

Percutaneous transluminal renal sympathetic denervation for resistant hypertension

Interventional procedures guidance

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www.nice.org.uk/guidance/ipg754

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 assess and reduce the environmental impact of implementing NICE recommendations wherever possible.

This guidance replaces IPG418.

1 Recommendations

- 1.1 Percutaneous transluminal renal sympathetic denervation for resistant hypertension 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.
 - Ensure that people (and their families and carers as appropriate) understand the procedure's safety and efficacy, and any uncertainties about these.
 - Take account of NICE's guidance on shared decision making, and NICE's information for the public.
 - 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.
- 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 potential complications, and clinicians with specific training in this procedure.

Why the committee made these recommendations

Evidence from a Cochrane review, a meta-analysis and clinical trials, supplemented by observational studies (registries) was reviewed by the committee.

The evidence suggests that there are no major safety concerns in the short term, and complications are well recognised such as renal artery damage. The evidence shows that it reduces blood pressure in the short and medium term. Overall, there are uncertainties about how well it works in the long term and whether there are long-term complications. So, it should only be used with special arrangements.

Hypertension can be a lifelong condition, so further evidence generation to establish the long-term outcomes of this procedure is particularly important.

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 10 sources, which was discussed by the committee. The evidence included 1 Cochrane review,

1 meta-analysis, 3 randomised controlled trials, 1 three-arm randomised trial and 4 case series (registries). It is presented in the [summary of key evidence section in the interventional procedures overview](#). The committee also considered additional confidential documentation provided by a company.

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

Committee comments

- 3.5 The committee noted that the technology has evolved and there are different methods for doing this procedure. Different devices may have different efficacy and safety profiles.
- 3.6 The committee noted that most of the evidence that the committee reviewed for this procedure is for resistant hypertension.
- 3.7 The committee was informed that the concept of 'resistant hypertension' is evolving and that this procedure may have a role in the treatment of 'uncontrolled hypertension'.

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Endorsing organisation

This guidance has been endorsed by [Healthcare Improvement Scotland](#).