ROPER ST. FRANCIS HEALTHCARE

# Renal Artery Denervation
# Roper Saint Francis Primary Care Symposium
# February 7, 2026

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# Renal denervation is a complementary option to lifestyle changes and pharmacological therapy[1]

## Recommended by cardiovascular experts

The **2023 SCAI position statement** recognizes renal denervation as a promising therapy for treating hypertension. Read the full statement to review recommendations for success, including patient selection, operator competency, procedural training and techniques, and organizational recommendations.

# Hypertension:
# Diagnosis and Treatment Strategies

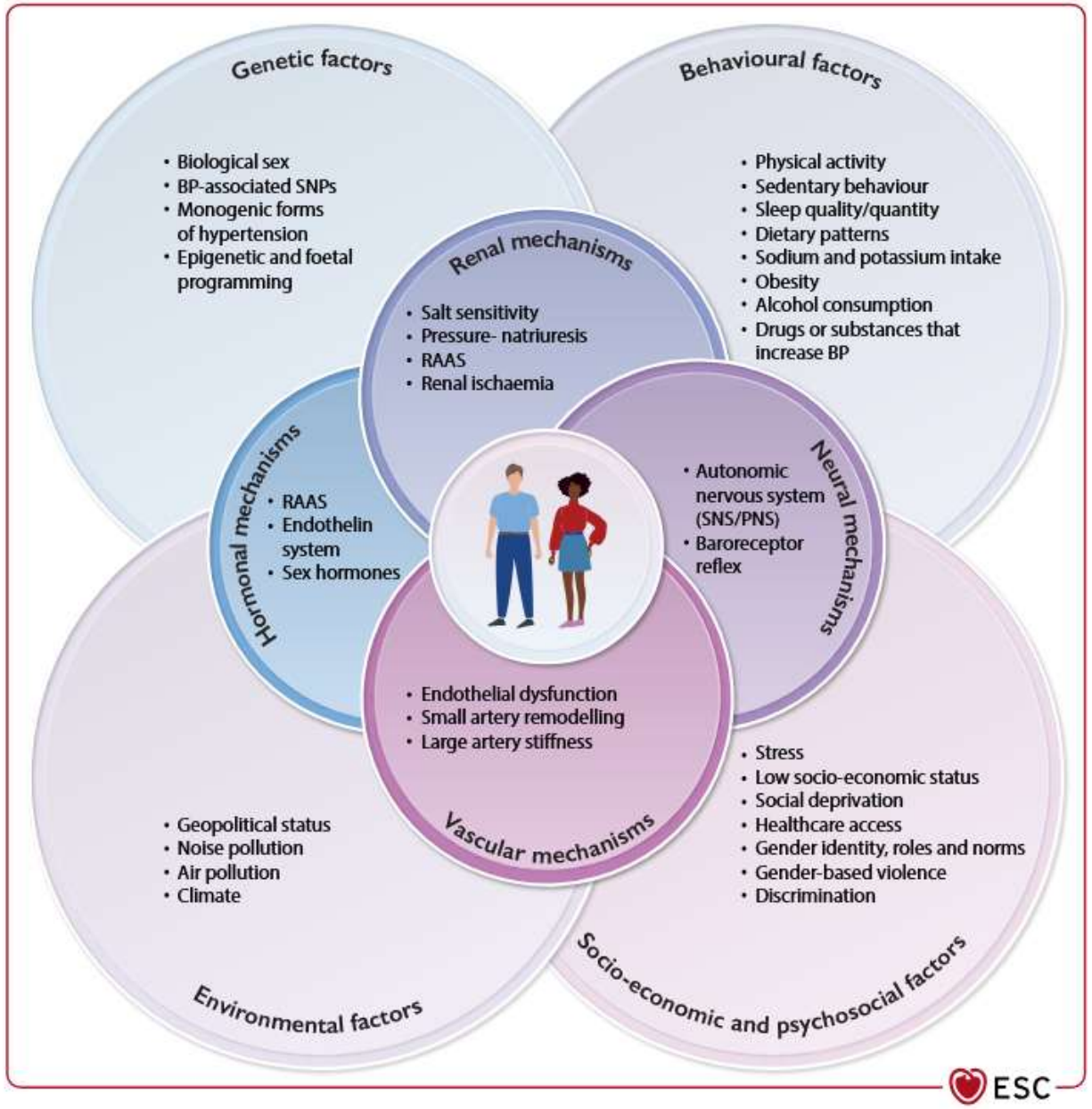



**Figure 1** Pathophysiology of elevated blood pressure and hypertension. BP, blood pressure; PNS, parasympathetic nervous system; RAAS, renin-angiotensin-aldosterone system; SNP, single-nucleotide polymorphism; SNS, sympathetic nervous system. Complex interplay between genes, environmental, and behavioural factors, organs, physiological systems, and neurohumoral processes contribute to BP regulation. Dysfunction of these processes leads to hypertension. The contribution of these factors to elevated BP and hypertension may differ among males and females.

