Intravesical immunotherapy

What is the evidence base for this information?
This leaflet includes advice from consensus panels, the British Association of Urological Surgeons, the Department of Health and evidence based sources; it is, therefore, a reflection of best practice in the UK. It is intended to supplement any advice you may already have been given by your urologist or nurse specialist as well as the surgical team at Addenbrooke’s. Alternative treatments are outlined below and can be discussed in more detail with your urologist or specialist nurse.

What does the procedure involve?
Instillation of BCG into the bladder for aggressive or recurrent superficial cancer of the bladder.

What are the alternatives to this procedure?
Repeated cystoscopy, radiotherapy, surgical removal of the bladder with urinary diversion or bladder reconstruction, systemic chemotherapy.

What should I expect before the procedure?
Your consultant urologist has referred you for treatment of your superficial bladder cancer. Superficial bladder cancer affects the lining of the bladder only but has the ability to progress to more aggressive disease.

The aim of the treatment, therefore, is to stop or slow down re-growth by instilling a drug into the bladder; this is called intravesical immunotherapy. The treatment recommended for you is BCG. BCG is a commonly used vaccine against tuberculosis (TB) and contains a bacterium from the same family as the TB bacterium which has been altered (attenuated) to reduce the risk of infection whilst retaining the ability to produce the immune reaction needed for its beneficial effect. It has been shown that putting liquid containing BCG vaccine into the bladder is an effective treatment for bladder cancer. Like all powerful treatments, it comes with some possible side-effects (see below) and the risk of these should be considered against the risk of the bladder cancer for which the treatment is being given.
There is also some evidence that BCG treatment can interact with influenza vaccine; for this reason, it is recommended that you do not undergo vaccination against influenza within six weeks of having an instillation of BCG.

Treatment involves weekly instillations for six weeks (induction treatment), followed by maintenance treatments for up to three years, which includes several doses of BCG, each one preceded by a flexible cystoscopy. The main reasons for patients failing to complete the full course are side-effects (see below) and/or disease progression. You should limit your fluid input for four hours before each treatment and two hours afterwards.

Your first treatment will take up to three hours and, depending on how well you tolerate the first treatment, future visits will take approximately 30 minutes.

On arrival in the clinic, you will be asked to pass urine which will be tested to ensure that you do not have an infection in the urine. If you do, your treatment will need to be postponed for one week while you are treated with antibiotics.

Please be sure to inform your urologist in advance of your surgery if you have any of the following:

- an artificial heart valve
- a coronary artery stent
- a heart pacemaker or defibrillator
- an artificial joint
- an artificial blood vessel graft
- a neurosurgical shunt
- Any other implanted foreign body
- a prescription for Warfarin, Aspirin, Rivaroxaban, Dabigatran, Apixaban, Edoxaban or Clopidogrel, Ticagrelor or blood thinning medication
- a prescription for anti-tuberculosis drugs like streptomycin, para-amino-salicylic acid (PAS), isoniazid (INH), rifampicin and ethambutol
- impaired immune response irrespective of whether this impairment is congenital or caused by disease, drugs or other therapy
- positive HIV serology
- pregnancy and lactation
- a previous or current MRSA infection
- high risk of variant CJD (if you have received a corneal transplant, a neurosurgical dural transplant or previous injections of human derived growth hormone)

What happens during the procedure?

A fine plastic tube (called a catheter) will be passed into the bladder and the medication (approximately half a cup of fluid) will be given through it. The catheter will then be removed. You will be asked not to pass urine for two hours to allow the medication to treat the bladder lining. During this time you should move around a little. This makes sure that the medication is spread around all of your bladder.

On your first visit, you will be asked to stay in the clinic for the duration of the treatment and you will be asked to pass urine before you go home. For the remaining treatments, if you live...
within 20 minutes of the hospital and have your own transport, you may be allowed to go home with the medication in your bladder and pass urine after two hours.

**What happens immediately after the procedure?**
Once the treatment has been completed, you will be able to go home.

Urine passed within the first six hours after you have been treated should be disinfected by pouring a quantity of undiluted household bleach (equal to the amount of urine passed) into the toilet; this should then be left for 15 minutes before flushing the toilet.

You should drink plenty of fluids (two to three litres) for a few days after the treatment.

Some patients find that, for a few days after BCG treatment, a glass of cranberry juice daily eases any bladder symptoms; cranberry juice, however, should not be used if you are taking warfarin.

**Are there any side-effects?**
Most procedures have a potential for side-effects. You should be reassured that, although all these complications are well recognised, the majority of patients do not suffer any problems after a urological procedure.

Please use the check boxes to tick off individual items when you are happy that they have been discussed to your satisfaction:

**Common (greater than one in 10)**
- Urinary tract infection requiring postponement of the next dose of BCG
- Some bladder discomfort after treatment
- Flu-like symptoms which can persist for two to three days
- Frequency and urgency of urination which can persist for two to three days
- Failure to complete the course of treatment due to bladder discomfort
- Blood in the urine
- Debris in the urine

**Occasional (between one in 10 and one in 50)**
- Stricture of the urethra (water pipe) following repeated use of a catheter
- A number of inflammatory reactions which can affect various parts of the body (the liver, joints and the back of the eye)

**Rare (less than one in 50)**
- Persistent or severe pain after treatment, sometimes requiring removal of the bladder
- Generalised and potentially serious infection with the BCG bacteria requiring treatment in hospital with powerful antibiotics. This is not TB and there is no risk of catching TB from the treatment.

