

Treating high blood pressure by destroying part of the nerve supply to the renal artery using radiofrequency energy

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 destroying part of the nerve supply to the renal artery using radiofrequency energy can be used in the NHS to treat people with drug-resistant high blood pressure. 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 patients 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 drug-resistant high blood pressure 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. Some sources of further information and support are on page 6.

What has NICE said?

Although there is some evidence to say the procedure works in the short and medium term, there is not much good evidence about how well this procedure works or how safe it is in the long term. If a doctor wants to use it for drug-resistant high blood pressure, they should make sure that extra steps are taken to explain this uncertainty. 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.

NICE is asking doctors to send information about everyone who has the procedure and what happens to them afterwards to a national register so that the safety of the procedure and/or how well it works can be checked over time.

The healthcare team that decides who should have this procedure should include a doctor experienced in managing high blood pressure and a specialist in endovascular procedures. The team should take into account the number of drugs the patient has tried that have failed to control their high blood pressure, and whether their renal arteries are suitable for this type of procedure. Only a specialist in endovascular intervention should carry out the procedure, and they should only carry it out in a centre where an emergency operation to insert a stent (expandable tube) into the artery can be done if needed.

NICE has encouraged further research into this procedure and may review it if more evidence becomes available.

Other comments from NICE

NICE noted the difficulties in treating people who have drug-resistant high blood pressure, and the risks they face as a result. NICE said that this is a promising procedure that could benefit many patients, but more evidence from well-designed trials is needed.

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This procedure may not be the only possible treatment for drug-resistant high blood pressure. Your healthcare team should talk to you about whether it is suitable for you and about any other treatment options available.

The medical name for this procedure is ‘percutaneous transluminal radiofrequency sympathetic denervation of the renal artery for resistant hypertension’. The renal arteries carry blood from the heart to the kidneys. Denervation involves destroying nerves.

The procedure is not described in detail here – please talk to your doctor for a full description.

High blood pressure increases the risk of cardiovascular disease such as heart attack or stroke, and of damage to the kidneys.

It can normally be lowered by making lifestyle changes and with drugs. But for some people neither of these work. This procedure is an alternative treatment for these people – its aim is to destroy the part of the nerve supply to the renal arteries that affects blood pressure, with the aim of lowering it.

The procedure is carried out using a local anaesthetic, light sedation and drugs to prevent blood clotting. A fine tube (catheter) is inserted through an artery in the groin into each renal artery under X-ray guidance. The catheter is connected to a device that delivers radiofrequency energy, which is applied to points along each renal artery to destroy its nerve supply.

What does this mean for me?

If your doctor has offered you this procedure for drug-resistant high blood pressure, he or she should tell you that NICE has decided that the benefits and risks, especially in the long term, are uncertain. This does not mean that the procedure should not be done, but that your doctor should fully explain what is involved in having the procedure and discuss the possible benefits and risks 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 it. 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?

Summary of possible benefits and risks

Some of the benefits and risks seen in the studies considered by NICE are briefly described below. NICE looked at 3 studies on this procedure.

How well does the procedure work?

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

In a study of 100 patients, the blood pressure of 49 patients treated by the procedure was significantly reduced (by an average of 31/12 mm Hg) when they were checked after 6 months. Blood pressure remained at the same level in the 51 patients who continued to receive their usual medication.

In a study of 153 patients treated by the procedure, blood pressure was reduced by an average of 25/11 mm Hg in the 86 patients checked after 6 months. Blood pressure had continued to reduce when 64 patients were checked again after 12 months, when 36 patients were checked after 18 months, and when 18 patients were checked after 24 months.

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 main success factors were less illness and fewer deaths as a result of problems with the heart and blood circulation, patients' kidneys working better, and reduced heart size.

Risks and possible problems

One patient's renal artery was damaged in the study of 153 patients treated with the procedure. A stent was inserted and the patient suffered no ill effects. In the study of 100 patients, 1 patient who was treated with the procedure needed to go to hospital because of nausea, fluid retention, and a drop in blood pressure which meant the blood pressure medication had to be reduced. Three patients in the same study continued on their normal medication and did not have the

procedure. Two of these had to go to hospital because they had a transient ischaemic attack (a 'mini-stroke'). One went to hospital with angina (severe chest pain) and needed a stent inserted into one of the blood vessels surrounding the heart.

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, in theory, problems could include a tear in the renal artery, narrowing or blockage of the artery due to hardening in the long term, low sodium levels in the blood and low blood pressure.

More information about drug-resistant high blood pressure

NHS Choices (www.nhs.uk) may be a good place to find out more. Your local patient advice and liaison service (usually known as PALS) may also be able to give you further information and support. For details of all NICE guidance on drug-resistant high blood pressure, visit our website at 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 'percutaneous transluminal radiofrequency sympathetic denervation of the renal artery for resistant hypertension'. This leaflet and the full guidance aimed at healthcare professionals are available at <http://guidance.nice.org.uk/IPG418>

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.

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