*JW McEvoy, et al European Heart Journal*, Volume 45, Issue 38, 7 October 2024, Pages 3912–4018

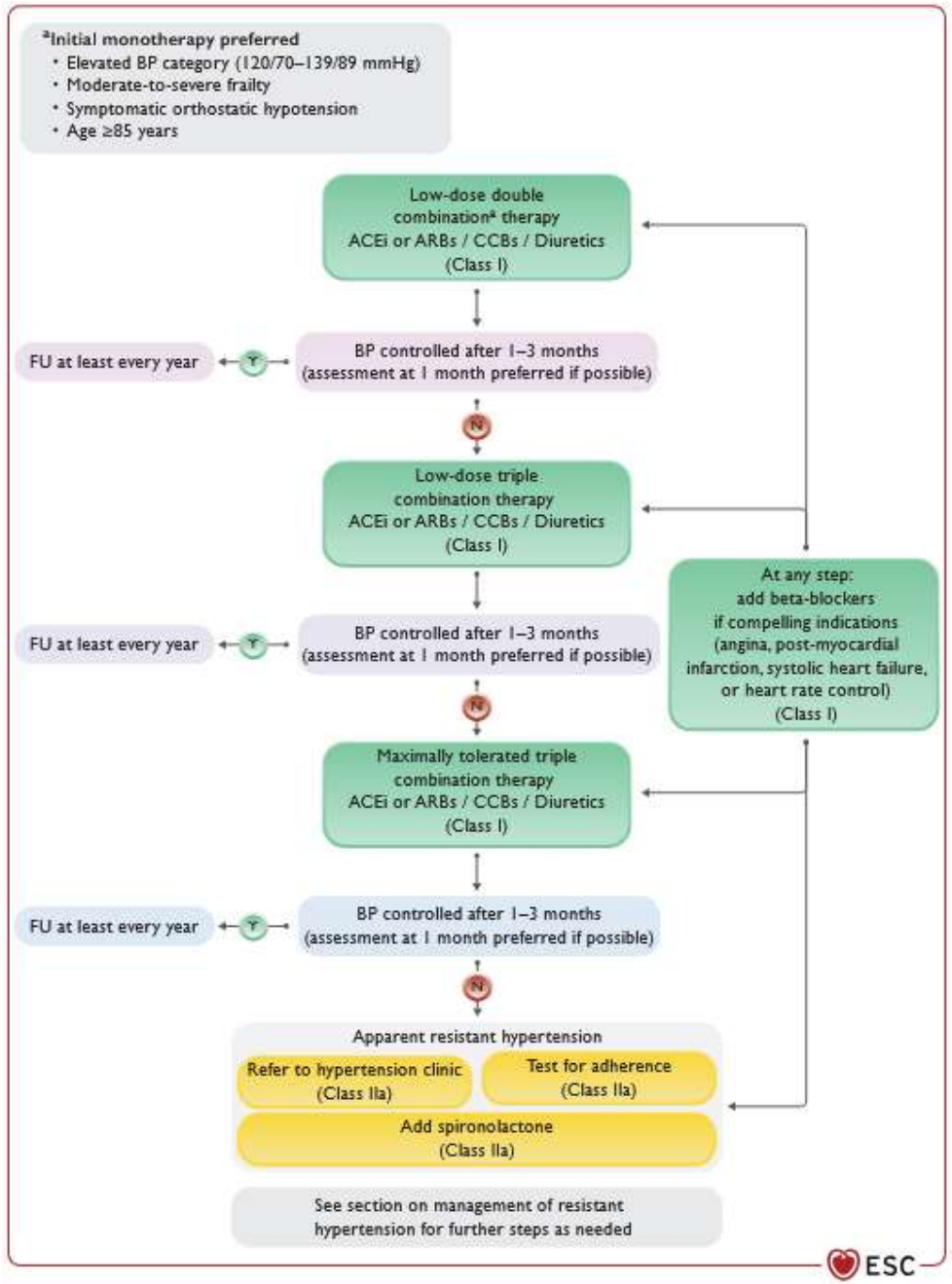



**Figure 18** Practical algorithm for pharmacological blood pressure lowering. ACEi, angiotensin-converting enzyme inhibitor; ARB, angiotensin receptor blocker; BP, blood pressure; CCB, calcium channel blocker; FU, follow-up.

