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LETTER FROM THE EDITOR

2013: The Year of Renal Denervation?

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Dear Colleague,

The year of 2013 in cardiology has been eventful with significant advances described in many fields including cardiac pharmacology, coronary artery intervention, percutaneous aortic valve implantation, heart failure, and electrophysiology. Perhaps one of the most rapidly expanding areas is that of renal denervation therapy (RDT) for treatment of resistant hypertension.

Catheter-based radiofrequency ablation of the efferent and afferent sympathetic nerves which lie within and just beyond the adventitia of the renal arteries has been shown to be a highly effective treatment for resistant hypertension (Fig. 1). Potential beneficial mechanisms include reduction in peripheral resistance, reduced renin release, favorable changes in water and salt handling, and reduction in whole-body sympathetic-nerve activity.

The first randomized trial, Symplicity HTN-2, assigned 106 patients with systolic blood pressure >160 mmHg (or >150 mmHg in type 2 diabetics) despite ≥3 anti-hypertensive drugs to RDT or to usual care [1]. RDT was performed using the single point electrode Simplicity catheter (Medtronic, MN, USA) advanced via the femoral artery into the renal artery. Up to six radiofrequency ablations (each for 2 min)

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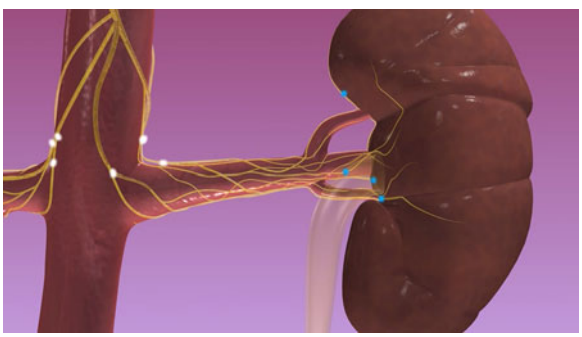

Fig. 1 Sympathetic nerves within and just beyond the adventitia of the renal arteries [2]

were applied at different longitudinal and rotational positions to try to ensure maximum nerve ablation. The primary end point, change in office-based systolic blood pressure at 6 months, was significantly reduced in the RDT group (32 systolic/12 diastolic mmHg; $P < 0.0001$) with no reduction in the control group (1/0 mmHg; P not significant). Ambulatory blood pressure drops of smaller magnitude but consistent with office measurements were noted. A durable effect was reported at TCT October 2013 for patients reaching 3-year follow-up ($n = 40$) with an average blood pressure reduction of −33/−14 mmHg ($P < 0.01$) from baseline and an overall response rate (systolic blood pressure drop ≥10 mmHg) in 85% of patients randomized to RDT [2]. Regarding safety, one procedural hematoma and one dissection occurred but no late decline in renal function or renal artery stenosis.

However, one limitation to the Simplicity flex device was the time taken to complete the required multiple ablation points. Several second generation devices have been developed with the aim of a faster, more efficient procedure. The OneShot device (Covidien, Dublin, Ireland) (Fig. 2) is a low-pressure (<1 atm) balloon with a 360° continuous spiral electrode on the surface, 8 irrigation holes alongside the electrode to reduce surrounding tissue damage (Fig. 2). Ablation time is 2 min per artery. Twelve-month results of the first in man study showed an average blood pressure reduction of 31/10 mmHg [3]. The Vessix catheter (Boston Scientific Corporation, Natick, MA, USA) is a low-pressure balloon with two pairs of bipolar low-wattage (1 W) surface electrodes providing four ablation points in a helical arrangement and an ablation time of 30 s per application (Fig. 3). Interim 6-month results from 139 of

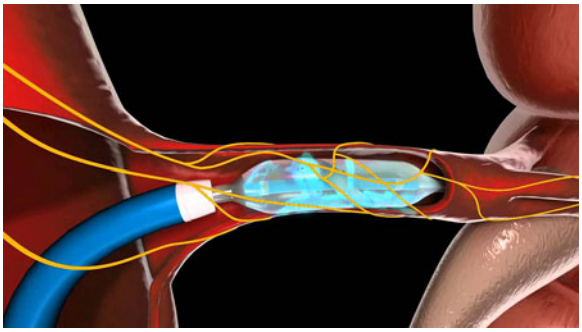

Fig. 2 OneShot renal denervation balloon catheter with continuous spiral electrode and 8 irrigation holes [3]

