



Alcohol-mediated perivascular renal sympathetic denervation for resistant hypertension

Interventional procedures guidance

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www.nice.org.uk/guidance/ipg801

Your responsibility

This guidance represents the view of NICE, arrived at after careful consideration of the evidence available. When exercising their judgement, healthcare professionals are expected to take this guidance fully into account, and specifically any special arrangements relating to the introduction of new interventional procedures. The guidance does not override the individual responsibility of healthcare professionals to make decisions appropriate to the circumstances of the individual patient, in consultation with the patient and/or guardian or carer.

All problems (adverse events) related to a medicine or medical device used for treatment or in a procedure should be reported to the Medicines and Healthcare products Regulatory Agency using the Yellow Card Scheme.

Commissioners and/or providers have a responsibility to implement the guidance, in their local context, in light of their duties to have due regard to the need to eliminate unlawful

discrimination, advance equality of opportunity, and foster good relations. Nothing in this guidance should be interpreted in a way that would be inconsistent with compliance with those duties. Providers should ensure that governance structures are in place to review, authorise and monitor the introduction of new devices and procedures.

Commissioners and providers have a responsibility to promote an environmentally sustainable health and care system and should <u>assess and reduce the environmental impact of implementing NICE recommendations</u> wherever possible.

1 Recommendations

- More research is needed on alcohol-mediated perivascular renal sympathetic denervation for treating resistant hypertension before it can be used in the NHS.
- 1.2 This procedure should only be done as part of a formal research study and a research ethics committee needs to have approved its use.

What research is needed

- 1.3 More research, in the form of adequately powered randomised controlled trials, is needed on:
 - patient selection
 - the number and types of antihypertensive medicine use and medication adherence
 - the effect of optimising antihypertensive medicines and other factors, such as lifestyle change
 - the effect on blood pressure and duration of any effect
 - quality of life (qualitative and quantitative outcomes)
 - complications.

Why the committee made these recommendations

The evidence for this procedure is limited. It does not show major safety concerns but this is based on limited evidence and needs confirming, because this procedure is invasive and has potential complications. There is also uncertainty about how well the procedure reduces blood pressure and how long this would last, because of the considerable placebo effect. This is a beneficial effect that is seen in a study even when no active treatment has been given. The reductions in blood pressure may have also been affected by the Hawthorne effect, which is when people change their behaviour because they are taking part in a study. For example, people may have taken their antihypertensive medicines correctly and changed their lifestyles. So, more research is needed to better understand the procedure's benefits and complications, and which people would benefit from it.

2 The condition, current treatments and procedure

The condition

2.1 Hypertension is a major risk factor for cardiovascular and chronic kidney diseases. Hypertension can be primary or secondary. Primary hypertension does not have a single known cause, but secondary hypertension develops because of an underlying medical condition. Hypertension is traditionally considered resistant if it is not controlled after treatment with 3 or more antihypertensive medicines from different classes.

Current treatments

2.2 <u>NICE's guideline on hypertension in adults</u> describes diagnosing and managing hypertension, including resistant hypertension. Current treatments for hypertension include lifestyle modifications and antihypertensive medicines. Blood pressure and treatment are regularly monitored and treatment is adjusted as needed. For resistant hypertension, treatment options include additional medicines and device-based antihypertensive therapies (such as radiofrequency or ultrasound renal denervation, and carotid baroreceptor stimulation).

The procedure

- 2.3 Before the procedure, renal artery imaging is done to evaluate renal arterial anatomy.
- The procedure is usually done under local anaesthesia, with sedation and anticoagulation. A catheter is introduced through the femoral artery and advanced into each renal artery under fluoroscopic guidance. The catheter has 3 guide tubes, each containing a microneedle. Once the catheter is positioned within the target site, the 3 tubes are simultaneously deployed against the intimal surface of the renal artery. The 3 microneedles are advanced through the renal artery wall into the adventitia and surrounding perivascular space. Microdoses of neurolytic agent (medical grade dehydrated alcohol) are then infused slowly into the perivascular space from the distal to proximal end of each renal artery. This ablates the renal nerves leading to the kidney, with the aim of disrupting neurogenic reflexes involved in blood pressure control.
- 2.5 After the catheter is withdrawn, renal artery imaging can be done to identify any adverse vascular events related to the device or the procedure.

3 Committee considerations

The evidence

- 3.1 NICE did a rapid review of the published literature on the efficacy and safety of this procedure. This comprised a comprehensive literature search and detailed review of the evidence from 5 sources, which was discussed by the committee. The evidence included 2 randomised controlled trials and 3 single-arm studies. It is presented in the summary of key evidence section in the interventional procedures overview. Other relevant literature is in the appendix of the overview.
- The professional experts and the committee considered the key efficacy outcomes to be: reduction in blood pressure, reduction in use of antihypertensive medicines, reduction in end-organ damage and improvement in quality of life.

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- The professional experts and the committee considered the key safety outcomes to be: pain, bleeding and damage to renal arteries or other structures.
- 3.4 Patient commentary was sought but none was received.

Committee comments

- There is a placebo effect on blood pressure reduction in the evidence, and the committee was informed that such an effect is common in hypertension trials.
- The evidence includes diverse groups and there may be subgroups who would benefit from the procedure.
- This is an invasive procedure. Although the evidence does not show major safety concerns, this is based on evidence from limited patient numbers and needs confirming over a longer term. So, more evidence is needed on safety.
- 3.8 This procedure is a single intervention and not intended to be repeated.
- Technology has evolved over time and renal accessory arteries can be reached using a smaller catheter to achieve a more compete denervation.

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Endorsing organisation

This guidance has been endorsed by Healthcare Improvement Scotland.