Guidelines Medical Therapy For Hypertension
(Where Does Renal Denervation Fit In)

Richard C Kovach, MD, FACC, FSCAI, FACP

Division Director, Interventional Cardiology
Medical Director, Cardiac Catheterization Laboratory
Assistant Director, Interventional Cardiology Fellowship Program
Deborah Heart and Lung Center, Browns Mills, New Jersey

Course Co-Director
NCVH-New Jersey

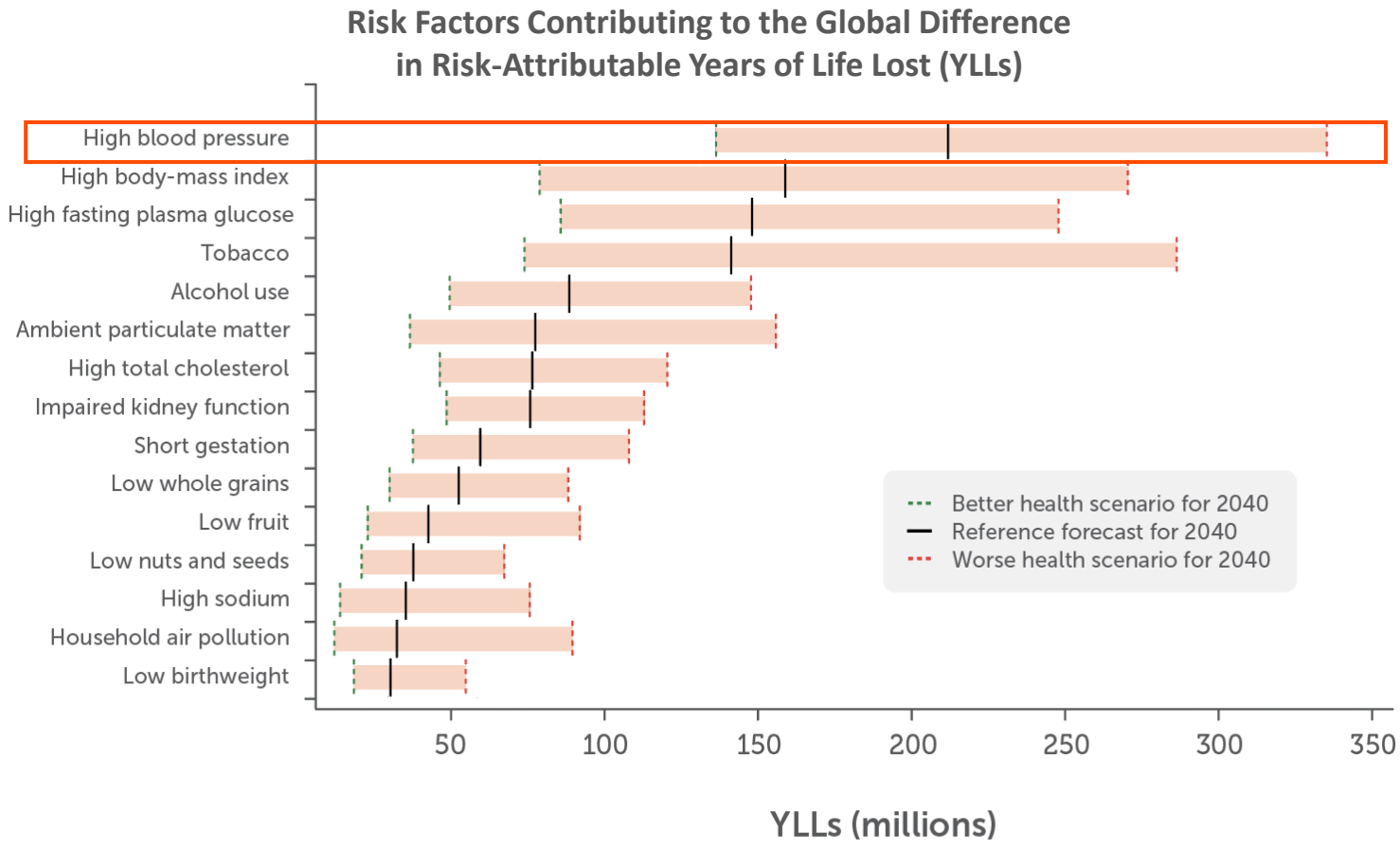
Associate Interventional Fellows Course Director
Cardiovascular Institute of Philadelphia

Cors at the Shore 2023

Disclosures:

- Phillips/Volcano: consultant, speaker, trainer
- Boston Scientific: Medical advisory board, speaker, educational grants, trainer, investigator
- Medtronic Corporation: speaker, educational grants, investigator
- Shockwave Medical: Medical Advisory Board
- Ostialcorp: Medical Advisory Board; stock holder
- Asia Pacific Medical Technologies: Stock Holder
- Endoshape, Inc.: Stock Holder
- Vasorum: Stock Holder
- Levee Medical: Stock Holder

