Periurethral bulking agent for stress urinary incontinence

Who is this leaflet for?
This leaflet provides information about having an injection of agent to treat stress urinary incontinence. It explains what is involved, the benefits and possible risks.

What is Stress Urinary Incontinence (SUI)?
This is a condition in which you leak urine on exertion, for example when you cough, sneeze, jump, run or perform exercises.

What is a bulking agent?
This is an injectable soft-tissue agent, which creates a bulk around the urethra (tube that brings urine out of the bladder). This treats female SUI that is primarily due to deficiency of the muscle that controls urinary leakage.

What are the benefits of this treatment?
This bulking agent is uniquely designed to create an open matrix to deposit collagen, thereby helping with symptoms of urinary leakage. There is no evidence of migration of this agent in clinical studies.

A tunnelling technique is used to inject bulking agent at the mid-urethral position

The cystoscopy ensures a controlled and precise procedure
What are the benefits?
The benefits of this treatment are:
• you will recover quickly
• you will be able to return to normal activities and work soon after
• overall improvement in stress incontinence (50-60%)
• suitable if your family is not complete or if you are overweight or medically unfit
• does not rule out the possibility of another surgical treatment at a later date.

What are the risks associated with this procedure?
Common risks:
• Bleeding – vaginal bleeding and discharge may take a couple of weeks to settle
• Pain – usually controlled with simple painkillers such as paracetamol
• Infection – requiring treatment with antibiotics
• Urinary retention – you may need to go home with a catheter for a few days / weeks. For about 1-5 in 100 women this may be a long term problem, requiring intermittent self catheterisation
• Urgency of urine - especially if you had this problem before
• Failure of operation to cure stress incontinence - 40-50% chance.

Uncommon risks:
• It can become less effective (20%) with time and you may need a repeat procedure after nine months to one year.

Are there any alternatives?
• Pelvic floor exercises – these are usually the first step in managing mild symptoms of SUI. They can also be effective in preventing incontinence from worsening. The exercises have to be performed daily and a cure rate of up to 70% may be expected in mild SUI. If exercises do not work or cannot be done, surgery will be the next option.
• Mid-urethral tapes [tension free vaginal tape (TVT) / transobturator tape (TOT)] – these procedures have an 85-90% success rate. However, there is a risk of bladder perforation (1 in 100), urine retention (1-5 in 100), urine urgency (5 in 100), tape exposing through the vagina, infection, pain and bleeding.
• Colposuspension – this procedure has an 85-90% success rate. However, it needs a general anaesthetic, there is usually a 2-3 day stay in hospital, and risks include pain, infection, bleeding and damage to bladder.

The pre-operative assessment
Before your visit, we will invite you to a pre-operative clinic where you will be assessed for surgery. This may be a telephone or face to face interview. You will be seen by a member of the nursing staff who will ask questions about your previous medical history and will arrange for some tests, such as a blood test. You may also have a chest X-ray. You will be given advice on whether or not you need to stop taking your medications on the day of the operation, and when to stop eating and drinking before your operation.

How do I prepare for the procedure?
You will be asked to take either two ibuprofen or paracetamol tablets at home on the morning of your treatment and then come to clinic. If you suffer from frequent water infections, to prevent cancellation on the day, please see your GP for a prescription of prophylactic antibiotics (antibiotics you take in advance to stop infection) for the three days before your surgery date.

If your procedure is in the morning, you must have nothing to eat or drink after midnight. If you are having your operation in the afternoon, please follow the instructions provided at your pre-operative assessment.
You need to have a bath or shower before you come into the hospital. Please leave any jewellery at home. If you are unable to remove any piece of jewellery, a protective tape will be placed over it.

**When will I be admitted to hospital?**
You will come in on the day of your procedure. Please bring into hospital any tablets or medicines you may be taking.

**What happens before the operation?**
When you arrive on the ward, the nurse will check your details, show you to your bed, help you to change into a gown and give you an identity wristband. If you are wearing any nail varnish or make up you will be asked to remove this. We will take some basic tests such as pulse, temperature, blood pressure and a urine sample. You will also need to remove contact lenses, glasses and false teeth.

