

High-risk non-muscle-invasive **Bladder Cancer**

A decision-making aid



It is widely acknowledged that this particular decision remains a very difficult one for High Risk Non Muscle Invasive Bladder Cancer patients and ABC UK are frequently approached by patients asking for advice.

In response to this continuing need, ABC UK produced this decision aid resource in 2019, and have now revised it to reflect varying treatment practice. This ABC UK resource is endorsed by BAUS (The British Association of Urological Surgeons).

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All ABC UK information materials are written and reviewed by bladder cancer patients and expert clinicians.

High-risk non-muscle-invasive Bladder Cancer



This Decision Aid gives you information about the three most common treatment options for high-risk non-muscle-invasive bladder cancer. This will help you have a full discussion with your clinical team about what's best for you personally, taking account of your overall health condition as well as your cancer grade and stage.

This Aid is not intended to make decisions for you, but it provides important information that will help you think about the effects each option may have on your life. Talk to your doctor and/or your cancer nurse specialist (named nurse). They will have

information from your test results and your medical history and will help you decide which option is best for you. We have suggested some questions to ask at the end of this leaflet. You will, of course, usually want to talk to your partner, family or carer. And you may find it helps to talk to someone who has gone through the treatment(s) that you are considering – your clinical nurse specialist or another member of your medical team should be able to put you in touch with someone. Action Bladder Cancer UK can also help to put you in contact with someone to speak to.

Deciding on a treatment

What is my individual risk?

The risk that your cancer will return depends on the stage of your cancer – the size, position, number and type of your tumour or tumours and how aggressive your cancer was found to be. Your doctor should explain this to you.

1

Some or all of your cancer will have been removed during your first TURBT (transurethral resection of a bladder tumour). A second TURBT and/or a CT scan or MRI may have been needed to check that the cancer had been fully removed and to make sure it was non-muscle invasive, meaning that it had not grown into the muscle of the bladder wall.

Although your cancer was confirmed as non-muscle invasive, this type of cancer often returns (recurs). It can spread into the muscle of the bladder wall (meaning that it progresses to muscle-invasive disease) and eventually it can spread to different places in the body. Further treatment helps to reduce the likelihood of this happening.

Different treatments are likely to work better for some people than others. But with the tests currently available, it's not possible to predict who is most likely to benefit from the different treatments.

This means that your decision about treatment will be influenced by your views and feelings about the 'pros' and 'cons' of each treatment and what is most important to you. But listen carefully to your consultant's explanations, comments and suggestions, which will take into account your personal risk (see Box 1) and your general health. Although the final decision is yours, it's important that you discuss all options with your clinical team before you make a decision.

The options

The main options after TURBT are:

- treatment directly into the bladder - most commonly immunotherapy treatment with BCG (or, possibly, chemotherapy treatment with Mitomycin C), which involves having the BCG vaccine (or Mitomycin C) delivered directly into your bladder over a course of treatments - although BCG has been used to treat bladder cancer since the 1970s, it's not completely clear how BCG works but it probably encourages your body's immune system to attack the cancer cells
- cystectomy, which involves surgically removing your bladder completely (the operation is called a radical cystectomy)

And in some (special) circumstances or as a matter of personal choice, another option is:

- surveillance (sometimes called watchful waiting or expectant management), which involves regular monitoring but no active treatment until a change is seen

In some areas of the UK, you may have other options (see Box 2 overleaf).

New developments

Treatments for bladder cancer are changing and new possibilities are emerging. The options offered to you may reflect local decisions about the best approach. In some areas of the country, you may be offered the following as well as, or in place of, some of the other options:

- Hyperthermic mitomycin, which involves delivering heated Mitomycin C (a chemotherapy drug used to treat different types of cancer) to your bladder
- Radiotherapy, which uses ionising radiation to stop cancer growing

Another recent change is that most hospitals are now using shorter schedules of BCG treatment with a minimum of 15 instillations over a period of about 15/18 months rather than the original standard schedule of up to 3 years.

Hyperthermic Mitomycin C has been used in some hospitals as a replacement for BCG. It is a form of chemotherapy rather than an immunotherapy like BCG, however it is delivered into the bladder in the same way.