Hypertension is the #1 Cause of Global Disease Burden

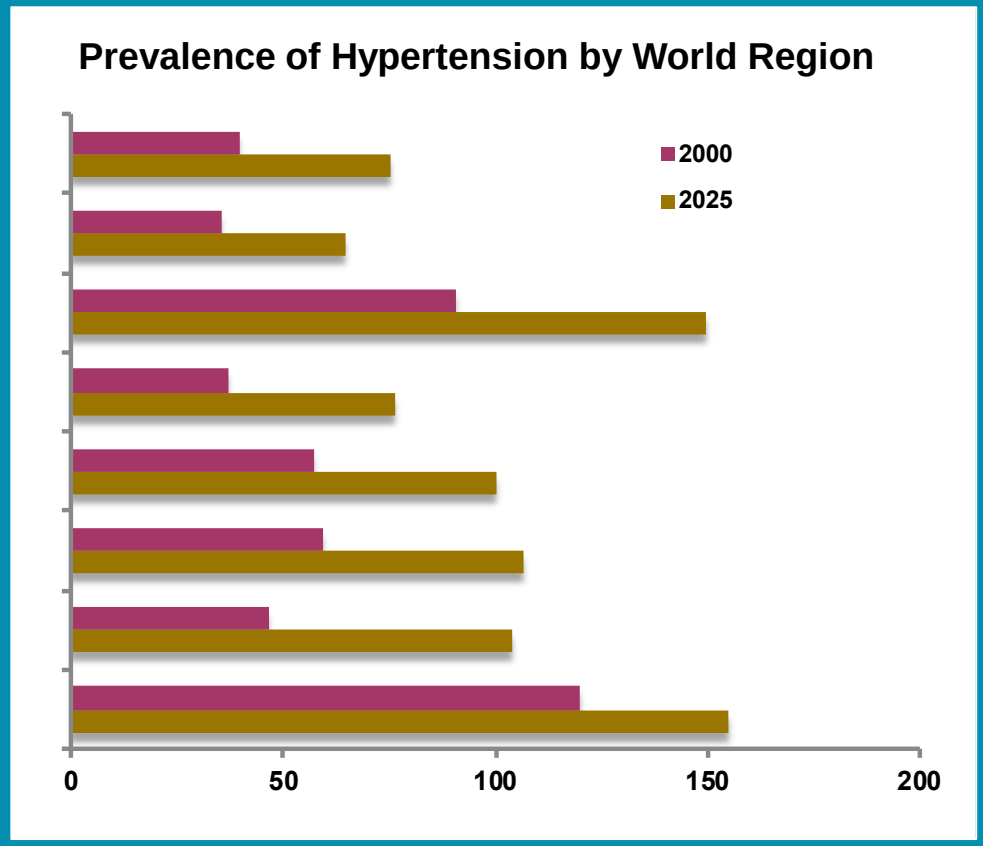


HIGH BLOOD PRESSURE projected to remain the leading risk factor in 2040.

Foreman et al. *Lancet* 2018; 392: 2052–90

World Wide Prevalence of HTN Increasing

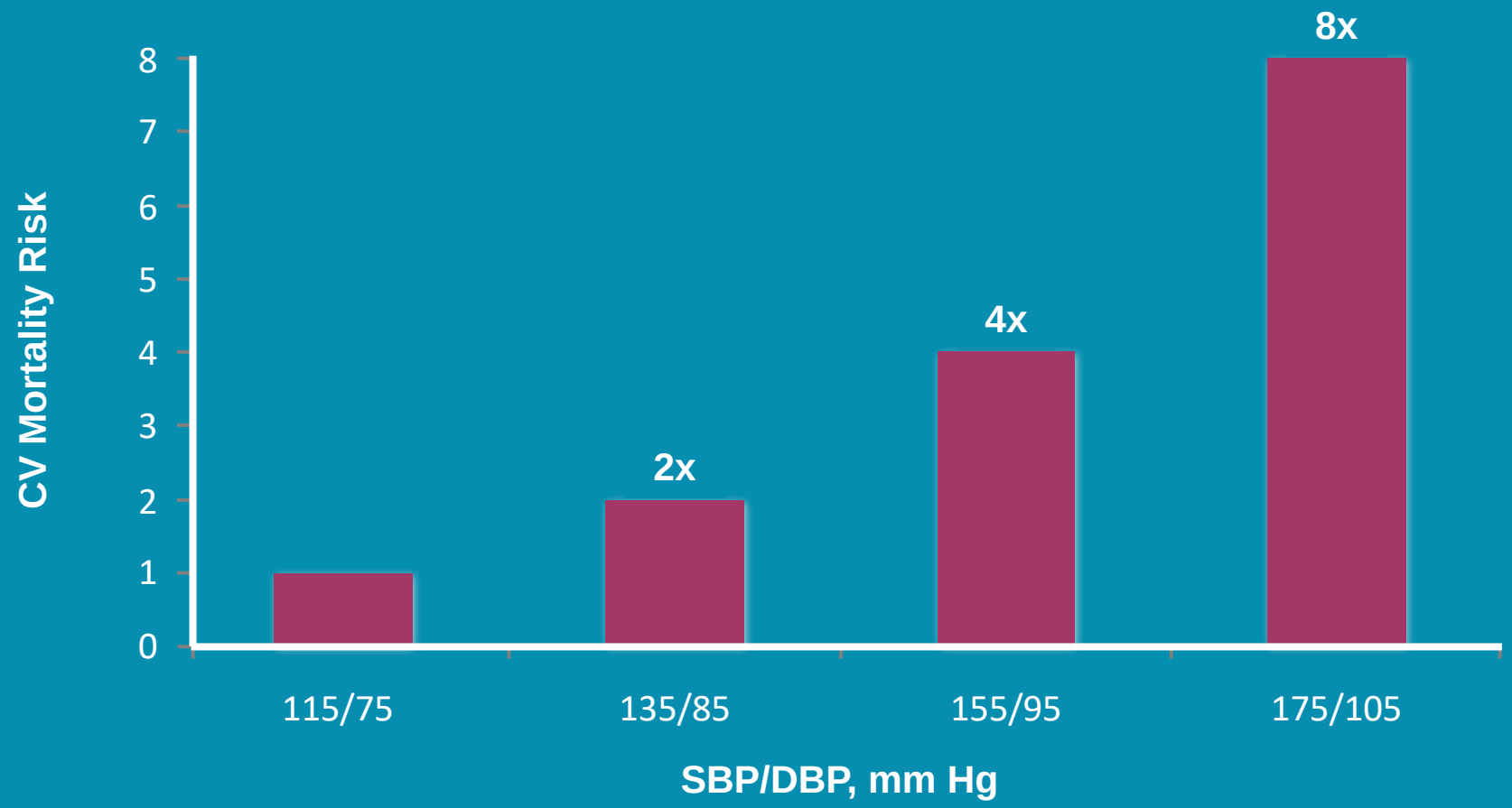
- In 2000, 972 million (26%), of the adult population had hypertension
- By year 2025, 1.56 billion (29%) are projected to have hypertension
- Most of the expected increase will be in economically developing regions



