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COMMENTARY

Cardiovascular and Interventional Radiological Society of Europe (CIRSE) Position Statement on Renal Denervation for Resistant Hypertension

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Hypertension is a major global healthcare challenge now recognised as the leading cause of mortality across the developed and developing world [1]. Resistant hypertension (systolic BP >140 mmHg on three or more medications) makes up a significant minority of this group (5–15 %) and is associated with a considerably increased risk of cardiovascular events. Renal denervation (RDN) is emerging as a significant step forward in the treatment of patients with resistant hypertension. The publication of the Symplicity I and II trials has firmly established the procedure with both proof of principle and short-term efficacy using randomised controlled trial methodology [2–4].

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Who is Eligible for RDN?

At present the evidence only supports its use in resistant hypertension. This was defined in the trials as a clinic systolic blood pressure ≥160 mmHg (≥150 mmHg in type 2 diabetes) on three or more antihypertensive medications. Ideally, this should be supported with ambulatory blood pressure measurements to exclude the "white coat phenomenon."

In the trials, patients were excluded if the estimated GFR <45 ml/min/1.73 m^2 and local protocols should be in place if patients with an eGFR <45 ml/min/1.73 m^2 are to be treated.

Imaging Constraints

At present, the minimum diameter for the renal artery to be treated is 4 mm and a 2 cm length of normal main renal artery is needed to deliver the energy safely. Delivery within 5 mm of a side-branch artery should be avoided. If there are multiple renal arteries present, then provided the above criteria apply, all can be treated. As the technology and knowledge advance, these restrictions will almost certainly require review. Access to high-quality imaging tools, such as multislice CTA or MRA, is recommended to screen potential patients for RDN.

The Multidisciplinary Team (MDT)

The taskforce believes that a multidisciplinary approach to RDN is essential, reflecting good practice and governance, to maximise patient safety and outcomes. The team should include, as an absolute minimum, a hypertension specialist

(or nephrologist/cardiologist specialising in hypertension) and a vascular interventionist. The interventionist must be familiar with renal artery catheterisation, renal stenting, tools, and techniques, together with endovascular rescue manoeuvres to manage rupture and thrombosis/embolisation. Typically, this would be a vascular interventional radiologist, although some interventional cardiologists now possess these skills. The decision-making process to select which patient should undergo treatment needs to be interdisciplinary to avoid bias, to ensure strict adherence to accepted indications and to control costs. There also should be access to nephrology, vascular surgery, or transplant urology services.

It is necessary that the multidisciplinary team makes all effort to exclude white coat hypertension, poor compliance, and treatable secondary causes of hypertension before considering RDN as an option. This may require brief hospitalisation, detailed hormone assays, and adrenal/renal imaging. Expertise from endocrinology also may be required.

RDN Procedure

Patients should be warned of the need for analgesic control during the procedure. Local protocols will vary, but one should be agreed and in place. A percutaneous transfemoral arterial puncture is almost universal and each renal artery is catheterised in turn. Antispasmodics and heparin should be used with ideally ACT monitoring of the coagulation status.

At the time of writing, there are five different devices on the European market with a CE mark (Symplicity (Medtronic, Mountain View, CA, USA), Paradise (ReCor Medical, Melo Park, CA, USA), OneShot (Covidien, Dublin, Ireland), EnligHTN (St Jude, Little Canada, MN, USA), Vessix (Boston Scientific, Natick, MA, USA)). However, the field is developing rapidly with other devices certain to become CE-marked. The operator should ensure complete familiarity with the chosen device and not assume that previous experience with another device is sufficient. A proctoring process, provided by the manufacturer, should be used until familiarity with the particular device is gained. Following successful denervation, the arterial puncture site can be controlled by manual compression or a closure device. Many centres now treat patients on a day-case basis, provided the procedure has been straightforward and a care pathway is in place.

Patient Follow-up

The hypertensive specialist should ensure appropriate clinical follow-up. Further imaging is not necessary but may be done as part of a research protocol.

Registries

All specialities agree on the need for data entry into a registry and in some countries, e.g., the United Kingdom and the Netherlands, this is mandatory in order to ensure reimbursement.

Several registries are in the development stage, whereas others are active. Centres should agree on a registry to use and identify clear lines of responsibility for data entry.

Future Research

RND is a rapidly developing field and many other indications are emerging that may be related to sympathetic overactivity. Future indications may include amongst others renal insufficiency, cardiac failure, diabetes mellitus, and sleep apnoea. Interventional radiologists are well placed to perform RDN, given their training and skills in diagnostic imaging and a long collaborative history in renovascular intervention with nephrologists and hypertension specialists. CIRSE encourages participation in clinical trials to ensure patient safety and to further knowledge of this field.

Conflict of interest Jonathan Moss reports Grants from Medtronic, outside the submitted work. Dierk Vorwerk, Anna Maria Belli, Jan Peregrin, Michael Lee and Jim Reekers has nothing to disclose.

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