

Understanding NICE guidance

Information for people who use NHS services

Relieving pelviureteric junction obstruction using an inflatable balloon with a heated cutting wire

NICE 'interventional procedures guidance' advises the NHS on when and how new procedures can be used in clinical practice.

This leaflet is about when and how an inflatable balloon with a heated cutting wire energy can be used in the NHS to treat patients with pelviureteric junction (PUJ) obstruction. It explains guidance (advice) from NICE (the National Institute for Health and Clinical Excellence).

Interventional procedures guidance makes recommendations on the safety of a procedure and how well it works. An interventional procedure is a test, treatment or surgery that involves a cut or puncture of the skin, or an endoscope to look inside the body, or energy sources such as X-rays, heat or ultrasound. The guidance does not cover whether or not the NHS should fund a procedure. Decisions about funding are taken by local NHS bodies (primary care trusts and hospital trusts) after considering how well the procedure works and whether it represents value for money for the NHS.

NICE has produced this guidance because the procedure is quite new. This means that there is not a lot of information yet about how well it works, how safe it is and which people will benefit most from it.

This leaflet is written to help people who have been offered this procedure to decide whether to agree (consent) to it or not. It does not describe PUJ obstruction or the procedure in detail – a member of your healthcare team should also give you full information and advice about these. The leaflet includes some questions you may want to ask your doctor to help you reach a decision.

What has NICE said?

There is not much good evidence about how well this procedure works and there is some concern about the risk of bleeding. If a doctor wants to use this procedure for PUJ obstruction, they should make sure that extra steps are taken to explain the uncertainty about how well it works and the risk of bleeding. This should happen before the patient agrees (or doesn't agree) to the procedure. The patient should be given this leaflet and other written information as part of the discussion. There should also be special arrangements for monitoring what happens to the patient after the procedure. The decision about who has the procedure, and the procedure itself, should be carried out only in hospitals that can offer a range of procedures including keyhole surgery to remove and reconstruct the blocked section of the PUJ (laparoscopic pyeloplasty).

Other comments from NICE

Balloon treatment is not often used because laparoscopic pyeloplasty is used more often. But the procedure might be useful in managing recurrence of the obstruction.

This procedure may not be the only possible treatment for pelviureteric junction obstruction. Your healthcare team should talk to you about whether it is suitable for you and about any other treatment options available.

Relieving pelviureteric junction obstruction using an inflatable balloon with a heated cutting wire

The medical name for this procedure is 'electrocautery cutting balloon treatment for pelviureteric junction obstruction'. The procedure is not described in detail here – please talk to your surgeon for a full description.

Urine passes from the kidneys to the bladder through a tube called the ureter. If the passageway between the kidney and the ureter (called the pelviureteric junction or PUJ) is blocked (obstructed) because it is narrow, the urine cannot drain away properly. This can cause low back pain and urinary infections. Treatments include open or keyhole surgery to reduce or remove the blockage. Another surgical technique uses instruments (a laser, heat-conducting device or a scalpel) inserted through the ureter.

With the patient under a general anaesthetic, the surgeon inserts the cutting balloon through the ureter into the PUJ, guided using an X-ray imaging device. The balloon is partly inflated to fix it into position and the heated wire cuts away the tissue causing the obstruction. The balloon is then fully inflated to help stop the bleeding. A tube called a stent is inserted into the PUJ to keep it open while it heals, and removed after several weeks.

Summary of possible benefits and risks

Some of the benefits and risks seen in the studies considered by NICE are briefly described here. NICE looked at 8 studies on this procedure.

What does this mean for me?

If your doctor has offered you this procedure, he or she should tell you that NICE has decided that the benefits and risks are uncertain. This does not mean that the procedure should not be done, but that your doctor should fully explain what is involved and discuss the possible benefits and risks – especially the risk of bleeding and of the obstruction coming back – with you. You should only be asked if you want to agree to this procedure after this discussion has taken place. You should be given written information, including this leaflet, and have the opportunity to discuss it with your doctor before making your decision. NICE has also decided that more information is needed about this procedure. Your doctor may ask you if details of your procedure can be used to help collect more information about this procedure. Your doctor will give you more information about this.

