Use of the Paradise™ Ultrasound Renal Denervation (uRDN) System for Treatment of Uncontrolled Hypertension

CMS Transitional Pass-Through Payment Effective January 1, 2025

CLD talks with Amir Kaki, MD

How does the Paradise ultrasound Renal Denervation (uRDN) technology work, and what sets it apart from other renal denervation technologies?

The Paradise ultrasound Renal Denervation (uRDN) System (Recor Medical, Inc.) uses circumferential ultrasound energy to thermally ablate and disrupt sympathetic nerves along the renal arteries. The Paradise uRDN System is distinct in comparison to the radiofrequency energy system in that you typically treat only the main renal branch, and do not have to treat the distal branches or the bifurcations. This is because the ultrasound energy reaches to a depth of about six millimeters, sufficient to ablate approximately 80% of the nerves in the renal artery.[1] Another distinction is that each ultrasound ablation requires only seven seconds of energy.[1] As a result, the ablation time is less than one minute to denervate both renal arteries, whereas the current radiofrequency platform usually takes over 5 minutes per side.[1,2] The ablation time is shorter with the Paradise uRDN System.[3] Its efficacy has borne out well in the three randomized, sham-controlled trials in patients with mild-to-moderate and resistant hypertension, which demonstrated that the Paradise uRDN System works as an adjunct therapy to reduce hypertension.[4-6]

Why is it that treating side branches and bifurcations is not required with the Paradise uRDN System?

In the Radiance studies with the Paradise uRDN System, we saw that treating just the main artery offered benefit and a reduction in blood pressure. The theory is that because of the depth of treatment, the Paradise Catheter is able to achieve a good ablation in the main renal artery, mitigating any need for distal branches or the bifurcations to be ablated.

The transitional pass-through payment for the Paradise uRDN System was approved by CMS starting January 1, 2025. What are you seeing as a result?

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The Paradise™ uRDN System delivers circumferential ultrasound energy to maximize coverage of renal nerves.

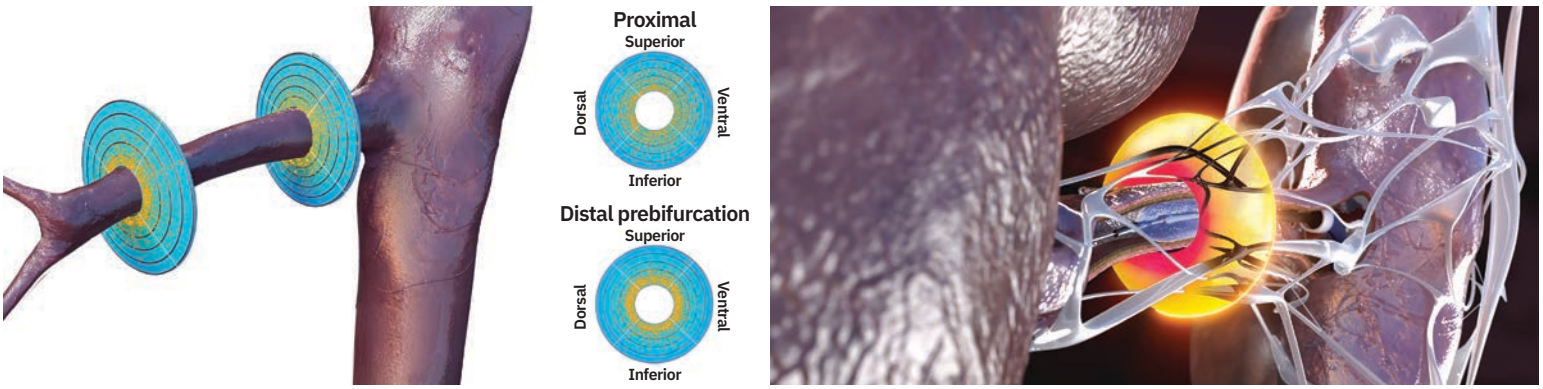

Figure 1. (Left) Designed to deliver a complete 360-degree ring of energy, ablating approximately 80% of the nerves surrounding each renal artery,[1] to reach a targeted depth of ~6mm.[2] (Right) Requires only two to three 7-second ablations on each side, without the need to ablate the distal branches.[2,3]

1. Sakakura K, et al. J Am Coll Cardiol. 2014 Aug;64(7):635–643. 2. Data on file, Recor Medical. 3. Paradise™ uRDN System IFU.

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Can you tell me about your work in treating uncontrolled hypertension patients?

We have a protocol within our private practice group. During our early experience of renal denervation, we are targeting patients described as resistant hypertension patients, defined as patients whose blood pressure is uncontrolled despite at least three medications. If we identify a patient whose blood pressure is uncontrolled on at least three medications, then we subject the patient to a workup for secondary hypertension. If the secondary hypertension workup concludes that it is essential hypertension and does not identify any reversible or treatable causes of a secondary hypertension etiology, then we consider the patient for renal denervation. We have now been using the Paradise uRDN System for approximately 8 months. We are targeting the highest risk group of patients so there is some selection bias as a result, but we have seen significant reductions in blood pressure and some reduction in blood pressure medications. We have observed a range of systolic blood pressure reduction from 10 mmHg to 40 mmHg in this select population.

What is the time period and process for patient evaluation to treatment?

