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Jury's still out on renal denervation

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Hypertension remains the number one attributable risk factor for mortality worldwide. Less than 50% of treated patients achieve blood-pressure (BP) control goals with treatment-resistant hypertension (7.6-18%) being a major problem.

Renal denervation (RDN) is a procedure (under local anaesthesia with substantial intravenous analgesia and sedation) whereby the renal nerves are ablated using a form of radio-frequency energy. These nerves travel along the renal arteries in the peri-adventitial space. Using femoral arterial access, a catheter is appropriately positioned in the renal artery, and energy delivered through the renal arteries (sequentially) to target the renal nerves.

The single arm Symplicity-1 study of RDN, demonstrated a significant and sustained reduction in systolic BP in patients with drug-resistant hypertension. The Symplicity-2 study, a randomised controlled trial of renal denervation and drug therapy versus drug therapy alone, also demonstrated a significant BP drop in the RDN arm with no change in the control arm.

The device was approved for use in Australia and Europe; in WA it was used strictly for patients with resistant hypertension at significantly elevated cardiovascular, cerebrovascular and renal risk and without other options.

In the Symplicity-3 study, patients were randomised to either undergo Renal Denervation or a 'Sham' procedure and were blinded to which they received. The RDN procedure met the safety but not its efficacy end-point. Both the RDN and Sham procedure caused similar BP drops.

This called into question the efficacy of the RDN procedure. WA Health stopped funding for this procedure in the public system unless as part of a research study. It has never been funded in the private system.

Despite good design, there were criticisms about how the Symplicity-3 study was conducted. Inexperienced operators performed a majority of the procedures (some for the very first time). When the ablation points were analysed, it seemed that less than 10% were optimally ablated. One obviously cannot expect a procedure to work well unless it is performed correctly. Another confounding factor was that 40% of patients had medication changes despite the protocol mandating that drug therapy shouldn't be altered during the study. Critics of the study are of the opinion that these are the reasons the procedure didn't demonstrate efficacy in this study.

Two studies with a somewhat different design were initiated and are currently recruiting patients. The future direction for RDN is largely dependent on the outcome of these two studies. Many physicians experienced in RDN believe it does work well in many but not all patients, providing a useful option in patients who often have no alternative solution. Until the results of the two current studies are available, this remains to be proven.

Critical evaluation of new procedures is what accurate clinical practice is all about but operator performance remains important.

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Author competing interests: The author has been a clinical proctor for Medtronic and St Jude for training physicians in the procedure. Questions? Contact the author on sshetty@perthcardio.com.au