatient clinic, but the following advice may reduce your risk if you have a general anaesthetic. Stop taking any hormones such as hormone replacement therapy (HRT) and some types of birth-control pills 4 weeks before surgery. These can usually be restarted 4 weeks following surgery when the risk of blood clots has reduced. Do not arrange surgery the day after a long car journey or flight. As soon as you are awake start moving your legs around. Keep mobile once you are at home and continue to wear your compression stockings during times when you are less mobile.

Before the procedure - Pre-op assessment

If you are to be admitted to hospital for a general anaesthetic, usually you are seen in a preoperative clinic some weeks before your planned operation. At that visit you will be seen by a nurse and possibly also a doctor. You will be asked about your general health and any medications you take. Your blood pressure will be checked and you may have tests to assess your heart and breathing. Blood tests will be taken to check you for anaemia and other things according to your medical condition. Swabs may be taken from your nose and groin to make sure that you do not carry MRSA (bacteria that are very resistant to antibiotics and may cause problems after your operation). You may be asked to sign a consent form if this has not been done already.

After the procedure - in hospital

- **Pain relief.** Pain is usually minimal after urethral bulking but any discomfort can be treated with pain killing tablets.
- **Drip.** This would be to keep you hydrated until you are drinking normally but you are unlikely to need one after urethral bulking.
- **Catheter.** You are very unlikely to have a tube (catheter) draining the bladder.
- **Eating and drinking.** You can drink fluids and eat soon after the operation.
- **Preventing DVT (deep vein thrombosis).** You will be encouraged to get out of bed and take short walks around the ward as soon as you are fully awake. This improves general wellbeing and reduces the risk of clots in the legs. If you have any condition that make you more likely to get a DVT you may be given a daily injection to keep your blood thin and reduce the risk of blood clots.
- **Going home.** You are usually only in hospital for one day. If you require a sick note or certificate please ask.

After the procedure – at home

- Mobilisation is very important; using your leg muscles will reduce the risk of clots in the back of the legs (DVT).
- Bath or shower as normal.
- You should be able to return to normal activities and work as soon as you have recovered from the anaesthetic which will usually be about 48 hours.
- You can drive as soon as you have recovered from the anaesthetic which will usually be about 48 hours.
- You can start having sex whenever you wish.
- You usually have a follow up appointment anything between 6 weeks and 6 months after the operation. This maybe at the hospital (doctor or nurse), with your GP or by telephone. Sometimes follow up is not required.

What to report to your doctor after surgery

- Severe pain
- High fever
- Pain or discomfort passing urine or blood in the urine
- Warm, painful, swollen leg
- Chest pain or difficulty breathing

Alternative Treatments

Non-surgical

Do nothing. If the stress incontinence is not bothersome treatment is not necessarily needed. Incontinence may or may get worse over time, but it is not easy to predict if this will happen.

Devices. There are a number of devices (an example of a vaginal ring is shown below) which can be inserted to block the urethra. The devices are inserted into the vagina. Devices inserted into the urethra are not recommended. They are not a cure but their aim is to keep you dry whilst in use, e.g. during exercise etc. Some women find inserting a tampon useful though care should be taken not to leave in place for too long as this can be harmful.



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

Pelvic floor exercises (PFE) – 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 perform these exercises with the correct technique. It is important that you try these to help to manage the symptoms of your prolapse and to prevent it becoming worse. It is also very important to continue with your pelvic floor exercises even if you have opted for other treatment options. These exercises have little or no risk.

Duloxetine. This is a medication that can help reduce incontinence. It needs to be taken continuously as stopping the drug will result in the leakage returning. Some women find that it causes unacceptable side effects. It is not usually recommended as a first line treatment but is an option to consider if you do not want to have a surgical procedure or are unfit to do so.

Surgical

The following table lists the different operations that can be considered to treat stress urinary incontinence. Further information on the operations is available in separate leaflets. All operations are not available in all hospitals. Your consultant may recommend a particular operation depending on his or her preference and expertise, or your individual needs.

Treatment	Advantages	Disadvantages
Urethral bulking injection	No incisions (cuts). Can be done under local anaesthetic with or without sedation Can be done as an outpatient treatment Less pain compared to the other operations Lower risk of complications compared to other operations Quick recovery	Long term success lower than for the other procedures
Midurethral synthetic mesh tape	Good chance of curing or improving stress incontinence	Worsening of urinary urgency Difficulty passing urine Mesh complications Mesh exposure and erosion into vagina, urethra or bladder Can cause pain in the pelvis which sometimes persists long term

