National Institute for Health and Clinical Excellence

Percutaneous transluminal radiofrequency sympathetic denervation of the renal artery for resistant hypertension

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NICE interventional procedure guidance 418

guidance.nice.org.uk/ipg418

Healthcare Improvement Scotland

NHS Evidence accredited provider

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1 Guidance

1.1 Current evidence on percutaneous transluminal radiofrequency sympathetic denervation of the renal artery for resistant hypertension is from limited numbers of patients, but there is evidence of efficacy in the short and medium term. There is inadequate evidence on efficacy in the long term; this is particularly important for a procedure aimed at treating resistant hypertension. The limited evidence suggests a low incidence of serious periprocedural complications, but there is inadequate evidence on long-term safety. Therefore this procedure should only be used with special arrangements for clinical governance, consent, and audit or research.

1.2 Clinicians wishing to undertake percutaneous transluminal radiofrequency sympathetic denervation of the renal artery for resistant hypertension should take the following actions.

- Inform the clinical governance leads in their Trusts.
- Ensure that patients understand the uncertainty about the procedure's safety and efficacy, and provide them with clear written information. In addition, the use of NICE's information for patients (Understanding NICE guidance) is recommended.

1.3 Patient selection should be carried out by a multidisciplinary team including a physician with expertise in hypertension and a specialist in endovascular interventions, giving consideration to the number of antihypertensive drugs that have failed to control the patient's blood pressure and the anatomical suitability of their renal arteries. The procedure should only be done by specialists who are experienced in endovascular interventions and with facilities for emergency stenting in case this is required.

1.4 NICE encourages further research on this procedure. Patient selection criteria should be described clearly and reported outcome measures should include adverse events and the long-term effect of the procedure on blood pressure.

1.5 NICE also encourages data collection and publication of outcomes on all patients having this procedure. Clinicians should submit data on all patients having this procedure to the national register when it becomes available.

2 The procedure

2.1 Indications and current treatments

2.1.1 Hypertension is a major risk factor for cardiovascular disease and chronic renal disease. First-line treatment usually involves lifestyle changes. Antihypertensive medications (in combinations, as required) are used if hypertension persists. Sympathetic denervation of the renal artery is considered if hypertension fails to respond adequately to these measures. An example of criteria used to select patients for the procedure is given in the Joint UK Societies' Consensus Statement on Renal Denervation for Resistant Hypertension.

2.2 Outline of the procedure

2.2.1 Percutaneous transluminal radiofrequency sympathetic denervation of the renal artery for resistant hypertension aims to disrupt neurogenic reflexes involved in blood pressure control.

2.2.2 The procedure is usually carried out using local anaesthesia, conscious sedation and anticoagulation. A catheter is introduced via the femoral artery and advanced into each renal artery under fluoroscopic control. The catheter is connected to a generator which delivers low-power radiofrequency energy in 2-minute applications to each renal artery at 4–6 points along its length, in a spiral pattern.

Sections 2.3 and 2.4 describe efficacy and safety outcomes from the published literature that the Committee considered as part of the evidence about this procedure. For more detailed information on the evidence see the overview

2.3 Efficacy

2.3.1 A randomised controlled trial of 100 patients treated by renal artery denervation (n = 49) or unchanged medical therapy (n = 51) reported an average reduction in blood

pressure of 32/12 mmHg and an increase of 1/0 mmHg respectively at 6-month follow-up ($p < 0.0001$ for both systolic blood pressure [SBP] and diastolic blood pressure [DBP] in the treatment group compared with $p = 0.83$ for SBP and $p = 0.77$ for DBP in the control group).

2.3.2 A case series of 153 patients reported a mean reduction in blood pressure of 25/11 mmHg at 6 months (n = 86), 23/11 mmHg at 12 months (n = 64), 26/14 mmHg at 18 months (n = 36) and 32/14 mmHg at 24 months (n = 18) (within-patient changes in both SBP and DBP from baseline were $p < 0.0001$ at all time points except at 24 months [$p = 0.002$]).

2.3.3 The Specialist Advisers listed key additional efficacy outcomes as reduction in cardiovascular morbidity and mortality, improvement in the parameters of renal function and regression in left ventricular mass.

2.4 Safety

2.4.1 Renal artery dissection was reported in 1 patient in the case series of 153 patients: this was stented with no adverse sequelae.

2.4.2 The following serious adverse events (requiring admission to hospital) were reported in 1 patient treated by renal artery denervation in the randomised controlled trial of 100 patients: nausea, oedema, and a hypotensive episode requiring a reduction in antihypertensive medication (timing of events not stated). Patients in the unchanged medical therapy group experienced the following serious adverse events (requiring admission to hospital): transient ischaemic attack in 2 patients and angina requiring a coronary stent in 1 patient (timing of events not stated).

2.4.3 The case series of 153 patients reported that 1 patient had bilateral flank pain which required analgesia (ibuprofen) for several months before it resolved.

2.4.4 The Specialist Advisers considered theoretical adverse events to include renal artery perforation, late stenosis or promotion of atheroma in the renal artery in the long term, sodium depletion and hypotension.

2.5 Other comments

2.5.1 The Committee was mindful of the difficulties in treating patients with drug-resistant hypertension and the serious risks these patients face from uncontrolled high blood pressure. It considered sympathetic denervation of the renal artery to be a promising procedure, which might offer benefit to many patients, but a larger evidence base of well-designed trials is required.

3 Further information

3.1 For related NICE guidance see the NICE website.

Information for patients

NICE has produced information on this procedure for patients and carers (Understanding NICE guidance). It explains the nature of the procedure and the guidance issued by NICE, and has been written with patient consent in mind.

About this guidance

NICE interventional procedure guidance makes recommendations on the safety and efficacy of the procedure. It does not cover whether or not the NHS should fund a procedure. Funding decisions are taken by local NHS bodies after considering the clinical effectiveness of the procedure and whether it represents value for money for the NHS. It is for healthcare professionals and people using the NHS in England, Wales, Scotland and Northern Ireland, and is endorsed by Healthcare Improvement Scotland for implementation by NHSScotland.

This guidance was developed using the NICE interventional procedures guidance process.

We have produced a summary of this guidance for patients and carers. Tools to help you put the guidance into practice and information about the evidence it is based on are also available.

Changes after publication

May 2012: minor maintenance

Your responsibility

This guidance represents the views of NICE and was arrived at after careful consideration of the available evidence. Healthcare professionals are expected to take it fully into account when

exercising their clinical judgement. This guidance does not, however, override the individual responsibility of healthcare professionals to make appropriate decisions in the circumstances of the individual patient, in consultation with the patient and/or guardian or carer.

Implementation of this guidance is the responsibility of local commissioners and/or providers. Commissioners and providers are reminded that it is their responsibility to implement the guidance, in their local context, in light of their duties to avoid unlawful discrimination and to have regard to promoting equality of opportunity. Nothing in this guidance should be interpreted in a way which would be inconsistent with compliance with those duties.

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