NATIONAL INSTITUTE FOR HEALTH AND CARE EXCELLENCE

Interventional procedures consultation document

Alcohol-mediated perivascular renal sympathetic denervation for resistant hypertension

High blood pressure (hypertension) can be caused by overactivity of nerves that help the kidneys (renal) control blood pressure. Sometimes, it does not get better with medicines (resistant). This procedure involves inserting a device through the skin into an artery in the thigh and then into a renal artery. Three small needles are pushed out from within the device. They go through the artery wall into the fluid-filled space that surrounds it (perivascular). The needles release small amounts of alcohol that destroy the nerves (sympathetic denervation). The aim is to lower blood pressure.

NICE is looking at alcohol-mediated perivascular renal sympathetic denervation for resistant hypertension.

NICE's interventional procedures advisory committee met to consider the evidence and the opinions of professional experts with knowledge of the procedure.

This document contains the draft guidance for consultation. Your views are welcome, particularly:

- comments on the draft recommendations
- information about factual inaccuracies
- additional relevant evidence, with references if possible.

NICE is committed to promoting equality of opportunity, eliminating unlawful discrimination and fostering good relations between people with particular protected characteristics and others.

This is not NICE's final guidance on this procedure. The draft guidance may change after this consultation.

After consultation ends, the committee will:

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- meet again to consider the consultation comments, review the evidence and make appropriate changes to the draft guidance
- prepare a second draft, which will go through a resolution process before the final guidance is agreed.

Please note that we reserve the right to summarise and edit comments received during consultation or not to publish them at all if, in the reasonable opinion of NICE, there are a lot of comments or if publishing the comments would be unlawful or otherwise inappropriate.

Closing date for comments: 26 September 2024

Target date for publication of guidance: February 2025

1 Draft recommendations

1.1 More research is needed on alcohol-mediated perivascular renal sympathetic denervation for resistant hypertension.

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.

More research

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 effect refers to 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 NICE's guideline on hypertension in adults 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.

2.4 The procedure is usually done under local anaesthesia, with deep 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.

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3.2 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.

3.3 The professional experts and the committee considered the key safety outcomes to be: pain, bleeding, damage to renal arteries or other structures, and transient microleaks of alcohol.

3.4 Patient commentary was sought but none was received.

Committee comments

3.5 There is a placebo effect on blood pressure reduction in the evidence, and the committee was informed that such an effect is common in hypertensive trials.

3.6 The evidence includes diverse groups and there may be subgroups who would benefit from the procedure.

3.7 This is an invasive procedure so more evidence is needed on safety.

3.8 This procedure is a single intervention and not intended to be repeated.

3.9 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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