*JW McEvoy, et al European Heart Journal*, Volume 45, Issue 38, 7 October 2024, Pages 3912–4018

# Definition of Resistant Hypertension

BP remaining above goal despite:

3 or more medications of different classes at maximum tolerated dosage, one of which is a thiazide type diuretic

And

*Attempted* adherence to lifestyle modification

- Weight loss
- Sodium restriction
- Increased exercise
- Alcohol reduction
- Sleep apnea treatment

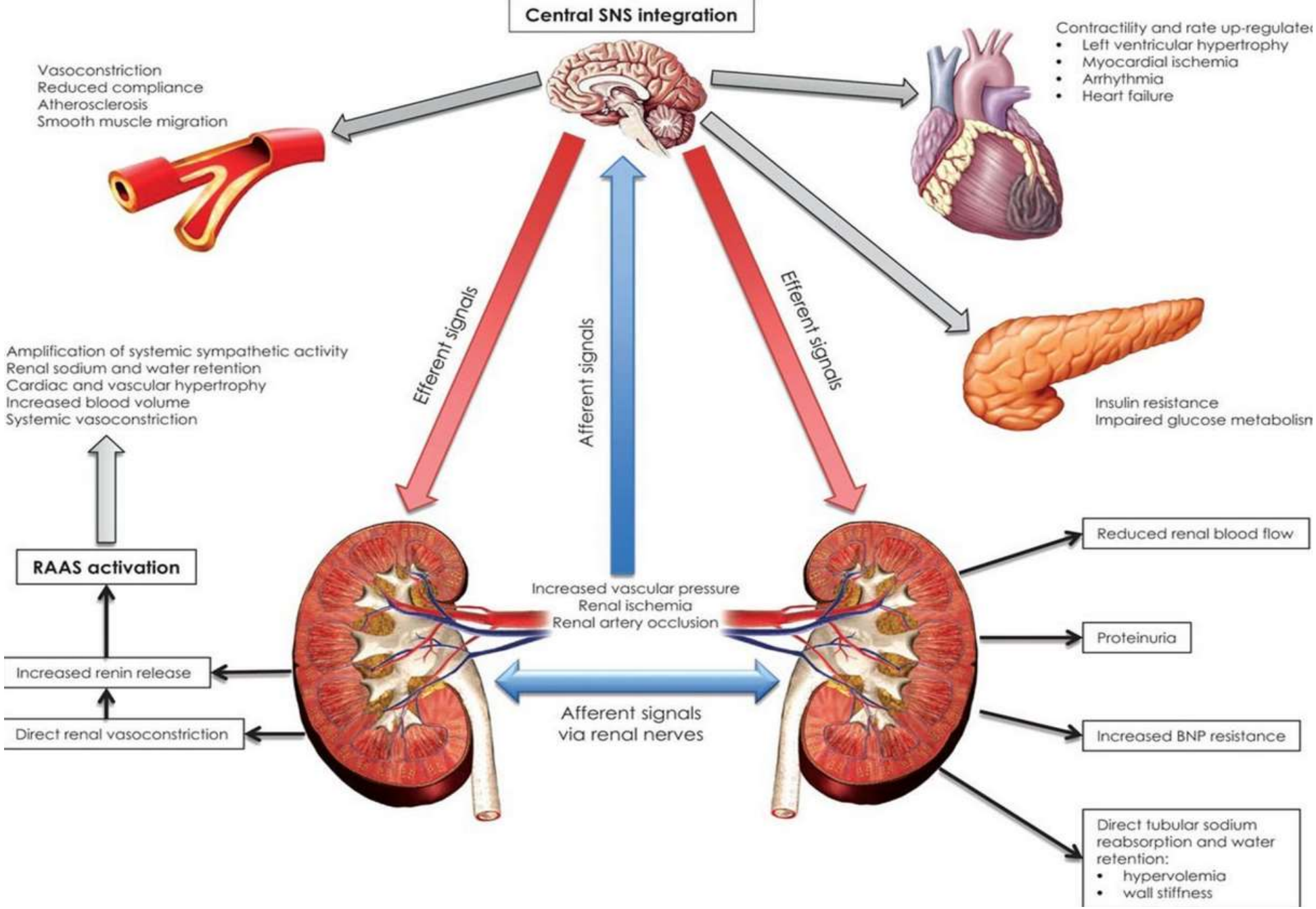
Patients with resistant hypertension should be considered for workup of secondary causes and referral to a specialist

# Evaluation for secondary causes of hypertension

| | |
|---|---|
| Primary Hyperaldosteronism | Aldosterone:Renin ratio |
| Renovascular Hypertension | Renal Duplex, CTA, MRA |
| Pheochromocytoma | Plasma free metanephrines |
| Obstructive sleep apnea | Sleep study |
| Cushing's | Random cortisol (?),24 hr urine cortisol, dex suppression |
| Hyperthyroid | TSH |
| Hyperparathyroidism | Ca++, phos, intact PTH |