Kearney PM, et al. *Lancet*. 2005;365:217-223.

Cors at the Shore 2023

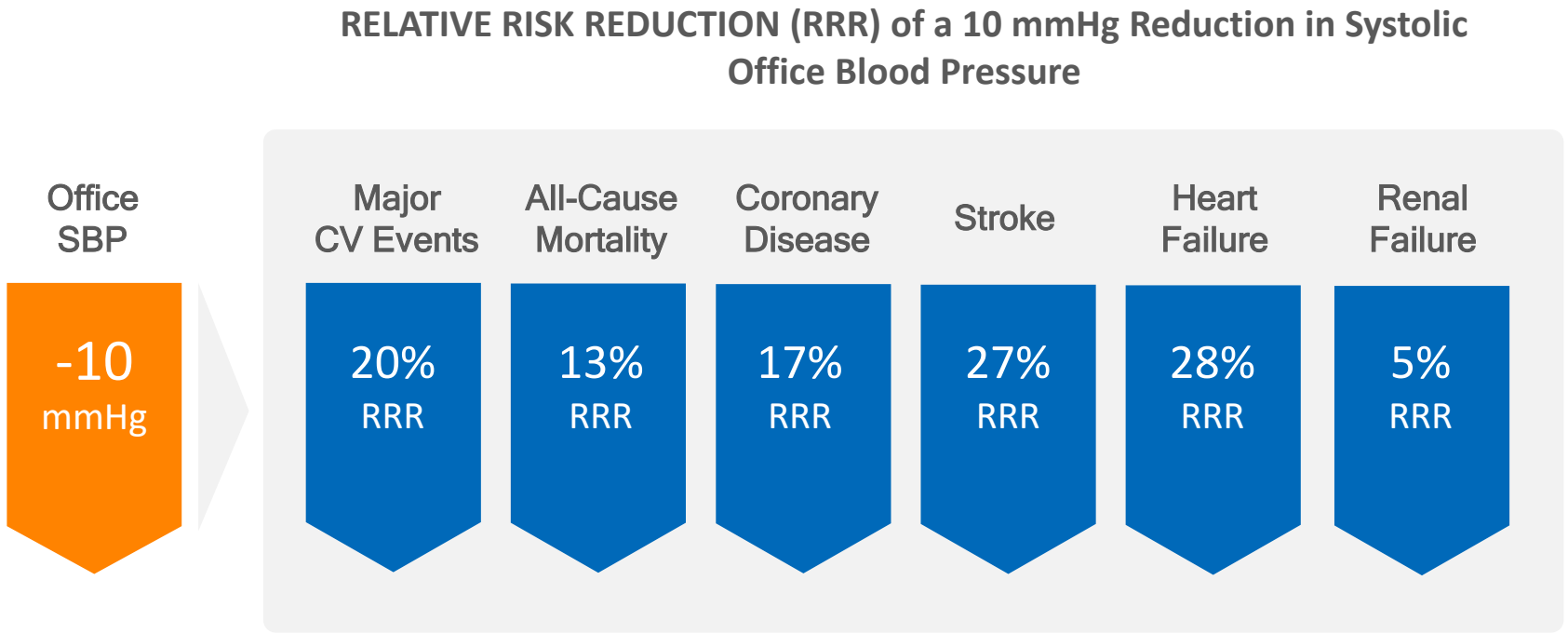
Cardiovascular Mortality Risk Doubles With Each 20/10 mm Hg Increase in BP*



CV=cardiovascular; SBP=systolic blood pressure; DBP=diastolic blood pressure .
*In individuals aged 40 to 69 years (10-year study period), starting at BP 115/75 mm Hg.
Lewington S, et al. *Lancet*. 2002;360:1903-1913.