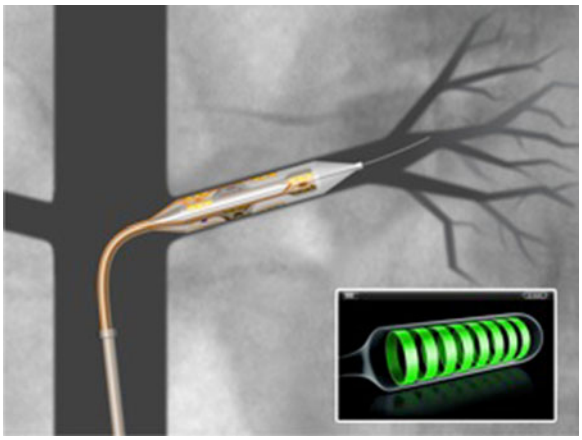

Fig. 3 Vessix renal denervation balloon catheter with two pairs of bipolar surface electrodes arranged in helical fashion [4]

145 enrolled patients in the REDUCE-HTN trial presented at TCT October, 2013 reported an office blood pressure reduction of 24.6/10.3 mmHg and ambulatory blood pressure reduction of 11.2/6.3 mmHg [4]. The St Jude EnligHTN catheter contains four electrodes mounted on an expandable basket design (Fig. 4). The second generation device has an ablation time of 90 s per set of four simultaneous ablations with two treatments typically performed per artery. Early results of this device in EnligHTN-III showed 26/9 mmHg reduction of office blood pressure at 3 months ($n = 20$) [5].

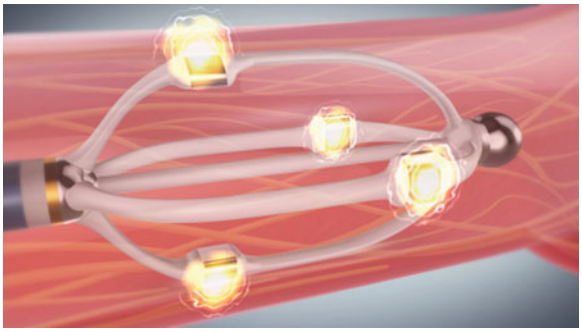

Fig. 4 EnligHTN renal denervation system with four electrodes mounted on an expandable basket catheter [5]

Other recently CE-marked devices include the Simplicity Spyral device (Medtronic) with four electrodes arranged in a helical-shaped nitinol catheter, the single-electrode Iberis catheter (Terumo, Tokyo, Japan) designed for use via radial access and a non-radiofrequency device—the Paradise catheter (ReCor Medical, Menlo Park, California, USA) comprising a central transducer within a low-pressure hydro-cooling balloon which emits ultrasound energy in circumferential fashion. Additional investigational technologies include the irrigated five-electrode spiral ThermoCool radiofrequency catheter (Cordis, NJ, USA), multiple other developmental radiofrequency devices, microinjection catheters for chemical neurolysis such as the Peregrine catheter (ablative solutions, Menlo Park, CA, USA) with three micro-needles (250 micron) for periadventitial injection of ethanol, and the non-invasive, externally delivered, focused ultrasound system from Kona Medical (Bellevue, WA, USA).

In addition to consistent improvements in blood pressure, patients with resistant hypertension often have associated comorbidities, some of which may benefit from reduction of excessive sympathetic drive achieved through RDT. Studies are currently underway evaluating RDT in fields such as congestive heart failure, atrial dysrhythmia, and glycemic control in diabetes.

In summary, while varying approaches and indications continue to be evaluated, 2013 in many countries has seen renal denervation move from being a largely research technique into clinical service.

CONFLICT OF INTEREST

IM is principal investigator in clinical trials currently being undertaken with Covidien and planned with Boston Scientific and St Jude Medical.

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