**Visit by the surgical team:**
A doctor will come and see you and explain the operation to you. If you have not already signed a consent form in the clinic, we will ask you to sign one which gives us permission to perform the procedure. If you have any questions, please ask.

**Visit by the anaesthetic team:**
If you are having the procedure under general anaesthetic, one of the anaesthetists who will be giving you your anaesthetic will come and see you. Please tell the anaesthetist about any allergies, chest problems, dental treatment and any previous anaesthetics you have had, and also any anaesthetic problems within the family. The procedure can be performed under local anaesthesia.

**What happens during the procedure?**
The procedure usually takes about 20-30 minutes, then you will stay in recovery for monitoring. If you are awake for the procedure, you may experience some discomfort and your bladder may feel rather full. Women often describe a sensation of stinging as the bulking agent is injected but this wears off soon afterwards.

**What happens afterwards?**
Following the procedure you will recover on a ward until you pass urine. You will be encouraged to pass urine and an ultrasound scan will be performed to check that you are able to empty your bladder. If you are unable to successfully empty your bladder, you may go home with a catheter. An appointment will be arranged for you to visit the emergency gynaecology unit to have the catheter removed, and to check you are able to adequately empty your bladder.

**Will I have any pain or discomfort?**
Following the procedure, you may have some pain during the first few hours. This can be controlled by medication, which will be given to you when you are discharged from the hospital.

**When can I eat and drink again?**
When you are on the ward after the procedure, the nurse will give you something to eat and drink.

**How long will I be in hospital?**
You will be able to go home after you pass urine. You should have eaten before you go and had a walk in the department. You must arrange for an adult to take you home in a private car or taxi. You will not be able to travel on public transport, as it can be painful and uncomfortable.
When can I resume intercourse?
We would advise that you wait for the review in the clinic (10-12 weeks) before resuming sexual intercourse. It is natural to feel nervous and uncomfortable at first, so you may need to use additional lubrication and to take things slowly. However in the longer term, most people report that sex feels the same or is less uncomfortable than prior to surgery. If you have any concerns or questions, please raise these when you come for your review appointment.

How will the operation affect my sex life?
In the long term there is no evidence that the operation will make any difference to your sex life. However if you previously leaked urine during intercourse, the operation often makes this better.

When can I drive?
Provided you are comfortable sitting in a car, and can perform an emergency stop without pain or discomfort, it is safe to drive. We recommend short distances initially, gradually building up to longer journeys. We strongly advise that you check with your insurance company regarding any restrictions.

How can I help myself?
Do’s:
• Taking regular baths or showers is safe after the operation.
• Tampons are safe to use for menstrual protection after any pain and bleeding from the operation has stopped; until this has settled you should use sanitary towels.
• Exercise is good for you and will speed up your recovery.
• Drink lots of fluids and eat fresh fruit and vegetables to avoid constipation and straining to open your bowels.

Don’ts:
• Avoid vaginal douches.
• Avoid heavy lifting or any sport that involves straining your pelvic muscles.
• Any constant cough is to be treated promptly. Please see your GP as soon as possible.

When can I resume work?
Usually after two weeks. However, if there are ongoing problems, contact your GP who will consider an extension of your sick leave.

When will I be seen again?
You will be seen 10-12 weeks after the procedure in the gynaecology outpatients department, by the team who performed your surgery.

What should I look out for?
Following your discharge from hospital, contact or attend the Gynaecology ward immediately if you have concerns regarding the procedure. These may include:
• if you are unable to pass urine
• severe vaginal bleeding
• high fever
• pain when passing urine or blood in the urine.
Contact us
If you have any questions or need any further information, please contact the RCHT switchboard on 01872250000 and ask for your consultant’s secretary.

Further information
For further details about recovery after this operation see www.rcog.org.uk/recoveringwell

Comments or concerns
If you have a problem when in hospital that the nurses and doctors are unable to resolve, you can contact the Patient Advice and Liaison Service (PALS) who will be happy to help you.

PALS offers assistance, advice and support for patients and their families. The service can help if you have concerns or worries about treatment or care. PALS may also be able to provide further information about tests and procedures. They also have a library of voluntary and support agencies. Their number is 01872 253545.