2

If you are offered additional options to the three ones described in detail in this Decision Aid, ask your doctor for the same information (for example, about the risks, benefits and survival statistics) to make it easier to compare treatments. You could show your doctor this decision aid and ask them about any new options they may recommend.

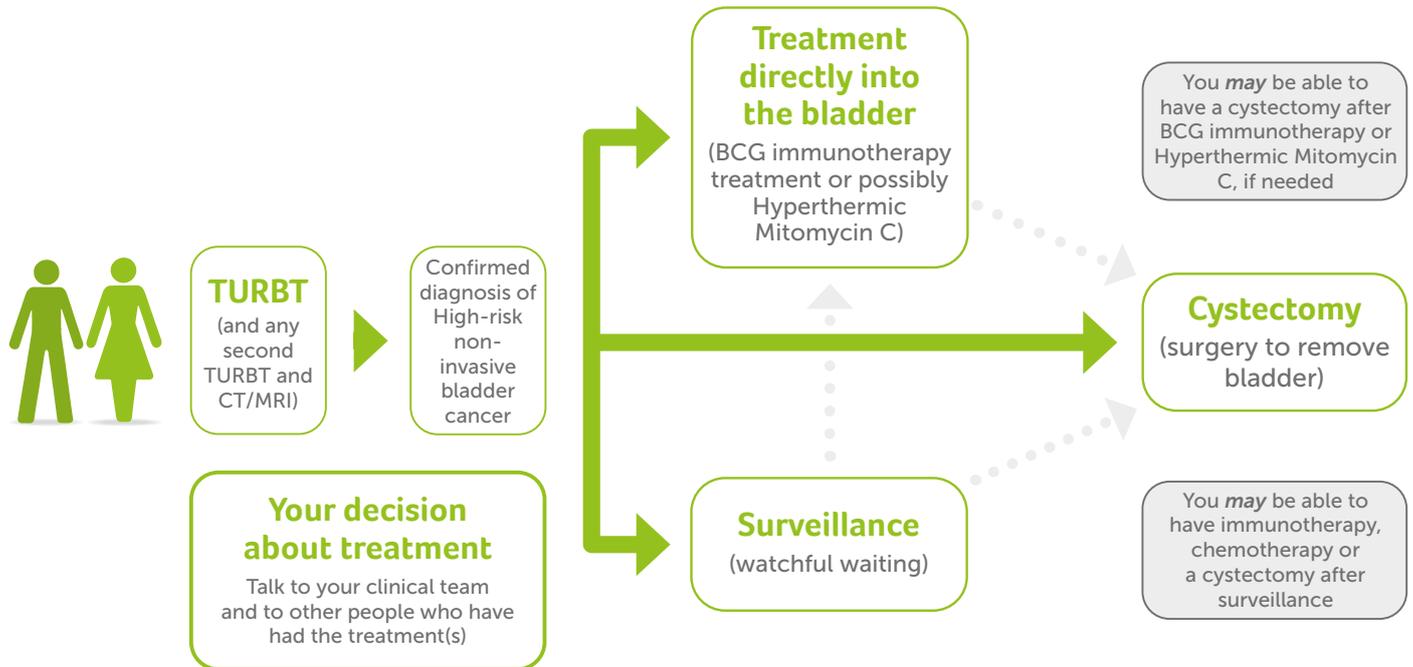
Clinical Trials

Some hospitals may offer enrolment in to trials for newer treatments that are still in the

developmental stage. This would be offered with full consent and as an alternative to other options.

There is some current research into new immunotherapy treatments for certain types of bladder cancer. Ask your doctor if there are any relevant clinical trials taking place at your hospital, or in another hospital nearby. You should note that not everyone is suitable for a trial, or that any appropriate trials may not be open for new patients when you require treatment.