Once the patient is identified, it usually takes about one to two weeks for us to do a workup for secondary hypertension. If the workup comes back such that there is no identifiable secondary or reversible cause, then the next step is getting the patient set up for renal denervation. That process has been challenging up until this point because of the private payers, so we must put the patients in what I call a funnel for a pre-authorization that our staff works with, depending on the patient's insurance.

Prior to the availability of renal denervation, what were the options for these patients?

Prior to renal denervation, our only options were adding more medications. And of course, emphasizing things that we should have been already doing early on, like lifestyle modification, weight loss, exercise, and restricting sodium. But many of these patients were put on more medications. The problem with polypharmacy is many of our patients not only have hypertension but often have other comorbid conditions that they take mediation for. When you are dealing with polypharmacy, what happens is that sometimes compliance goes down. Unfortunately, patients become overwhelmed by all these medications and end up not taking some of them or all of them. Then, the last thing the patient wants to hear is that we must add more medications. They always respond, "I'm already on 12 medications" or "I'm already on 16 medications". As a provider, unfortunately, we did not have any other tools in the toolbox, particularly if their blood pressure still was running high despite our best efforts. It can be disappointing to the patients to recommend more medications, and it takes time to explain to them the risk and the benefits of more medication, and the risk of running hypertensive. Often patients will agree to add more medications, but even if you get the agreement early on, I have noticed that if you check these patients in a few months, there is a significant attrition rate with their compliance to medications, which has also been described in the literature.[7]

Are patients seen by a single physician or is it a multidisciplinary approach?

Typically, a general cardiologist does the workup, but an interventionalist, nephrologist, internal medicine doctor, or a primary care doctor with an interest in hypertension could also do it. The workup itself does not require much expertise. It involves blood tests and some imaging to rule out a reversible secondary cause for the hypertension, which can be done really by anyone who has interest in the space. I do think if you make these patients undergo multidisciplinary evaluation, or some have suggested hypertension clinics, it brings unnecessary barriers to access, potentially delaying or causing inertia that might lead the patient to not receive the appropriate treatment.

Can you share your experience with any learning curve for the Paradise uRDN System?

In the Radiance studies with the Paradise uRDN System, we saw that treating just the main artery offered benefit and a reduction in blood pressure. The theory is that because of the depth of treatment, the Paradise Catheter is able to achieve a good ablation in the main renal artery, mitigating any need for distal branches or the bifurcations to be ablated.

Most operators can comfortably use the Paradise uRDN System after a single case, because it is fairly automated, and you are putting the device just in the main branch of the renal artery.

How do you know that you were successful?

When the balloon is inflated, we do an angiogram and see if the balloon is occlusive, which confirms that it is apposed to the renal artery. It is an efficient and practical option that effectively tells you what you need to know, and it is now standard for us to do an angiogram when the balloon is inflated to determine whether it is occlusive. If that is the case, then we feel confident we are making contact with the renal artery and delivering the energy.

This is a long-awaited tool that will be transformational in the treatment of hypertension, especially when more patients get access.

Any final thoughts?

If you are limited in your resources and must be selective in your use of the Paradise uRDN System, my advice would be to take those patients who are resistant, who are on the greatest number of medications, and who have the highest blood pressure at baseline. This is a long-awaited tool that will be transformational in the treatment of hypertension, especially when more patients get access. ■

REFERENCES

1. Paradise® 6Fr Catheter IFU and data on file Recor Medical.
2. Symplicity Spyral™ Catheter Instructions for Use Manual Rev.(A) Symplicity Spyral™ Clinical Study Summary M041982C001 A 2023-08-14.
3. Fengler K, Rommel KP, Blazek S, et al. A three-arm randomized trial of different renal denervation devices and techniques in patients with resistant hypertension (RADIOSOUND-HTN). *Circulation*. 2019 Jan 29;139(5):590-600. doi:10.1161/CIRCULATIONAHA.118.037654
4. Azizi M, Schmieder RE, Mahfoud F, et al; RADIANCE-HTN Investigators. Endovascular ultrasound renal denervation to treat hypertension (RADIANCE-HTN SOLO): a multicentre, international, single-blind, randomised, sham-controlled trial. *Lancet*. 2018 Jun 9; 391(10137): 2335-2345. doi:10.1016/S0140-6736(18)31082-1
5. Azizi M, Sanghvi K, Saxena M, et al; RADIANCE-HTN investigators. Ultrasound renal denervation for hypertension resistant to a triple medication pill (RADIANCE-HTN TRIO): a randomised, multicentre, single-blind, sham-controlled trial. *Lancet*. 2021 Jun 26;397(10293): 2476-2486. doi:10.1016/S0140-6736(21)00788-1
6. Azizi M, Saxena M, Wang Y, et al; RADIANCE II Investigators and Collaborators. Endovascular ultrasound renal denervation to treat hypertension: the RADIANCE II randomized clinical trial. *JAMA*. 2023 Feb 28; 329(8):651-661. doi:10.1001/jama.2023.0713
7. Zhou X, Zhang X, Gu N, et al. Barriers and facilitators of medication adherence in hypertension patients: a meta-integration of qualitative research. *J Patient Exp*. 2024 Mar 27; 11: 23743735241241176. doi:10.1177/23743735241241176

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