<p>Colposuspension (suspension of the neck of the bladder and urethra through the tummy)</p>	<p>Does not involve insertion of mesh Can be done via key-hole surgery Success rate similar to a mesh tape Treats prolapse of the anterior (front) wall of the vagina (cystocele)</p>	<p>Usually requires a general anaesthetic Worsened urinary urgency similar to a mesh tape Difficulty passing urine similar to a mesh tape Higher risk of bleeding than mesh tape Stitches causing bladder stones if they work their way into the bladder over time Developing a prolapse of the posterior (back) wall of the vagina (rectocele) Longer recovery</p>
<p>Autologous fascial sling (a suspension of the urethra and bladder neck using your own tissue).</p>	<p>Does not involve insertion of mesh Success rate similar to a synthetic mesh tape</p>	<p>Usually requires a general anaesthetic Requires a cut across the bottom of your tummy (not done via key-hole surgery) Longer recovery Higher risk of difficulty passing urine than with other procedures Higher risk of urinary urgency than other procedures Similar risk of bleeding to colposuspension Risk of hernia developing through the scar Not available in all hospitals</p>

More information

If you would like to know more about stress urinary incontinence and the treatments available for it, you may try the following sources of information.

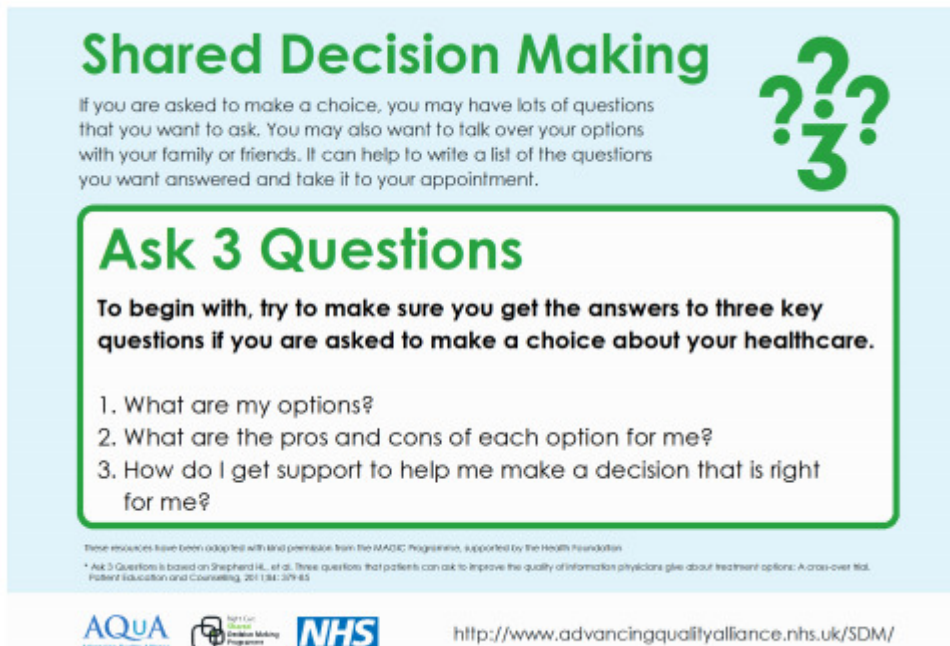
- Ask your GP.
- Ask the Doctor or Nurse at the hospital.
- Look at a website such as
 - NHS choices at <http://www.nhs.uk/pages/home.aspx>
 - Patient UK at <http://patient.info/health>
 - International Urogynaecology Association (IUGA) patient information leaflet – Urethral Bulking at http://c.ymcdn.com/sites/www.iuga.org/resource/resmgr/leaflet/Urethral_Bulking.pdf
 - The British Association of Urological Surgeons (BAUS) patient information leaflet – Urethral Bulking at <http://www.baus.org.uk/userfiles/pages/files/Patients/Leaflets/Urethral%20bulking.pdf>
 - Patient information leaflets for your own hospital and others (usually available on line)

Acknowledgements

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



Shared Decision Making

If you are asked to make a choice, you may have lots of questions that you want to ask. You may also want to talk over your options with your family or friends. It can help to write a list of the questions you want answered and take it to your appointment.

Ask 3 Questions

To begin with, try to make sure you get the answers to three key questions if you are asked to make a choice about your healthcare.

1. What are my options?
2. What are the pros and cons of each option for me?
3. How do I get support to help me make a decision that is right for me?

These resources have been adapted with kind permission from the MAGIC Programme, supported by the Health Foundation
* Ask 3 Questions is based on Shepherd H., et al. Three questions that patients can ask to improve the quality of information physicians give about treatment options: A cross-over trial. Patient Education and Counselling, 2011, 84: 379-85

AQUA Advancing Quality Alliance Right Care, Right Time Decision Making Programme NHS <http://www.advancingqualityalliance.nhs.uk/SDM/>

Please list below any questions you may have, having read this leaflet.

1).....

2).....

3).....

Please describe what your expectations are from surgery.

1).....

2).....

3).....