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Editorial

Renal Denervation, Come Back Time?

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▸ See the article "An Open-label, Single-arm, Multicenter Feasibility Study Evaluating the Safety of Catheter-based Renal Denervation with DENEX™ in Patients with Uncontrolled Hypertension on Standard Medical Therapy" in volume 51 on page 43.

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Renal denervation (RDN) has been a treatment option for resistant hypertension. Despite of initial enthusiasm, it also experienced typical rises and falls during its development as most new innovative technologies did. As such, in contrast to the previous promising results of lowering blood pressure (BP) with RDN, SYMPLICITY HTN-3 study did not show the efficacy of BP reduction as compared to sham procedures.[1)]

Some argue a few shortcomings in the study design and performance were responsible for the negative results; large portion of the enrolled patents with African-American who are more likely to be salt sensitive which could make RDN futile in the point of view of pathophysiological mechanism of developing hypertension, poor compliance of anti-hypertensive medication and incompleteness of RDN procedure in some facilities.[1)]

However recent other sham-controlled randomized controlled trials of SPYRAL HTN ON MED and SPYRAL HTN OFF MED have indicated the promising results of BP lowering by 5–7.4 mmHg in 24-hour ambulatory BP monitoring (ABPM) systolic BP and by 6.8–7.7 mmHg in office systolic BP.[2)3)]

Although those studies also had innate limitation of small sized and proof-of-concept design, they had value in demonstrating the potential benefit of RDN therapy. The most important cause, I consider, what makes the different result as compared to those from SYMPLICITY HTN-3 study was the advance of RDN device which could provide adequate contact to arterial wall and full delivery of radiofrequency to ablate renal sympathetic innervation. The new spiral form RDN device has 4 electrode positioned in 4 different directions with some distance along the spiral cylindrical structure for effective circumferential energy delivery.[4)]

In this issue of *Korean Circulation Journal*, Kim et al.[5)] reported the first-in-man study results with new RDN device, DENEX™ for the treatment of resistant hypertension. They demonstrated the safety of no complication of renal artery evaluated by computed tomography or duplex ultrasound as well as renal function. They also showed efficacy with significant reduction of ABPM systolic BP by 13.1 mmHg and office systolic BP by 24.4 mmHg at 3 month. Attainment rate of office systolic BP <140 mmHg which was generally regarded as one of BP target was 38.5%.

The DENEX™ RDN system has 3 electrode, each positioned at three wings with 120° angle with some distances, and the profile appears trapezoid, which is in contrast to spiral RDN system above mentioned. This structure might be better fit for complete contact to the renal arterial wall and full circumferential delivery of energy than spiral form system despite that the electrode number 3 is smaller than 4 of that system.

This pilot study has value in its first testing new RDN system developed in Korea and showing the safety and efficacy for resistant hypertension patients although having the limitation of not presenting sham treatment comparator group.

For the clinical application of DENEX™ RDN system, large scale sham controlled randomized trial is warranted. The promising of RDN therapy is not only for treatment of resistant hypertension, but also for some cardiovascular disease (CVD), like heart failure, chronic kidney disease and arrhythmias of which the increased sympathetic nervous activity contributes to the development and progression.[6-10]

We are expecting further studies investigating the role of RDN using DENEX™ system on preventing or slowing progression of CVD as well as resistant hypertension treatment.

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