Cors at the Shore 2023

Correlation Between Blood Pressure Reduction and CV Events



20% RELATIVE RISK REDUCTION of Major CV Events with 10 mmHg BP Drop

Based on meta-analysis of 613,815 patients from 123 studies

Ettehad et al, Blood pressure lowering for prevention of cardiovascular disease and death, *Lancet* 2016; 387: 957-67

So to start:

ACC/AHA Guidelines for RX and Definitions for HTN

Definition of HTN

BP Category	SBP		DBP
Normal	<120 mm Hg	and	<80 mm Hg
Elevated	120–129 mm Hg	and	<80 mm Hg
Hypertension			
Stage 1	130–139 mm Hg	or	80–89 mm Hg
Stage 2	≥140 mm Hg	or	≥90 mm Hg

*Individuals with SBP and DBP in 2 categories should be designated to the higher BP category.

BP indicates blood pressure (based on an average of ≥2 careful readings obtained on ≥2 occasions, as detailed in Section 4); DBP, diastolic blood pressure; and SBP, systolic blood pressure.

Diagnosis and Screening

COR	LOE	RECOMMENDATION
I	A^{SR}	1. Out-of-office BP measurements are recommended to confirm the diagnosis of hypertension (Table 11) and for titration of BP-lowering medication, in conjunction with telehealth counseling or clinical interventions (S4.2-1–S4.2-4).

2023 Cors at the Shore

Screening to R/O “White Coat” HTN

COR	LOE	RECOMMENDATIONS
IIa	B-NR	1. In adults with an untreated SBP greater than 130 mm Hg but less than 160 mm Hg or DBP greater than 80 mm Hg but less than 100 mm Hg, it is reasonable to screen for the presence of white coat hypertension by using either daytime ABPM or HBPM before diagnosis of hypertension (S4.4-1–S4.4-8).
IIa	C-LD	2. In adults with white coat hypertension, periodic monitoring with either ABPM or HBPM is reasonable to detect transition to sustained hypertension (S4.4-2,S4.4-5,S4.4-7).
IIa	C- LD	3. In adults being treated for hypertension with office BP readings not at goal and HBPM readings suggestive of a significant white coat effect, confirmation by ABPM can be useful (S4.4-9,S4.4-10).
IIa	B-NR	4. In adults with untreated office BPs that are consistently between 120 mm Hg and 129 mm Hg for SBP or between 75 mm Hg and 79 mm Hg for DBP, screening for masked hypertension with HBPM (or ABPM) is reasonable (S4.4-3,S4.4-4,S4.4-6,S4.4-8,S4.4-11).
IIb	C-LD	5. In adults on multiple-drug therapies for hypertension and office BPs within 10 mm Hg above goal, it may be reasonable to screen for white coat effect with HBPM (or ABPM) (S4.4-3,S4.4-7,S4.4-12).
IIb	C-EO	6. It may be reasonable to screen for masked uncontrolled hypertension with HBPM in adults being treated for hypertension and office readings at goal, in the presence of target organ damage or increased overall CVD risk.
IIb	C-EO	7. In adults being treated for hypertension with elevated HBPM readings suggestive of masked uncontrolled hypertension, confirmation of the diagnosis by ABPM might be reasonable before intensification of antihypertensive drug treatment.

Non-Pharmacologic Treatment for Primary HTN

COR	LOE	RECOMMENDATIONS
I	A	1. Weight loss is recommended to reduce BP in adults with elevated BP or hypertension who are overweight or obese (S6.2-1–S6.2-4).
I	A	2. A heart-healthy diet, such as the DASH (Dietary Approaches to Stop Hypertension) diet, that facilitates achieving a desirable weight is recommended for adults with elevated BP or hypertension (S6.2-5–S6.2-7).
I	A	3. Sodium reduction is recommended for adults with elevated BP or hypertension (S6.2-8–S6.2-12).
I	A	4. Potassium supplementation, preferably in dietary modification, is recommended for adults with elevated BP or hypertension, unless contraindicated by the presence of CKD or use of drugs that reduce potassium excretion (S6.2-13–S6.2-17).
I	A	5. Increased physical activity with a structured exercise program is recommended for adults with elevated BP or hypertension (S6.2-3,S6.2-4,S6.2-12,S6.2-18–S6.2-22).
I	A	6. Adult men and women with elevated BP or hypertension who currently consume alcohol should be advised to drink no more than 2 and 1 standard drinks* per day, respectively (S6.2-23–S6.2-28).