# Sympathetic Activation

The Rationale for Renal Artery Denervation



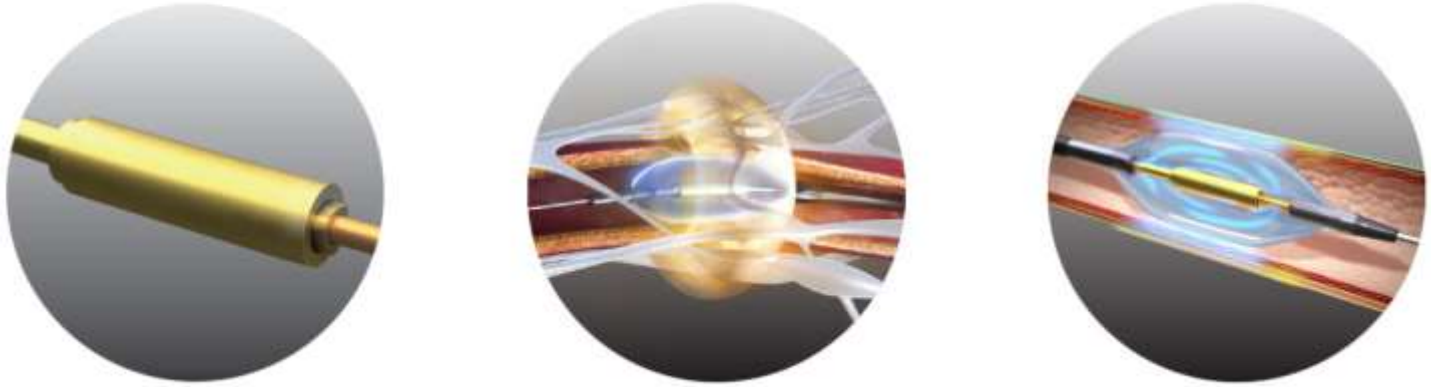

Jorbenadze, A et (2021). Extra-Cardiac Targets in the Management of Cardiometabolic Disease: Device-Based Therapies. ESC Heart Failure. 8. 10.1002/ehf2.13361.

# Two Commercially Available Systems

Paradise Ultrasound Renal Denervation (uRDN) – Recor Medical

Symplicity Spyral Radio Frequency Renal Denervation (rfRDN) - Medtronic

# Paradise® Ultrasound Renal Denervation System

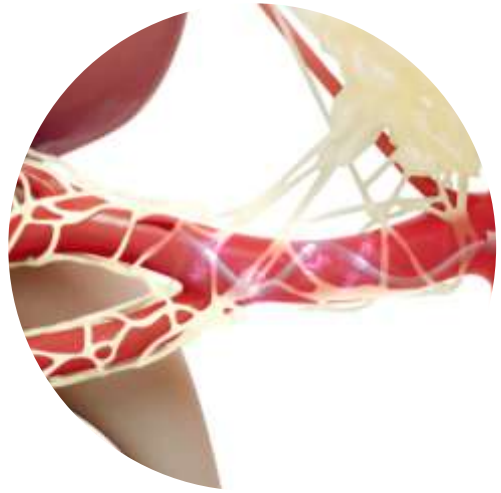



Images courtesy Recor Medical

# Symplicity Spyral™ Radiofrequency Renal Denervation System

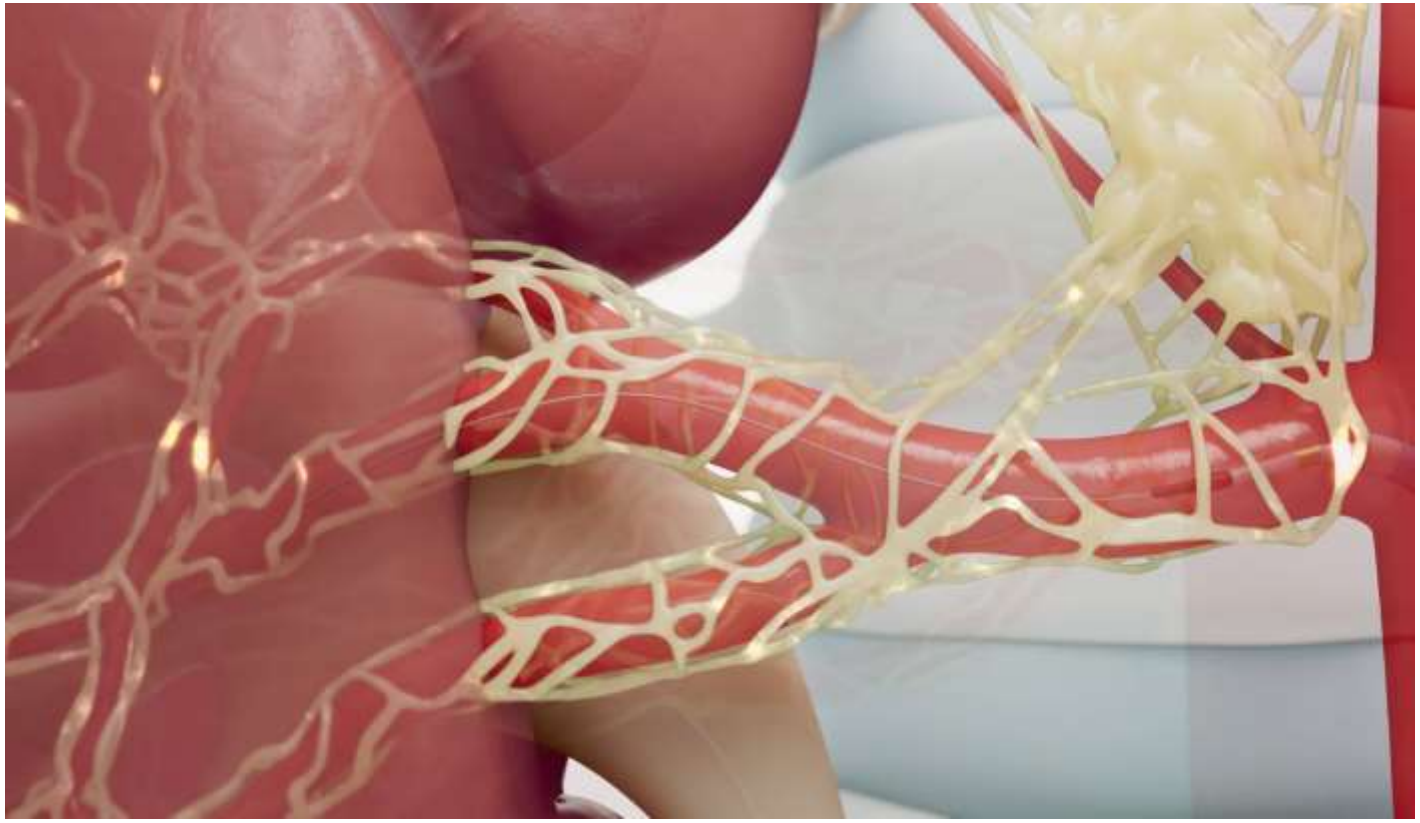
Symplicity Spyral multi-electrode renal denervation catheter