TURBT - the options



A brief guide to what is involved



Treatment directly into the bladder

Immunotherapy with BCG (or chemotherapy with Hyperthermic Mitomycin C)

- BCG vaccine (or Hyperthermic Mitomycin C) is injected into the bladder
- Treatments are given once a week for 6 weeks (the induction course)
- A series of maintenance courses of 3 BCG (or Mitomycin C) treatments would in most cases be offered for up to 3 years
- Each hospital treatment takes up to 2 hours, with a short period of recovery needed at home
- A cystoscopy is needed 6 weeks after each course of treatments
- Follow-up tests and scans are needed several times a year for at least 5 years



Surgery

- The bladder is removed and a new urine outlet system created
- Needs a hospital stay of up to 1 to 2 weeks
- Takes 6–12 weeks to fully recover at home
- For patients who have bladder reconstruction a cystoscopy may be needed after 3 to 6 months and then usually an annual cystoscopy is needed for 5 years
- Follow-up blood tests and annual CT scans are needed for up to 10 years



Surveillance

- There is no active treatment
- Regular monitoring is carried out, with cystoscopy at regular intervals, depending on the cancer

Treatment directly into the bladder?

The big question

If you have immunotherapy treatment with the BCG vaccine (or chemotherapy treatment with Hyperthermic Mitomycin C), there is a good chance that the treatment will be effective – that is, it will reduce the risk of the cancer returning or worsening.

But the treatment can have some unpleasant side-effects. These may be relatively minor, but for some people these are enough to stop the treatment altogether. Another important point is that if the cancer does worsen while you're having immunotherapy (or treatment with Mitomycin C), it can mean that by the time you have surgery, it has spread and the surgery is less likely to be successful. Or you may have become unable to have the surgery due to other complications or health factors.

About 1 in every 4 people who have immunotherapy with BCG or surveillance eventually have a cystectomy.*

Research shows that if 1000 people had BCG treatment and 1000 people had cystectomy straightaway, the cancer would have worsened in 45 more people in the BCG group than in the cystectomy group.*

Bear in mind:

- Clinicians commonly give a 5-year survival rate for BCG treatment of around 75% or more (meaning at least 75 out of 100 people will be alive after 5 years). It's important to know that some of these 75 people may have had a cystectomy after BCG but still within those 5 years.
- At the moment, doctors cannot yet predict who will respond well to BCG treatment and who would be better opting for a cystectomy straightaway.

**This research was looked at by the National Institute for Health and Care Excellence (NICE) when it was producing its bladder cancer guidelines. NICE noted that the studies it looked at were of poor quality and asked for better research to be done to compare treatments.*

Risks: Most people (more than 70 in every 100) get some side effects at some stage of their treatment. Serious side effects happen in fewer than 5 in every 100 people, but it's common to feel tiredness, pain/discomfort and urinary symptoms (increased need to urinate frequency, irritation) during and after treatments. About 10 people in every 100 cannot tolerate the effects of treatment and have to stop.

Daily life: Daily life: People having BCG treatment or treatment with Hyperthermic Mitomycin C need to continue to go to hospital for several years for ongoing treatment and to regularly check that their cancer has not returned. You will have to take time out of your normal activities to attend the BCG or Mitomycin sessions and to deal with the BCG or Mitomycin affected urine at home (special precautions are needed). Whilst undergoing active treatment it is possible that the effects of treatment may affect your daily life, however neither BCG immunotherapy nor Mitomycin C usually have significant or long-lasting effects.

Continence: Immunotherapy is very unlikely to give you permanent urinary incontinence. Most people find that they have to pass urine more frequently during the day and night during each set of BCG treatments and for a few weeks afterwards. You may also experience some bladder pain and/or a sensation that you urgently need to urinate. Incontinence may occur with either treatment, and may be permanent - however, this is rare.

Sex life: Immunotherapy in itself does not usually seem to affect people's sex life. But the tiredness and discomfort that can happen with this treatment may. People having BCG treatment should not have sex (including oral sex) for 2–3 days after treatment and then need to use condoms for several weeks afterwards. People having Mitomycin C should also follow these precautions.

Effect on fertility: In most cases there is no overall effect on fertility. However, treatment may affect a baby in the womb, so it is important that you do not become pregnant, or father a child, whilst having treatment and for at least 6 months afterwards. Rarely, BCG treatment may affect a man's sperm, so sperm preservation before treatment may be possible or advised. Treatment may have an effect on pregnancy—you may be advised to wait at least 2 years before becoming pregnant and treatment may affect your ability to become pregnant. Talk to your clinical team if this is important for you.