*In the United States, 1 "standard" drink contains roughly 14 g of pure alcohol, which is typically found in 12 oz of regular beer (usually about 5% alcohol), 5 oz of wine (usually about 12% alcohol), and 1.5 oz of distilled spirits (usually about 40% alcohol) (S6.2-29).

2023 Cors at the Shore

Secondary HTN

COR	LOE	RECOMMENDATIONS
I	C-EO	1. Screening for specific form(s) of secondary hypertension is recommended when the clinical indications and physical examination findings listed in Table 13 are present or in adults with resistant hypertension.
IIb	C-EO	2. If an adult with sustained hypertension screens positive for a form of secondary hypertension, referral to a physician with expertise in that form of hypertension may be reasonable for diagnostic confirmation and treatment.

Causes of Secondary HTN

- Renal parenchymal disease
- Renovascular disease
- Primary aldosteronism
- OSA
- Drug/alcohol induced
- Pheochromocytoma/paraganglioma
- Cushing’s syndrome
- Hypothyroidism/hyperthyroidism
- Aortic coarctation
- Primary hyperparathyroidism
- Congenital adrenal hyperplasia
- Mineralocorticoid excess syndrome other than primary aldosteronism
- Acromegaly

Recommendations for Medical Rx of Primary HTN

COR	LOE	RECOMMENDATIONS
I	SBP: A DBP: C-EO	1. Use of BP-lowering medications is recommended for secondary prevention of recurrent CVD events in patients with clinical CVD and an average SBP of 130 mm Hg or higher or an average DBP of 80 mm Hg or higher, and for primary prevention in adults with an estimated 10-year atherosclerotic cardiovascular disease (ASCVD) risk of 10% or higher and an average SBP 130 mm Hg or higher or an average DBP 80 mm Hg or higher (S8.1.2-1–S8.1.2-9).
I	C-LD	2. Use of BP-lowering medication is recommended for primary prevention of CVD in adults with no history of CVD and with an estimated 10-year ASCVD risk <10% and an SBP of 140 mm Hg or higher or a DBP of 90 mm Hg or higher (S8.1.2-3,S8.1.2-10–S8.1.2-13).

*ACC/AHA Pooled Cohort Equations (http://tools.acc.org/ASCVD-Risk-Estimator/) (S8.1.2-13a) to estimate 10-year risk of atherosclerotic CVD. ASCVD was defined as a first CHD death, non-fatal MI or fatal or non-fatal stroke.

Cors at the Shore 2023

BP Goals

COR	LOE	RECOMMENDATIONS
I	SBP: B-R[SR] DBP: C-EO	1. For adults with confirmed hypertension and known CVD or 10-year ASCVD event risk of 10% or higher (see Section 8.1.2), a BP target of less than 130/80 mm Hg is recommended (S8.1.5-1–S8.1.5-5).
IIb	SBP: B-NR DBP: C-EO	2. For adults with confirmed hypertension, without additional markers of increased CVD risk, a BP target of less than 130/80 mm Hg may be reasonable (S8.1.5-6–S8.1.5-9).

SR indicates systematic review.

2023 Cors at the Shore

Antihypertensive Meds

COR	LOE	RECOMMENDATION
I	A^{SR}	1. For initiation of antihypertensive drug therapy, first-line agents include thiazide diuretics, CCBs, and ACE inhibitors or ARBs. (S8.1.6-1,S8.1.6-2)

SR indicates systematic review.

COR	LOE	RECOMMENDATION
III: Harm	A	1. Simultaneous use of an ACE inhibitor, ARB, and/or renin inhibitor is potentially harmful and is not recommended to treat adults with hypertension (S8.1.4-1–S8.1.4-3).

COR	LOE	RECOMMENDATIONS
I	C-EO	1. Initiation of antihypertensive drug therapy with 2 first-line agents of different classes, either as separate agents or in a fixed-dose combination, is recommended in adults with stage 2 hypertension and an average BP more than 20/10 mm Hg above their BP target.
IIa	C-EO	2. Initiation of antihypertensive drug therapy with a single antihypertensive drug is reasonable in adults with stage 1 hypertension and BP goal <130/80 mm Hg with dosage titration and sequential addition of other agents to achieve the BP target.

Antihypertensive Rx in Stable IHD

COR	LOE	RECOMMENDATIONS
I	SBP: B-R DBP: C-EO	1. In adults with SIHD and hypertension, a BP target of less than 130/80 mm Hg is recommended (S9.1-1–S9.1-5).
I	SBP: B-R DBP: C-EO	2. Adults with SIHD and hypertension (BP ≥130/80 mm Hg) should be treated with medications (e.g., GDMT (S9.1-6) beta blockers, ACE inhibitors, or ARBs) for compelling indications (e.g., previous MI, stable angina) as first-line therapy, with the addition of other drugs (e.g., dihydropyridine CCBs, thiazide diuretics, and/or mineralocorticoid receptor antagonists) as needed to further control hypertension (S9.1-7–S9.1-10).
I	B-NR	3. In adults with SIHD with angina and persistent uncontrolled hypertension, the addition of dihydropyridine CCBs to GDMT (S9.1-6) beta blockers is recommended (S9.1-8,S9.1-11,S9.1-12).
IIa	B-NR	4. In adults who have had a MI or acute coronary syndrome, it is reasonable to continue GDMT (S9.1-6) beta blockers beyond 3 years as long-term therapy for hypertension (S9.1-13,S9.1-14).
IIb	C-EO	5. Beta blockers and/or CCBs might be considered to control hypertension in patients with CAD (without HF*r*EF) who had an MI more than 3 years ago and have angina.