Symplicity G3™ generator



**Symplicity™ blood pressure procedure**

# The Symplicity Spyral™ RDN system



[1] Medtronic Symplicity Spyral Multi-Electrode Renal Denervation Catheter Instructions for Use.
[2] Coates P, et al. *Cardiovasc Revasc Med*. 2022;42:171–177.

# Randomized Sham-Controlled Clinical Trial Results

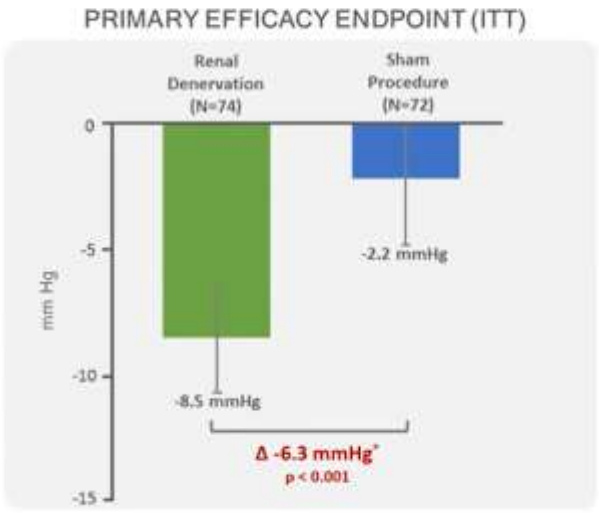
RADIANCE Trial Program of uRDN
SPYRAL Trial Program of rfRDN

# RADIANCE Trial Program uRDN

## RADIANCE-HTN SOLO

Off meds x 2 months prior to enrollment

**RADIANCE-HTN SOLO Primary Endpoint**
**Change in Daytime Ambulatory Systolic BP at 2 Months**

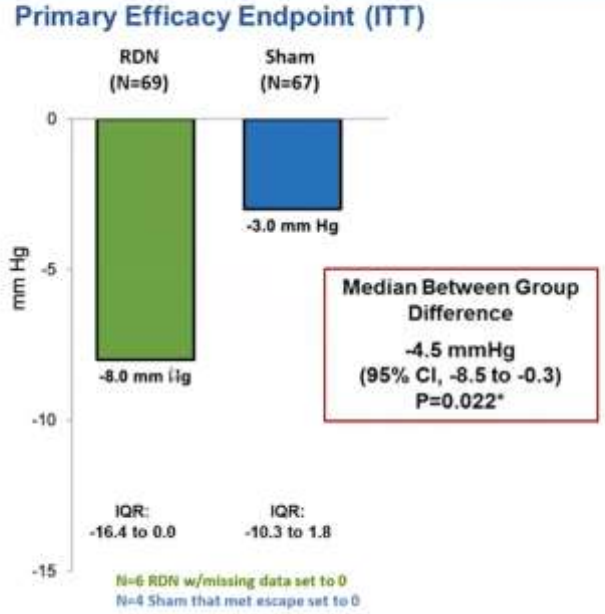



Azizi et al Lancet 2018:391 (10137)