BCG is the most commonly used immunotherapy treatment offered to those with high-risk non-muscle invasive bladder cancer. You may be offered alternative treatment into the bladder (intravesical), such as Mitomycin C. There have been occasional issues regarding the supply and distribution of BCG (and, to a lesser degree, of Mitomycin C) and alternative approaches have been adopted.

If you have any questions about your immunotherapy treatment ask your medical team at the hospital.

Should I have a cystectomy straightaway?

The big question

There is some evidence from research that having surgery straightaway gives most people the best chance of cure (that is, the cancer won't worsen or return). For example, research looking at how many people were alive 5 years after treatment shows that 99 fewer people in 1000 would die from bladder cancer if everyone had a cystectomy straightaway rather than having a cystectomy later, after unsuccessful BCG therapy.*

But some of those people who had a cystectomy straightaway would not have needed to have this major surgery as their cancer would not have worsened or returned if they'd had immunotherapy or treatment with Hyperthermic Mitomycin C. So the cystectomy was a more extreme treatment than they needed. This is important to think about

as the operation is major surgery that needs a long stay in hospital. Complications are quite common. You would also need to have a new urine system constructed, and this will affect your day to day life.

Bear in mind: how difficult it is to predict who would benefit from a cystectomy straightaway.

**This research was looked at by the National Institute for Health and Care Excellence (NICE) when it was producing its bladder cancer guideline. NICE noted that it was poor quality and asked for better research to be done to compare treatments.*

Risks: Problems that can happen because of a cystectomy fall into two groups:

- those that can happen with any major operation and general anaesthetic, such as heart attack, chest infection, wound infection – the risk of these is quite low
- those that are specific for cystectomy, such as leakage from the surgical joints created in the operation and hernia affecting the area (just after the surgery or after a longer time).

In every 100 people who have a cystectomy:

- 1 to 2 people die from the effects of the operation
- 25 to 50 people develop a complication, but one that is treatable (more surgery may be needed).

Ask your clinical team for your hospital's statistics for the operation.

There remains a small percentage chance of recurrence in the remaining parts of your urinary system after the surgery (usually quoted as 5/8%).

Should I have a cystectomy straightaway? *(continued)*

Daily life: People who have their bladder removed need to get used to another way of managing the drainage of urine from their body. The options for draining the urine are:

Urinary Stoma: a common option is the creation of a urinary stoma, where a short section of bowel is used to form an outlet that passes through a stoma from your abdomen. Urine is collected in an external removable bag which attaches to the lower part of your tummy/abdomen.

Internal pouches or reservoirs: a section of your bowel is isolated from the rest of the bowel and then re-worked into a urine pouch, which replaces the bladder. This could be either connected to the urethra to allow a person to store and pass urine more or less normally - this is called a Neobladder or, more rarely, connected to the outside of the tummy/abdominal wall, where it can be emptied through a plastic tube - this is called a Mitrofanoff pouch or reservoir.

Most people find having a stoma and using an external bag simple and easy to use. The internal pouches need more time and effort for people to get used to them. People with an internal pouch need more follow-up visits after surgery.

Some people may find it hard to come to terms with the stoma or internal pouch, or to manage it. This can affect relationships with partners, family, friends or work colleagues.

Continence: Cystectomy may lead to some urinary incontinence, depending on the type of surgery. A stoma (external bag) can leak if the bag does not stick to the tummy correctly. A stoma nurse or nurse specialist would be able to help you to sort out any problems. People who have a bladder substitute or neobladder may find it difficult to control the flow of urine at first. After this type of surgery, eventually

Continence (cont.): about 9 out of 10 people say that they can control their urination during the day, and about 8 out of 10 say they can control it during the night.

After recovery from surgery (which takes 6–12 weeks), people are usually able to return to their usual work, unless they do heavy physical work.

Sex life: Having a cystectomy affects a person's sex life. For men, the nerves that control erections are likely to be damaged during surgery. This means that almost all men who have cystectomy either do not get any erections after their surgery or do not get erections firm enough for sex. Men almost always have their prostate gland removed with the bladder during the operation, so they cannot ejaculate after surgery.

But there are a number of treatments for erectile problems that can help, including medication (both tablets and injections) and vacuum pumps. There can be side effects with some of these medications.

In women, surgery to remove the bladder can make the vagina shorter and narrower. This may make having sex painful or difficult.