2023 Cors at the Shore

Other Antihypertensive Guidelines

- Prevention of heart failure/HFrEF/HFpEF
- CKD/Renal transplantation
- Acute intracranial hemorrhage; acute ischemic stroke
- Secondary stroke prevention
- PAD; DM; A-fib
- Valvular heart disease
- Aortic disease
- Race/Ethnicity
- Pregnancy
- Older patients
- Hypertensive crisis and emergencies
- Prevention of cognitive decline and dementia
- Surgical procedures

Cors at the Shore 2023

The Problems With Guidelines and Antihypertensive Medical RX

- Awareness
- Diagnosis
- Initial lack of symptoms
- Race, age, sex and gender differences in response to Rx
- Concurrent medical conditions that contribute to HTN or interfere with Rx
- Emotional and psychiatric issues
- Substance abuse
- Cost of Rx

HTN causes and management are truly multifactorial and and multifaceted

2023 Cors at the Shore

Despite Hypertension Treatment, Many Patients are Not Controlled

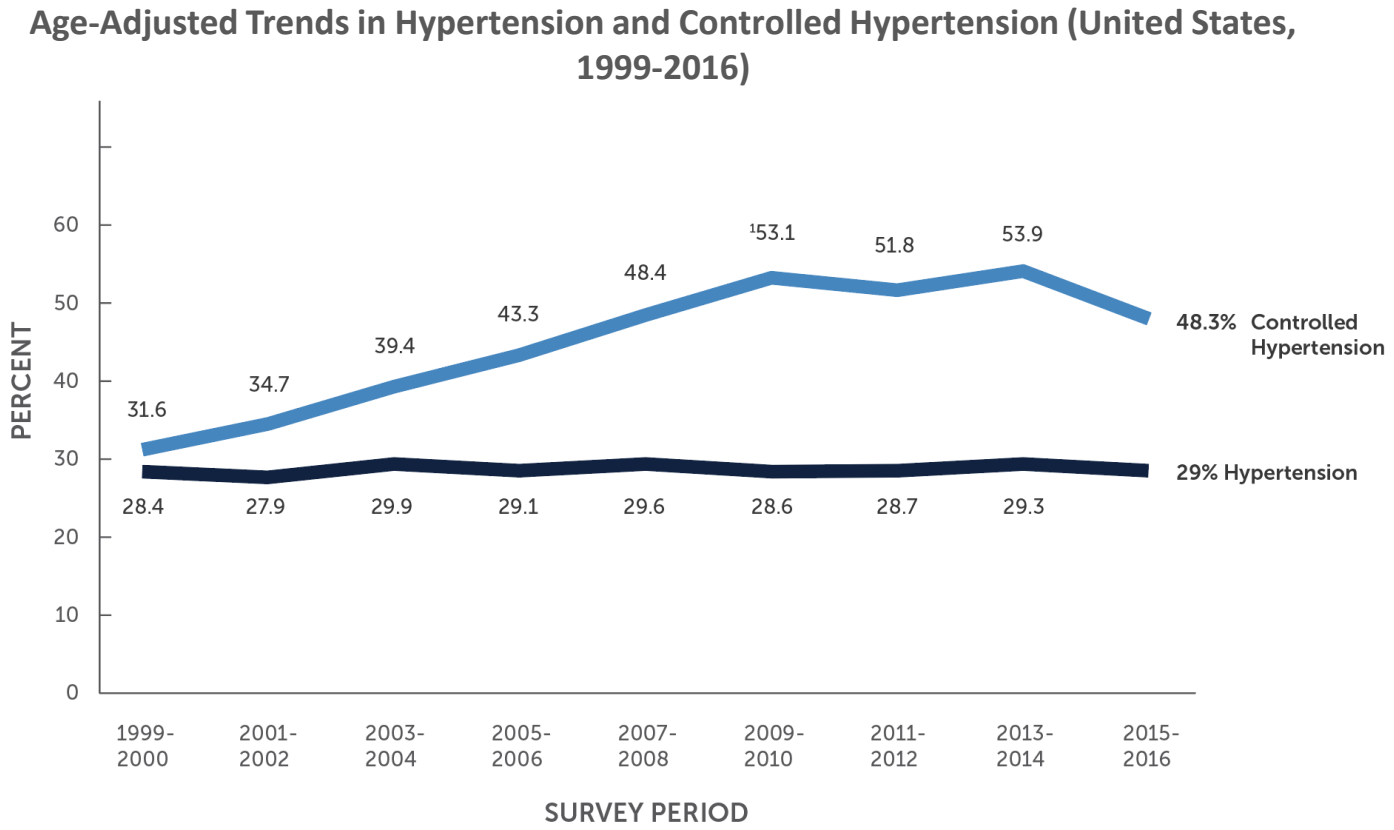
Established Market Economies (EME)