## RADIANCE-HTN TRIO

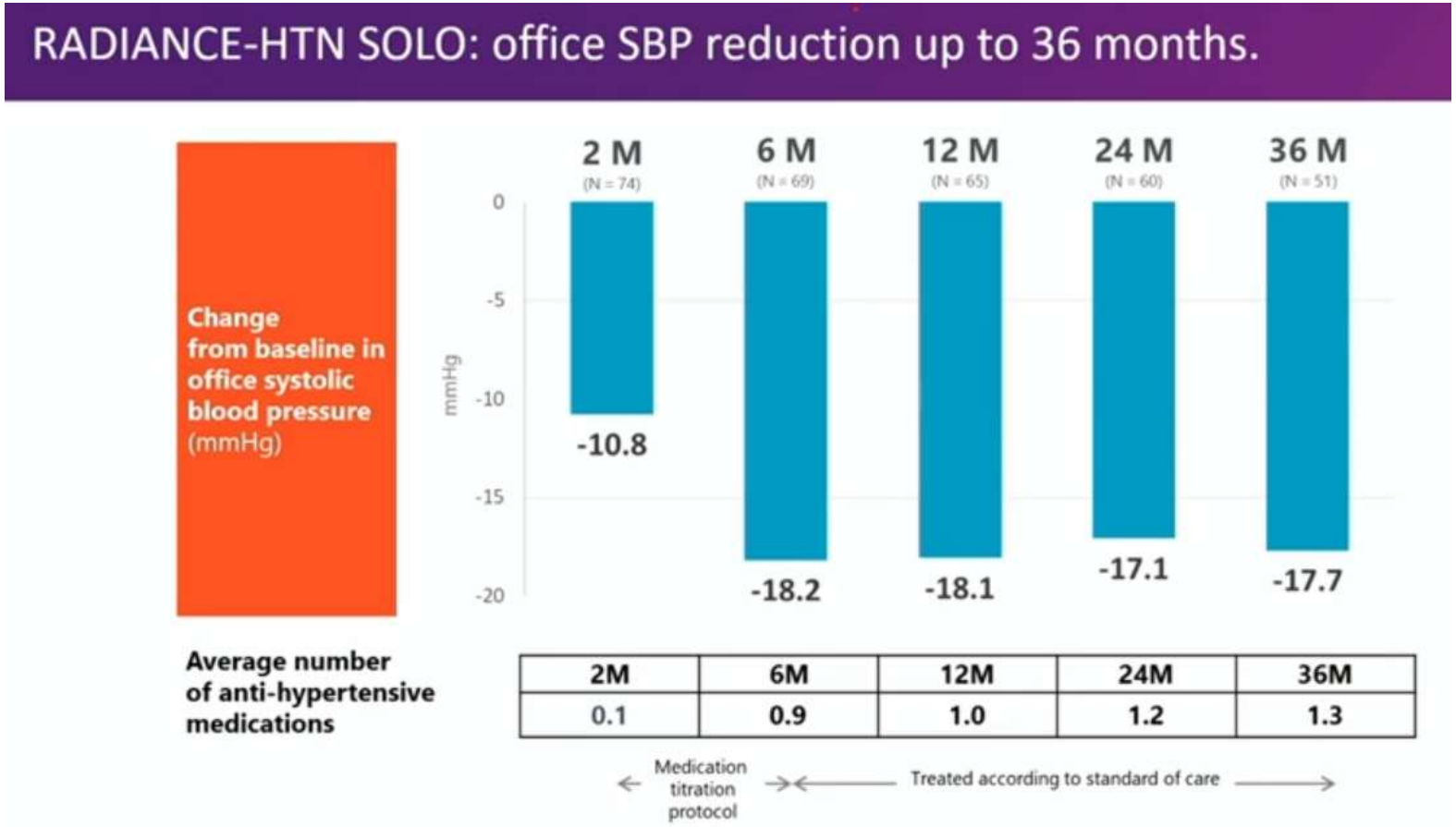
Resistant HTN, on 3 med fixed dose pill

**Primary Efficacy Endpoint:**
**Change in Daytime Ambulatory SBP at 2 Months**




Azizi et al Lancet 2021: 26 2476-2486

# Long-term follow up RADIANCE-HTN SOLO



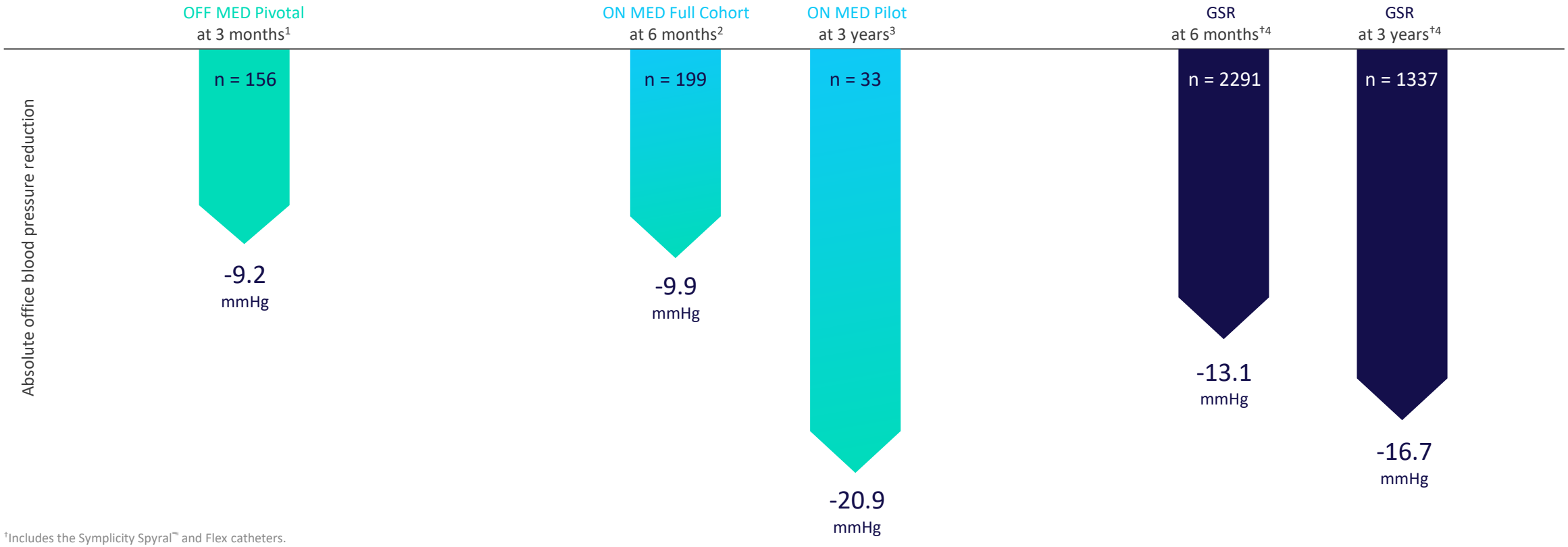

Rader et al Eurointervention 2022 18e677-e685

