The Power of 360° Ultrasound Renal Denervation for Blood Pressure Reduction

Exploring the mechanism of action, workflow, and overall benefits of the Paradise® Ultrasound Renal Denervation System for fast, safe blood pressure control.

With Sripal Bangalore, MD, MHA

What are the scientific and technologic differences between ultrasound renal denervation (uRDN) and radiofrequency RDN (rfRDN)? Specifically, how do the mechanisms of uRDN and rfRDN differ?

Both uRDN and rfRDN denervate the nerves surrounding the renal arteries, thereby disrupting nerve signals to the kidneys and reducing sympathetically mediated high blood pressure (BP). However, the technology and mechanisms of action are vastly different. The Paradise® uRDN system (Recor Medical) is a balloon-based system that uses ultrasound energy to generate thermal energy, in turn denervating the nerves. Water is circulated within the balloon to cool and help protect the inner surface of the artery wall from damage. Paradise uRDN, given that it is a balloon-based system with an emitter placed in the middle of the vessel lumen, produces circumferential ablation.

Conversely, rfRDN uses electrodes on a catheter to deliver radiofrequency (RF) energy. It administers ≤ 4 spot ablations simultaneously in a spiral pattern by creating heat from the RF energy, which is delivered to each quadrant of the renal artery using electrodes. This technology relies on adequate vessel wall contact of the electrode.

Additionally, the Paradise system is designed to have a tissue penetration depth of 6 mm compared to an average of 2 to 4 mm with rfRDN.[1-3]

How do these differences translate into the procedure workflow?

The difference between the two technologies has direct, practical workflow implications. The renal nerves around the renal artery are positioned at a greater depth in the proximal part of the renal artery and converge closer to the artery more distally. Given this anatomic arrangement, a technology such as rfRDN with less tissue penetration is used more distally (ie, in the branch vessel) for complete ablation, whereas a technology with high tissue penetration (such as uRDN) can accomplish this by ablating more in the proximal/main renal artery.

Since balloon-based systems are commonly used in interventional cardiology practice, the Paradise uRDN balloon catheter represents a readily adaptable technology to practitioners. Given the effective tissue penetration and circumferential ablation provided by the Paradise ultrasound system, clinical studies and device instructions for use support that 2 to 3 ablations in each of the main renal arteries are typically sufficient, without the need to ablate distal branch arteries. Each ablation lasts 7 seconds, resulting in a short total procedure time. As with rfRDN, the larger accessory renal artery typically also needs to be ablated.

How does this impact the operator, the cath lab staff, and the patient?

For operators and cath lab staff, uRDN being balloon based means it is already familiar to them; it shares similarities with other interventional procedures. The aforementioned workflow differences with uRDN mean an overall short procedure time, translating to efficient cath lab throughput, patient comfort, and potentially fewer procedure-related complications. In the single-center, 3-month head-to-head RADIOSOUND-HTN trial, ablation time was significantly lower (< 1 min vs > 8 min) with uRDN compared to rfRDN, as were contrast volume and fluoroscopy time.[4]

What are the most meaningful benefits of uRDN for patients, physicians, and care teams compared to other hypertension (HTN) management strategies?

The uRDN procedure is minimally invasive, typically allowing for short procedure time and fast recovery. Many

patients are able to go home the same day and resume normal activities soon after.

BP lowering with medications depends on patient compliance with their medication, as well as the half-life of the medication used. As such, BP control may not be uniform throughout a 24-hour period or in the long term. With RDN, once the procedure is done, the effects are "always on," with 24-hour BP reduction.[5] It is thus less dependent on patient adherence. That being said, RDN should not be considered an excuse for diet and medication noncompliance.

Can you walk us through the clinical evidence supporting uRDN, particularly around the efficacy, safety, and durable results of the BP reduction?

uRDN has been studied in the RADIANCE-HTN SOLO, RADIANCE-HTN TRIO, and RADIANCE II randomized trials.[6-8] All three trials met their primary efficacy endpoints, showing statistically significant reductions in daytime ambulatory systolic BP compared to sham at 2-month follow-up. The reduction in BP was seen in all phases of BP control (daytime, nighttime, and 24-hour ambulatory BP) and across different modalities of BP assessment (ambulatory, office, and home). The trials spanned from patients with mild-to-moderate HTN to those with resistant HTN. For the overall cohort of the three randomized trials, the sham-adjusted reduction in ambulatory BP was around 4 to 6 mm Hg of additional BP lowering. The reduction in ambulatory BP was even greater at 14 to 17 mm Hg in the subset of patients who were responders to RDN. In addition, the magnitude of BP reduction was greater in patients with higher baseline BP. Long-term follow-up of a prospective, single- arm study (ACHIEVE) has suggested sustained reductions at up to 8 years of follow-up (n = 27).[9]

RADIOSOUND-HTN (a single-center, randomized trial with 3- and 6-month follow-up) was a head-to-head comparison of Paradise uRDN and rfRDN.[4] Change in systolic daytime ambulatory BP at 3 months was evaluated in three cohorts: (1) an ultrasound group treated with Paradise in only the main renal artery; (2) a group treated with rfRDN in only the main renal artery; and (3) a second rfRDN group treated in the main renal artery and distal branches. The study found higher BP reduction with ultrasound-based ablation of the main renal arteries compared to RF ablation of the main renal arteries. Further, the BP reduction effect was similar when rfRDN intervenes in both the main and distal branches, concluding that rfRDN requires intervention in both territories to achieve a similar efficacy as uRDN.