Country	Study Year	Age Range	Hypertension			Treated Hypertensives
			Aware (%)	Treated (%)	Controlled (%)	Controlled (%)
United States	1999-2000	18-80+	69	58	31	53
Canada	1986-1992	18-74	58	39	16	41
Spain	1990	35-64	45	32	5	16
England	1998	16-75	46	32	9	29
Germany	1994-1995	25-74	60	35	12	34
Greece	1997	18-90	61	55	27	50
China*	2000-2001	35-74	45	28	8	29
Japan	1980	30-74	–	41 (M) 55 (W)	24 (M) 36 (W)	56 (M) 65 (W)

Cors at the Shore 2023

M=men. W=women.
*Based on World Bank criteria used in this study, China was not considered an established market economy at time of publication.
Adapted and reproduced with permission from Kearney PM, et al. *J Hypertens*. 2004; 22:11-19. =

Hypertension Control Rates are No Longer Improving

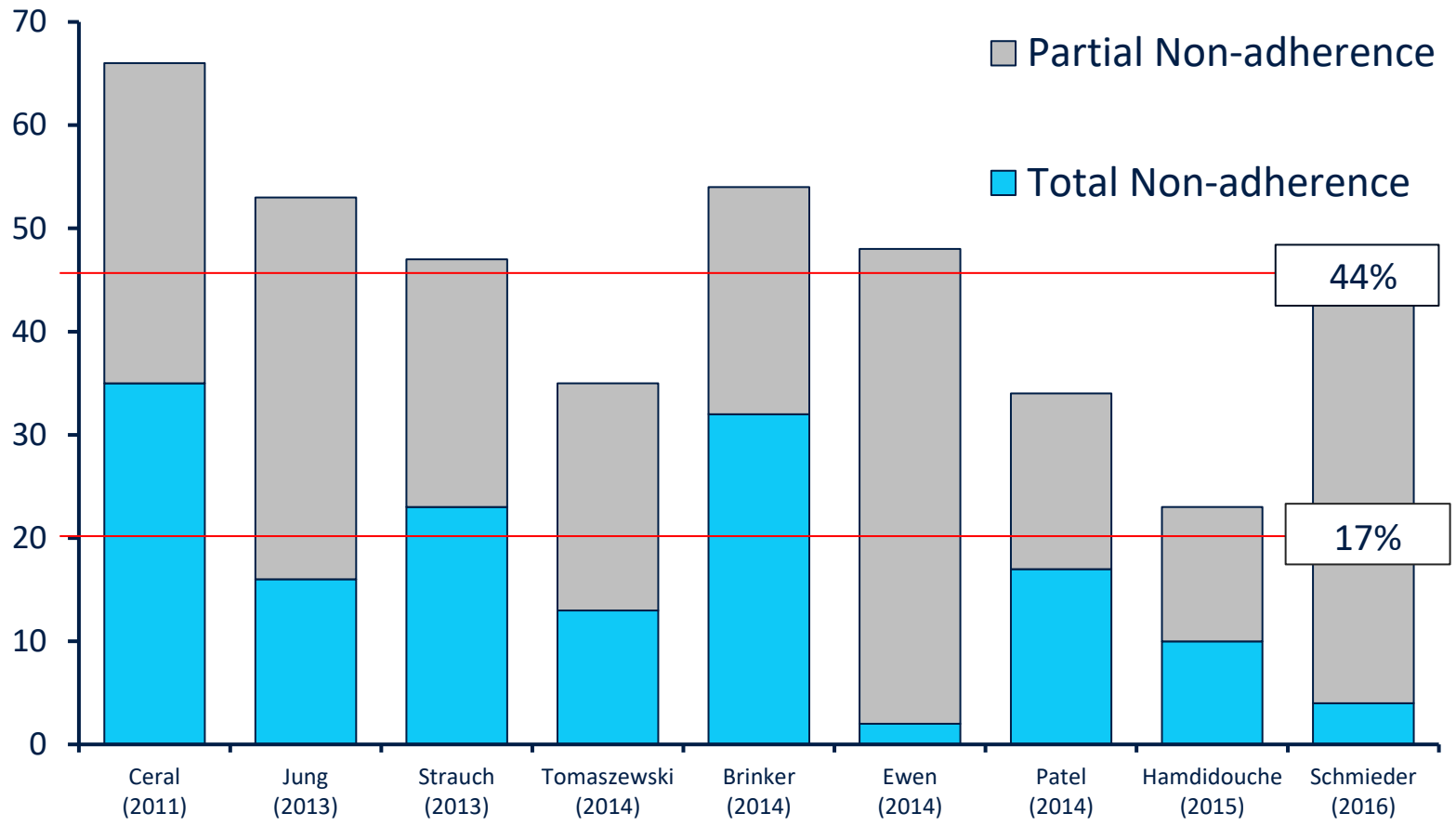


No significant changes observed from 2009 - 2010 through 2015 - 2016

Fryar CD, NCHS Data Brief, No 289, October 2017, cdc.gov/nchs/data/databriefs/db289.pdg