# Sham-controlled randomized controlled trials OFF and ON medications and real-world registry

**OFF MED**
Scientific evidence of efficacy without meds

**ON MED**
Prospective evidence in the presence of meds

**GSR†**
Large dataset of multiple subgroups in real-world setting

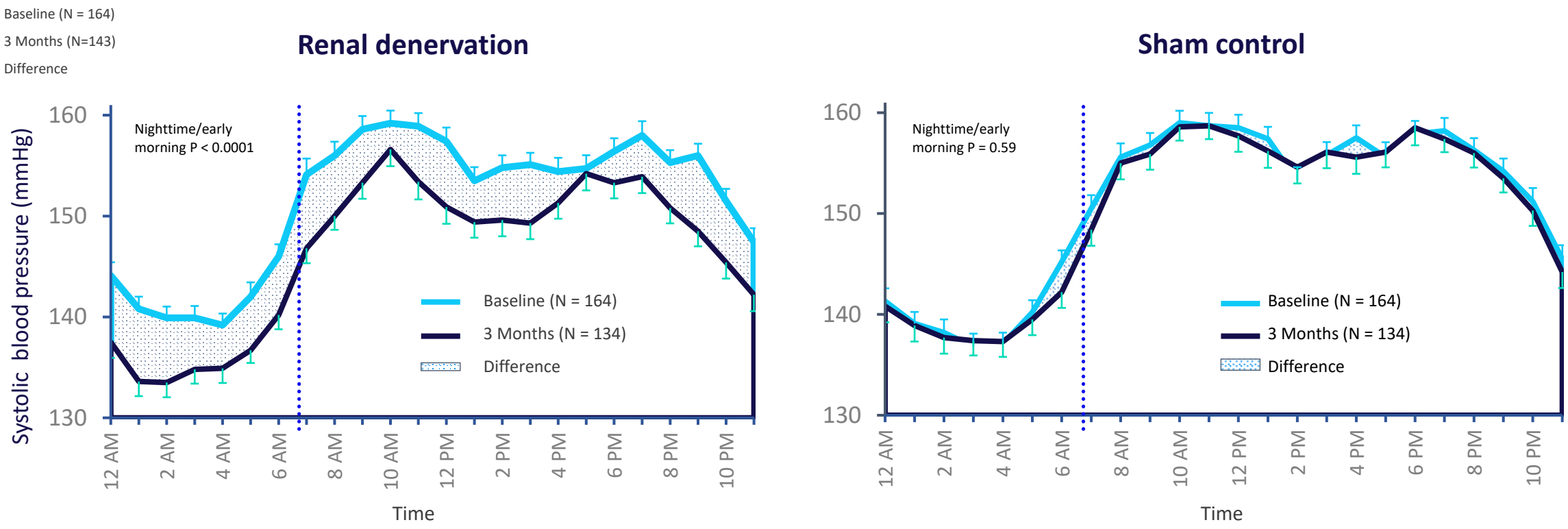



†Includes the Symplicity Spyral™ and Flex catheters.