Data Protection
During your visit you will be asked for some personal details. This is kept confidential and used to plan your care. It will only be used by staff who need to see it because they are involved in your care and we may send details to your GP.

Information about you may be used for audit purposes and shared within the NHS. Your consent is required for this which you have a legal right to refuse.

Smoking
RCHT is a no smoking hospital. If you would like help to stop smoking before you come into the hospital, there is a smoking cessation help line that you can call. Visitors must not smoke at all in the hospital or in hospital grounds.

If you would like this leaflet in large print, Braille, audio version or in another language, please contact the Patient Advice and Liaison Service (PALS) on 01872 252793
STATEMENT OF HEALTH PROFESSIONAL (to be filled in by health professional with appropriate knowledge of proposed procedure, as specified in consent policy)

I have explained the procedure to the patient. In particular, I have explained the intended benefits and summarised the risks, as below:

- To relieve your symptoms of urinary stress incontinence

Significant, unavoidable or frequently occurring risks:

- Failure (50 - 60%), urinary retention needing catheterisation, pain, swelling in vagina

Uncommon possible later issues:

- It can become less effective (20%) with time and you may need a repeat procedure after nine months to one year.

Any extra procedures which may become necessary during the procedure:

- For example - Blood transfusion
- Other (please specify):

I have also discussed what the procedure is likely to involve, the benefits and risks of any available alternative treatments (including no treatment) and any particular concerns of this patient.

I have given and discussed the Trust’s approved patient information leaflet for this procedure: Periurethral bulking agent for stress urinary incontinence (RCHT1470) which forms part of this document.

I am satisfied that this patient has the capacity to consent to the procedure.

This procedure will involve: ☐ General and/or regional anaesthesia ☐ Local anaesthesia ☐ Sedation

Health Professional signature: ________________________________ Date: ____________________

Name (PRINT): ____________________________________________ Job title: ____________________

STATEMENT OF INTERPRETER (where appropriate)

I have interpreted the information above to the patient to the best of my ability and in a way in which I believe he/she can understand.

Interpreter signature: ___________________________ Name (PRINT): _______________________ Date: ____________________
STATEMENT OF PATIENT

Please read this form carefully. If your treatment has been planned in advance, you should already have a copy of the patient information leaflet which describes the benefits and risks of the proposed treatment. If not, you will be given a copy now. If you have any further questions, do ask - we are here to help you. You have the right to change your mind at any time, including after you have signed this form.

I agree to the procedure or course of treatment described on this form.

I understand that you cannot give me a guarantee that a particular person will perform the procedure. The person will, however, have appropriate experience.

I understand that I will have the opportunity to discuss the details of anaesthesia with an anaesthetist before the procedure, unless the urgency of my situation prevents this. (This only applies to patients having general or regional anaesthesia).

I understand that any procedure in addition to those described on this form will only be carried out if it is necessary to save my life or to prevent serious harm to my health.

I understand that tissue samples will only be taken in relation to the procedure explained to me. No samples will be taken for quality control, clinical education or research purposes.

I have been told about additional procedures which may become necessary during my treatment. I have listed below any procedures which I do not wish to be carried out without further discussion.

I have received a copy of the Consent Form and Patient Information leaflet: Periurethral bulking agent for stress urinary incontinence (RCHT1470) which forms part of this document.

Patient signature: __________________________ Name (PRINT): __________________________ Date: __________________________

A witness should sign below if this patient is unable to sign but has indicated his or her consent.
Young people / children may also like a parent to sign here (see guidance notes).

Witness signature: __________________________ Name (PRINT): __________________________ Date: __________________________

CONFIRMATION OF CONSENT (to be completed by health professional when the patient is admitted for the procedure, if the patient has signed the form in advance).

On behalf of the team treating the patient, I have confirmed with the patient that they have no further questions and wish the procedure to go ahead.

Health Professional signature: __________________________ Date: __________________________

Name (PRINT): __________________________ Job title: __________________________

Important notes (tick if applicable):

☐ See advance decision to refuse treatment  ☐ Patient has withdrawn consent (ask patient to sign/date here)

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