**Hospital-acquired infection (overall risk for Addenbrooke’s)**
- Colonisation with MRSA (0.01%, two in 15,500)
- Clostridium difficile bowel infection (0.02%; three in 15,500)
- MRSA bloodstream infection (0.00%; 0 in 15,000)
(These rates may be greater in high risk patients eg with long term drainage tubes, after removal of the bladder for cancer, after previous infections, after prolonged hospitalisation or after multiple admissions.)

**What should I expect when I get home?**

If you think you have a urine infection (ie pain on passing urine, frequency or foul-smelling urine) or if you develop a high temperature with backache, it is important to contact your GP and get treatment with antibiotics.

**What else should I look out for?**

Because this treatment is put directly into the bladder and not into the bloodstream, you will not experience the side-effects often associated with other cancer drug treatments.

**Are there any other important points?**

You should wash your hands and genitals after you have passed urine and it is advisable to bring a wash bag with you to hospital when you come for the treatment.

Men should pass urine sitting down on the first occasion after the instillation but, thereafter, may pass urine in the normal fashion (standing).

You are advised not to have sexual intercourse for at least 24 hours after the treatment as this can cause some discomfort. For the duration of the treatment course, and for one week after the course, you should use a condom during sexual intercourse.

If you are a smoker, you should be aware that smoking seems to encourage recurrence of bladder cancer.

**Driving after surgery**

It is your responsibility to ensure that you are fit to drive following your surgery.

You do not normally need to notify the DVLA unless you have a medical condition that will last for longer than three months after your surgery and may affect your ability to drive. You should, however, check with your insurance company before returning to driving. Your doctors will be happy to provide you with advice on request.

**Privacy & dignity**

Same sex bays and bathrooms are offered in all wards except critical care and theatre recovery areas where the use of high tech equipment and/or specialist one to one care is required.

**Hair removal before an operation**

For most operations, you do not need to have the hair around the site of the operation removed. However, sometimes the healthcare team may need to remove hair to allow them to see or reach your skin. If the healthcare team consider it is important to remove the hair, they will do this by using an electric hair clipper, with a single-use disposable head, on the day of the surgery. Please do not shave the hair yourself, or use a razor for hair removal, as this can increase the risk of infection to the site of the operation. If you have any questions, please ask the healthcare team who will be happy to discuss this with you.
Is there any research being carried out in this field at Addenbrooke’s Hospital?

There is no specific research in this area at the moment but all operative procedures performed in the department are subject to rigorous audit at a monthly audit and clinical governance meeting.

Who can I contact for more help or information?

**Oncology nurses**

Uro-oncology nurse specialist
01223 586748

Bladder cancer nurse practitioner (haematuria, chemotherapy and BCG)
01223 274608

Prostate cancer nurse practitioner
01223 274608 or 216897 or bleep 154-548

Surgical care practitioner
01223 348590 or 256157 or bleep 154-351

**Non-oncology nurses**

Urology nurse practitioner (incontinence, urodynamics, catheter patients)
01223 274608 or 586748 or bleep 157-237

Urology nurse practitioner (stoma care)
01223 349800

Urology nurse practitioner (stone disease)
01223 349800 or bleep 152-879

**Patient advice and liaison service (PALS)**

Telephone:
+44 (0)1223 216756 or 257257
+44 (0)1223 274432 or 274431

PatientLine: *801 (from patient bedside telephones only)

Email: pals@addenbrookes.nhs.uk

Mail: PALS, Box No 53
Addenbrooke’s Hospital
Hills Road, Cambridge, CB2 2QQ
What should I do with this leaflet?
Thank you for taking the trouble to read this patient information leaflet. If you wish to sign it and retain a copy for your own records, please do so below.

If you would like a copy of this leaflet to be filed in your hospital records for future reference, please let your urologist or specialist nurse know. If you do, however, decide to proceed with the scheduled procedure, you will be asked to sign a separate consent form which will be filed in your hospital notes and you will, in addition, be provided with a copy of the form if you wish.

I have read this patient information leaflet and I accept the information it provides.

Signature……………………………….……………Date……………………………………

We are now a smoke-free site: smoking will not be allowed anywhere on the hospital site. For advice and support in quitting, contact your GP or the free NHS stop smoking helpline on 0800 169 0 169.

Other formats:
If you would like this information in another language, large print or audio, please ask the department where you are being treated, to contact the patient information team: patient.information@addenbrookes.nhs.uk.

Please note: We do not currently hold many leaflets in other languages; written translation requests are funded and agreed by the department who has authored the leaflet.

Document history
Authors Mr Nikesh Thiruchelvam (on behalf of the consultant urologists)
Pharmacist Olufolake Ajose-Adeogun
Department Department of Urology, Box No 43
Cambridge University Hospitals NHS Foundation Trust, Hills Road, Cambridge, CB2 0QQ www.cuh.org.uk / www.camurology.org.uk
Contact number 01223 216575/ Fax 01223 216069
Publish/Review date October 2017 / October 2020
File name PIN2049_ Intravesical_immunotherapy_ V7.doc
Version number/Ref V6 / PIN2049 / Document ID 8150
Local Ref number 80/Urol_04_14