Is 2014 the Year of Renal Denervation?

By Kurtis Pivert

This year could see the introduction of renal nerve ablation for the treatment of uncontrolled refractory hypertension to the American market. Already approved for use in Europe, Canada, and Australia, the Symplicity Renal Denervation System (Medtronic) is poised to move beyond investigational status in the United States. An application could be filed depending on the results of the Symplicity 3 clinical trial, which will be released sometime after the final estimated completion in January. It would be the first non-pharmacologic treatment approved for treatment-resistant hypertension.

The renal sympathetic nervous system plays a large role in essential hypertension. Renal denervation—delivering radiofrequency energy through the wall of the renal artery to ablate target nerves—may interrupt the renin-angiotensin-aldosterone system cascade, and could have additional beneficial physiological effects.

In 2012, the Centers for Disease Control and Prevention estimated more than 35 million Americans had uncontrolled hypertension, and of those nearly 45 percent were currently receiving medications (1). Although resistance to three or more antihypertensive medications for hypertension is the most commonly accepted indicator of uncontrolled treatment-resistant hypertension, a good definition of treatment-resistant hypertension is lacking, said Efrain Resin MD, FASN, Chief of the Division of Nephrology and Hypertension of the Louisiana State University Health Science Center. Other criteria, including medication compliance and sole reliance on office blood pressure levels, can complicate a diagnosis of true treatment-resistant hypertension.

The Symplicity 3 trial included 530 patients at 88 centers in the United States randomized to either baseline antihypertensive or renal denervation plus continuation of baseline antihypertensive medications. This trial will report both office and ambulatory blood pressure levels, as well as stabilization of renal function, but larger studies are needed to confirm these preliminary findings.

The Symplicity device is just one of several renal nerve ablation systems in use outside the United States, but appears to be positioned to be the first submitted for approval in the United States. At press time, St. Jude Medical announced the EnligHTN IV trial of their EnligHTN renal denervation device was being cancelled before its initiation due to the slow pace of enrollment. Patient recruitment for a sham-controlled trial (the design of the EnligHTN IV study) could be more difficult if the Symplicity device is approved this year.

Even if renal denervation is approved in 2014, it is unknown how and whether the procedure will be reimbursed by payers, a concern for both patients and physicians.

Reference