Additionally, uRDN was associated with less contrast agent use and fluoroscopy time compared to rfRDN (mean, 98.7 mL and 8.1 min vs 143.1 mL and 16.8 min, respectively).[4,10]

Similarly, in a meta-analysis of randomized trials that we published, we compared uRDN and rfRDN with sham control. For the gold standard endpoint of ambulatory BP reduction, uRDN reduced 24-hour, daytime, and nighttime ambulatory BP compared to sham control. At 4-month follow-up, a significantly greater reduction in ambulatory BP was seen with uRDN than rfRDN.[11] In addition to the efficacy data, pooled analysis of the studies has shown a favorable safety profile, with no cases of renal artery stenosis > 70% and a very low rate of adverse safety events.[12]

What is the current landscape for patient access to uRDN, and what are the available or emerging reimbursement pathways that may shape broader adoption?

The RDN landscape is currently in an early phase of adoption, awaiting definitive reimbursement pathways. The Paradise uRDN system was FDA approved in 2023. In 2024, the Centers for Medicare & Medicaid Services (CMS) approved a New Technology Add-On Payment to cover the cost of the device for inpatient procedures. Similarly, a Transitional Pass-Through Payment was made effective in January 2025 to cover the cost of the device for outpatient procedures. There are many eagerly awaited timelines in the reimbursement landscape that will further move toward definitive reimbursement and potentially greater usage. National Coverage Determination by CMS is expected in October 2025, which will further open patient access to the procedure.

How would you summarize the overall value proposition of uRDN?

In appropriate patients with uncontrolled HTN, uRDN with the Paradise system offers a minimally invasive procedure with procedural advantages, including low contrast use and low fluoroscopy time, as demonstrated in clinical studies.[4,10] Clinical trials have shown a very low rate of significant renal artery stenosis. Further, uRDN has consistently delivered reductions in BP, including 24-hour BP reduction,[6-8] with durable effects observed for years in follow-up studies.[5,9,13,14] While ongoing research will continue to refine our understanding, uRDN expands the armamentarium of treatment options for patients with uncontrolled and resistant HTN and may help improve cardiovascular outcomes through better BP control. ■

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Sripal Bangalore, MD, MHA
Professor of Medicine, New York University School of Medicine
Director, Invasive and Interventional Cardiology (Bellevue)
Director, Cardiovascular Outcomes Group, NYU Langone Health
New York, New York
sripal.bangalore@nyulangone.org
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Paradise is a registered trademark of Recor Medical, Inc. The Paradise System is FDA approved in the United States, is CE Marked and approved for sale in markets where the CE Mark is accepted per approved indications for use, and received manufacturing and marketing approval in Japan.

Important Safety Information

Rx Only. Brief Summary - Prior to use, please reference the Instructions for Use

Indications for Use
The Paradise Ultrasound Renal Denervation System (Paradise System) is indicated to reduce blood pressure as an adjunctive treatment in hypertension patients in whom lifestyle modifications and antihypertensive medications do not adequately control blood pressure.

Contraindications
The Paradise Catheter is contraindicated in any of the following:
- Renal arteries diameter < 3 mm and > 8 mm
- Renal artery Fibromuscular disease (FMD)
- Stented renal artery
- Renal artery aneurysm
- Renal artery diameter stenosis >30%
- Pregnancy
- Presence of abnormal kidney (or secreting adrenal) tumors
- Iliac/femoral artery stenosis precluding insertion of the catheter

Warnings
- Failure to use the recommended balloon size may result in renal artery stenosis, dissection, perforation, aneurysm, significant vasospasm requiring intervention, ablation of unintended tissues or structures, and/or no ablation of target tissue achieved.
- Energy emission in an unintended location may result in unintended tissue damage.
- Do not move the Paradise Catheter during sonication.
- Do not sonicate in renal artery at locations with visible plaque.
- Do not deliver sonications in an overlapping arterial target zone.

Precautions
- Patients with known allergy to contrast medium may be at increased risk of hypersensitivity reactions.
- Only use specified coolant (Sterile water) for fluid supply. DO NOT USE SALINE.
- Avoid multiple balloon inflations to achieve apposition of the balloon to the renal artery wall; multiple balloon inflations may result in increased vessel trauma.
- The Paradise Catheter is for single use only. Do not resterilize or reuse. Reuse, reprocessing, or resterilization will compromise device integrity which may result in patient injury, illness, or death.
- Do not touch the Paradise Catheter balloon during sonication, as it may result in serious injury.
- The Paradise System may interfere with or adversely affect the operation of cardiac pacemakers or other active implants, unless proper precautions have been taken or managed per the manufacturer's instructions. When in doubt regarding possible hazards, seek qualified advice and/or consult with the manufacturer(s) prior to initiating a procedure. The Paradise Catheter is a Type CF, defibrillation-proof Applied Part.

Potential risks of renal denervation procedure/response to treatment
Ablation or thermal injury to vessel, adjacent tissue or other structures, Acute kidney injury, Angina, Anxiety, Arrhythmia, Atrial tachycardia, Bradycardia, Gastrointestinal complications (diarrhea, nausea, vomiting), Hypotension/ Dizziness and/or Headaches, Hypertension, Hyperhidrosis, Pain (transient abdominal, lower back), Renal failure or renal insufficiency, Renal artery aneurysm or pseudoaneurysm, Renal infarction, Renal artery dissection, or perforation, Renal artery stenosis, Vasospasm, Vasovagal response, Stroke or transient ischemic event

Potential risks of arterial catheterization procedure
Allergic reaction to contrast, Arterio-enteric fistula, Arterio-venous fistula, Bleeding, Cardiopulmonary arrest, Complications related to pain and anti-anxiety medications, Death, Deep vein thrombosis, Edema, Embolism (pulmonary, renal, peripheral vasculature, plaque), Hematuria, Infection, Myocardial infarction, Pain, Vascular access site complications (pseudoaneurysm, pain, swelling, hematoma)