NATIONAL INSTITUTE FOR HEALTH AND CARE EXCELLENCE

Interventional procedures consultation document

Percutaneous transluminal renal sympathetic denervation for resistant hypertension

High blood pressure (hypertension) can be caused by overactivity of a type of nerve (sympathetic) that helps the kidneys (renal) control blood pressure. Sometimes medicines to treat it do not work well enough (resistant). In this procedure, using a local anaesthetic, sedation and anticoagulation, a device is inserted through the skin (percutaneous) into an artery in the thigh and then into the renal arteries (transluminal). It sends radio or sound waves to destroy the nerves in the renal arteries (sympathetic denervation). The aim is to lower blood pressure.

This is a review of NICE's interventional procedures guidance on percutaneous transluminal radiofrequency sympathetic denervation of the renal artery 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This document contains the draft guidance for consultation.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 The draft guidance may change after this consultation.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:

- meet again to consider the consultation comments, review the evidence and make appropriate changes to the draft guidance

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- 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: 21 October 2022

Target date for publication of guidance: March 2023

1 Draft recommendations

1.1 Evidence on the short-term safety of percutaneous transluminal renal sympathetic denervation for resistant hypertension is adequate. Evidence on its efficacy is limited in quality. Therefore, this procedure should only be used with special arrangements for clinical governance, consent, and audit or research. Find out what special arrangements mean on the NICE interventional procedures guidance page.

1.2 Clinicians wanting to do percutaneous transluminal renal sympathetic denervation for resistant hypertension should:

- Inform the clinical governance leads in their healthcare organisation.
- Give people (and their families and carers as appropriate) clear written information to support shared decision making, including NICE's information for the public.
- Ensure that people (and their families and carers as appropriate) understand the procedure's safety and efficacy, and any uncertainties about these.
- Audit and review clinical outcomes of everyone having the procedure. The main efficacy and safety outcomes identified in this guidance can be entered into NICE's interventional procedure outcomes audit tool (for use at local discretion).
- Discuss the outcomes of the procedure during their annual appraisal to reflect, learn and improve.

1.3 Healthcare organisations should:

- Ensure systems are in place that support clinicians to collect and report data on outcomes and safety for everyone having this procedure.

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- Regularly review data on outcomes and safety for this procedure.

1.4 Further research should include randomised controlled trials or analysis of registry data. It should report details of patient selection, technique used and long-term outcomes.

1.5 Patient selection should be done by a multidisciplinary team including experts in managing hypertension, and clinicians with specific training in this procedure.

2 The condition, current treatments and procedure

The condition

2.1 Hypertension is a major risk factor for cardiovascular disease and chronic kidney disease. Hypertension can be primary or secondary. Primary hypertension does not have a single known cause, whereas secondary hypertension develops because of an underlying medical condition or disease. Hypertension is considered resistant if it is not controlled after treatment with at least 3 antihypertensive medications 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 medications. Blood pressure and treatment are regularly monitored and treatment is adjusted as needed. For resistant hypertension, additional medications and device-based antihypertensive therapies (for example renal denervation and carotid baroreceptor stimulation) can be considered.

The procedure

2.3 This procedure is usually done using 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 is connected to a generator which delivers radiofrequency or ultrasound energy (depending on the type of system used) 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. There are different systems with different technologies in use for renal sympathetic denervation.

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 9 sources, which was discussed by the committee. The evidence included 1 Cochrane review, 1 meta-analysis, 2 randomised controlled trials, 1 3-arm randomised trial and 4 case series (registries). It is presented in the summary of key evidence section in the interventional procedures overview.

3.2 The professional experts and the committee considered the key efficacy outcomes to be: reduction in blood pressure, reduction in use of antihypertensive drugs and reduction in end-organ damage.

3.3 The professional experts and the committee considered the key safety outcomes to be: pain and renal artery damage.

3.4 Patient commentary was sought but none was received.

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Committee comments

3.5 The committee noted that the technology has evolved and there are different methods of doing this procedure.

3.6 The committee noted that most evidence that the committee reviewed for this procedure is for resistant hypertension. This guidance does not cover using the procedure for other forms of hypertension.

Tom Clutton-Brock
Chair, interventional procedures advisory committee
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