You may want to ask the questions below

- What does the procedure involve?
- What are the benefits I might get?
- How good are my chances of getting those benefits? Could having the procedure make me feel worse?
- Are there alternative procedures?
- What are the risks of the procedure?
- Are the risks minor or serious? How likely are they to happen?
- What care will I need after the procedure?
- What happens if something goes wrong?
- What may happen if I don't have the procedure?

How well does the procedure work?

Two studies measured 'success' of the procedure (defined as patients' symptoms getting better and the obstruction being cleared). In a study of 40 patients, 13 out of 20 who had the balloon procedure and 17 out of 20 who had a laser procedure felt the procedure had been successful when their progress was checked after 30 months. Another study of 64 patients showed there was no significant difference in success rates between the procedures, when the patients' progress was checked after 76 months. In another study of 149 patients, who were checked after 16 months, 85% of 52 patients who had the balloon procedure felt their discomfort had improved by 50% or more, compared with 90% of 40 patients treated with heat without the balloon. One patient out of 17 who had the balloon procedure in a study of 64 had to have another operation. None of the 18 patients treated using heat had to have another operation, but 5 of the 29 treated using a scalpel did.

As well as looking at these studies, NICE also asked expert advisers for their views. These advisers are clinical specialists in this field of medicine. The advisers said that the aims of the procedure are short-term pain relief, to clear the obstruction, and for the obstruction not to return.

You might decide to have this procedure, to have a different procedure, or not to have a procedure at all.

Risks and possible problems

Two patients out of 27 who had the balloon procedure in a study of 64 had bleeding problems needing treatment (including a blood transfusion), but none of the 37 patients who had the laser procedure did. In a study of 76 patients who had the balloon procedure 5 had bleeding problems needing treatment (including a blood transfusion). Three patients out of 20 in another study had blood in their urine 2–5 days after having balloon treatment but this did not need treatment. In a study of 2 patients, 1 had blood collected around the kidney because an abnormal artery was cut, which had to be tied off during open surgery. The other patient had a ruptured artery, which was repaired. The wire from the balloon broke off in 1 patient. In the study of 40 patients, the balloon tore in 1.

As well as looking at these studies, NICE also asked expert advisers for their views. These advisers are clinical specialists in this field of medicine. The advisers said that possible problems include infection and the need for a blood transfusion.

More information about pelviureteric junction obstruction

Your local patient advice and liaison service (usually known as PALS) may also be able to give you further information and support. For all NICE guidance on PUJ obstruction, go to www.nice.org.uk

About NICE

NICE produces guidance (advice) for the NHS about preventing, diagnosing and treating different medical conditions. The guidance is written by independent experts including healthcare professionals and people representing patients and carers. They consider how well an interventional procedure works and how safe it is, and ask the opinions of expert advisers. Interventional procedures guidance applies to the whole of the NHS in England, Wales, Scotland and Northern Ireland. Staff working in the NHS are expected to follow this guidance.

To find out more about NICE, its work and how it reaches decisions, see www.nice.org.uk/aboutguidance

This leaflet is about 'electrocautery cutting balloon treatment for pelviureteric junction obstruction'. This leaflet and the full guidance aimed at healthcare professionals are available at www.nice.org.uk/IPG324

*You can order printed copies of this leaflet from NICE publications (phone 0845 003 7783 or email publications@nice.org.uk and quote reference N2057). The NICE website has a screen reader service called *Browsealoud*, which allows you to listen to our guidance. Click on the *Browsealoud* logo on the NICE website to use this service.*

We encourage voluntary organisations, NHS organisations and clinicians to use text from this booklet in their own information about this procedure.