For some patients, surgery can be done in a way that attempts to preserve nerves involved with sensation during sex. If this sort of surgery is possible and safe for your particular cancer, this may reduce the impact of surgery on your sex life and you should discuss this option with your consultant or specialist nurse.

Effect on fertility: If you are at an age when you may still want children, you should discuss this with your health team. Cystectomy is likely to leave you with infertility. In men, the prostate gland is usually removed. In women, the womb and fallopian tubes are usually removed and sometimes the ovaries and part of the vagina are taken out during surgery.

Should I opt for surveillance only?

The big question

There has not been any research published that compares how long people with NMIBC live if they opt for surveillance rather than active treatment. You may want to think about surveillance if your general health is poor – would your quality of life be better without having the effects of surgery or BCG immunotherapy? Or might anxiety about your cancer affect your health?

As with BCG immunotherapy and Hyperthermic Mitomycin C treatment, it may be possible to have other treatment after a period of surveillance (possibly including surgery), but treatment is less likely to be successful if your cancer or your general health has worsened.

Risks and effects: You will have to go to hospital for monitoring – how often will depend on your cancer, but it could be every 3 months for 2 years, then every 6 months for 2 years, then every year. As you are not having any active treatment, there won't be any effects of treatment on your daily life but you will, of course, continue to have the risk that the cancer will return and/or progress.

What are my options if treatment isn't successful?

- If you have a cystectomy, your bladder will be removed, so you won't be able to have the other treatments discussed here at a later time.
- If you have immunotherapy, or treatment with Hyperthermic Mitomycin C, you may be able to opt for a cystectomy later – especially if you stay physically fit and your cancer has not spread to other parts of your body.
- Surveillance (without any further treatment after your TURBT) clearly carries a higher risk of your cancer returning and/or progressing. If your bladder cancer returns and/or progresses, you may be able to have further treatment at that stage.
- If your bladder cancer has recurred after surveillance or following the use of first-line intravesical agents (eg: BCG or Mitomycin C) you may still be offered new research-based options for treating bladder cancer within a clinical trial.

Useful links

- **NICE** guideline on bladder cancer diagnosis and management. Version for lay readers available at www.nice.org.uk/guidance/ng2/ifp/chapter/About-this-information
- **ABC UK's** website has a range of useful bladder cancer patient information: <https://actionbladdercanceruk.org/resources/>
- **ABC UK** at <https://actionbladdercanceruk.org/grading-and-staging/>
- **CRUK** has information on treatment decisions and procedures here www.cancerresearchuk.org/about-cancer/bladder-cancer/treatment/early/decisions

Next steps

Talking to your doctor or nurse about the options

Before your appointment, think about how much you agree or disagree with these statements:

- I want a treatment that gives me the best chance of curing my bladder cancer
- I want to have a treatment that reduces the worry about continuing checks and biopsy results
- I don't want treatment side effects or complications that will affect my life
- I want to spend as little time as possible in hospital and recovering from treatment
- I don't want to have to have continuing regular and ongoing treatment
- It's important to me that my sex life is not affected by treatment

Questions to ask:

What is the outlook with my specific cancer type?

- How likely is it my cancer will spread further into the bladder (that is, become muscle-invasive)?
- How likely is it my cancer will spread to different places around my body (called metastatic cancer)?
- How likely is it that I will die from bladder cancer?
- What is the risk that my cancer is actually more advanced than this (this is particularly important if you are thinking of opting for surveillance)?
- Will I have to have continuing, regular or on-going treatment and/or checks? And, if so, what will this be?
- Will my sex life be affected by the treatment? And, if so, in what way will it be affected?

What are the pros and cons of the options for me?:

- Do I have health issues that might affect my treatment?
- How likely is it that BCG (or Hyperthermic Mitomycin C) would be successful, and if the cancer returns, what would be my options?
 - What would treatment involve?
 - How often would I have hospital appointments afterwards?
- How likely is it that cystectomy would be successful, and if the cancer returns, what would be my options?
 - What would surgery involve?
 - How often would I have hospital appointments afterwards?
- If I'm considering surveillance, what's my outlook and what would be my options if my cancer worsens or spreads?
- Are there any other options available locally or elsewhere?



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