[1] Böhm M, et al. *Lancet*. 2020;395:1444–1451.
[2] Kandzari D, et al. J Am Coll Cardiol. 2023 Nov 7;82(19):1809-1823
[3] Mahfoud F, et al. *Lancet*. 2022;399:1401-1410.
[4] Mahfoud F, et al. Outcomes following radiofrequency renal denervation according to antihypertensive medications: subgroup analysis of the Global SYMPLICITY Registry DEFINE. EuroPCR 2023.

# RDN demonstrated an “always on” effect on 24-hour blood pressure reductions

SPYRAL HTN-OFF MED Pivotal 24-hour systolic ABPM trend at three months[1]




[1] Böhm M, et al. *Lancet*. 2020;395:1444–1451.
[2] Amodeo C, et al. *Blood Press Monit*. 2014;19:199–202.
[3] Boggia J, et al. *Lancet*. 2007;370:1219–1229.

# Safe

## Evaluated across the SPYRAL Clinical Program and Global SYMPLICITY Registry (GSR)

### Excellent safety profile

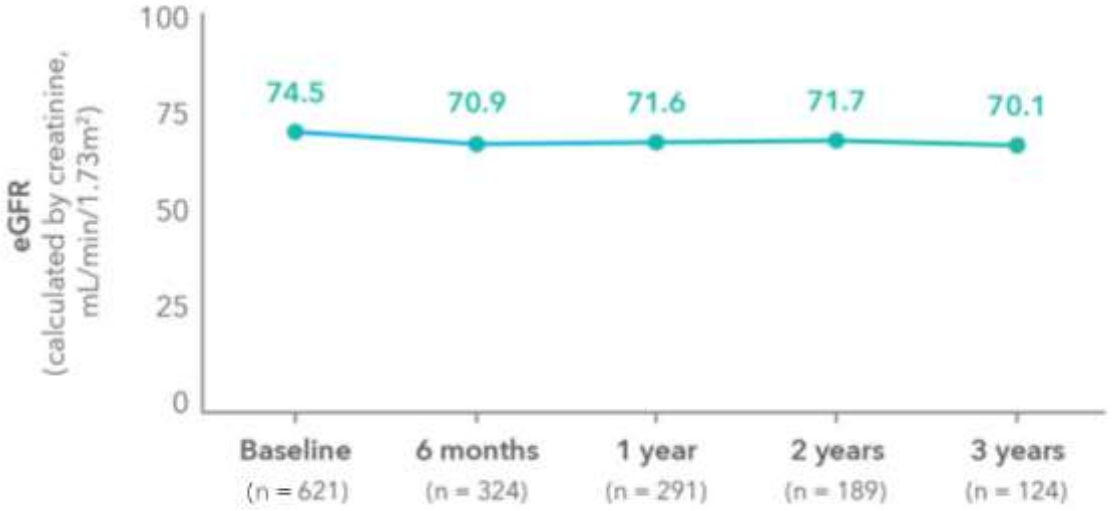
Pooled data from the **SPYRAL HTN-OFF MED** and **SPYRAL HTN-ON MED** trials indicated low incidence of procedural related and clinical adverse events.[1]

**0.4%**

major adverse event rate at composite endpoint, including no new incidence of renal artery stenosis (>70%) at 1 month.[1] (N=253)

### Stable kidney function in real-world patients

**The Global SYMPLICITY Registry** study showed stable kidney function at three-year follow-up.[2]




[1] Kandzari DE, et al. *J Am Coll Cardiol*. 2023;82:1809–1823.
[2] Schlaich M, et al. Long-term safety and efficacy of renal denervation with the Symplicity Spyral catheter in the Global SYMPLICITY Registry. Presented at American Society of Nephrology Kidney Week, San Diego, CA. November 4–7, 2021.

# SCAI position statement on renal denervation for hypertension

**Expert roundtable of multidisciplinary physicians regarding:**

- Patient selection
- Operator competence
- Training and techniques
- Organizational recommendations

## Selection criteria appropriate for renal denervation

- **Patients with uncontrolled hypertension** despite attempting lifestyle modification and antihypertensive medication but who are either intolerant of additional medication or do not wish to be on additional medications and who **are willing to undergo renal denervation after shared decision-making**
- Patients with **higher cardiovascular risk** who may have the greatest benefit from BP reduction
- **Patients with resistant hypertension, defined by blood pressure > 130/80 mmHg despite being on three medications with maximally tolerated dose**s from classes with outcomes data (angiotensin-converting enzyme inhibitors or angiotensin II receptor blockers, calcium channel blockers, thiazide diuretics, and beta blockers)

Source: Swaminathan RV, et al. *JSCAI*. 2023;2:101121.

# Who is an appropriate candidate?

CMS National Coverage Determination (NCD) Oct 2025

- Diagnosis of uncontrolled hypertension (> 140 systolic or > 90 diastolic) despite active management
- No secondary cause of HTN identified/untreated
- Uncontrolled defined by ambulatory blood pressure monitoring or serial home BP readings
- Uncontrolled despite:
  - Lifestyle modification
  - Maximally tolerated GDMT antihypertensive therapy on stable meds > 6 weeks

# Questions?