Non-adherence to prescribed antihypertensive drugs in clinical studies

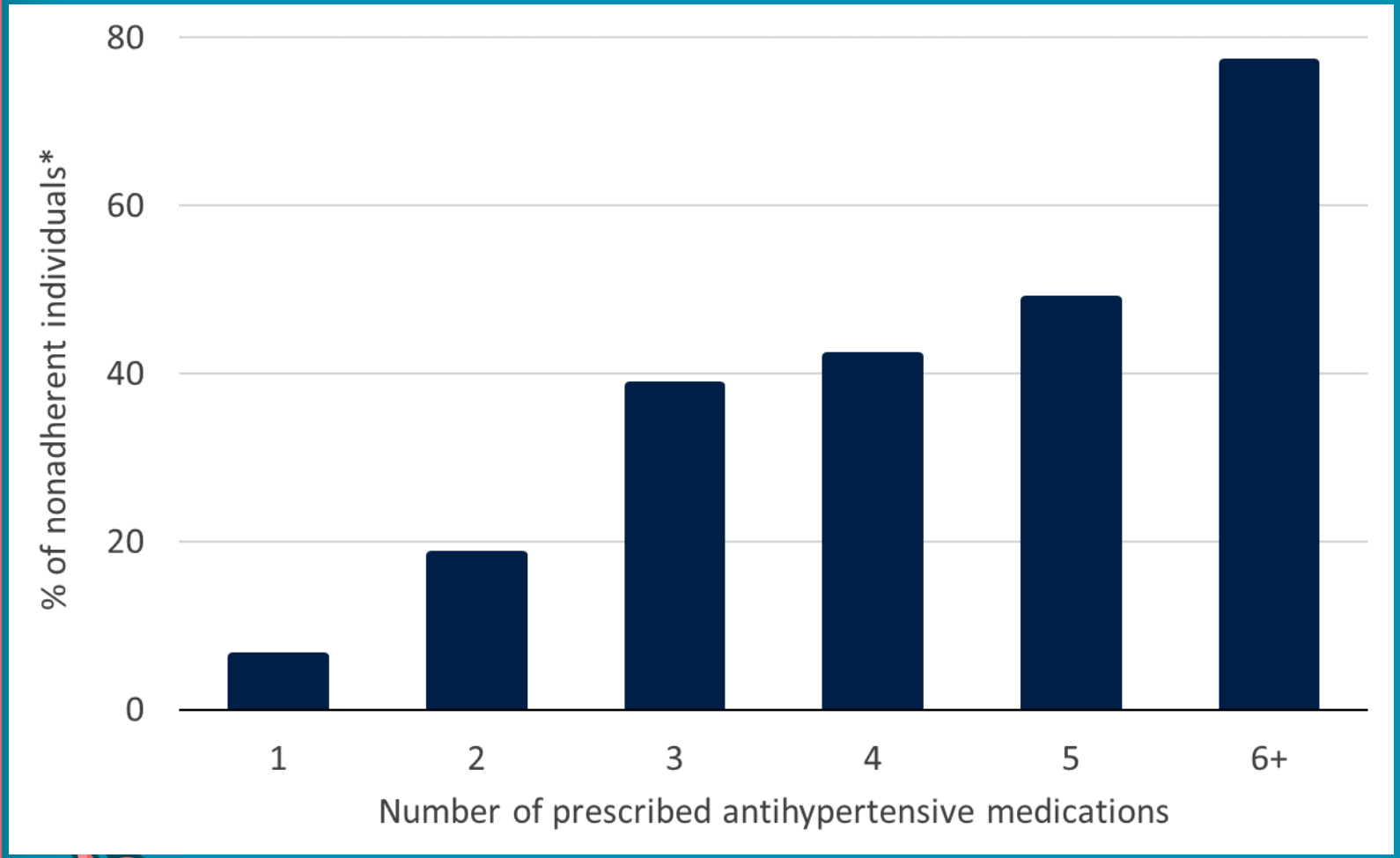
- 30 to 50% non-adherence rate is consistent between clinical trials
- Poor and dynamic adherence introduces variability to trial endpoints
  - Not easily controlled, even with rigorous trial design



- Berra E, et al. Hypertension. 2016;68:297-306

Non-Adherence Increased with Pill Burden

When Is It Time to Consider a Non-drug Therapy?



- Going from 2 to 3 medications doubled non-adherence
- Patients on 5 medications are nearly 50% non-adherent
- Majority of patients prescribed 6+ medications were nonadherent

Cors at the Shore 2023

Adapted from Gupta P, et al. *Hypertension*. 2017;70:1042-1048

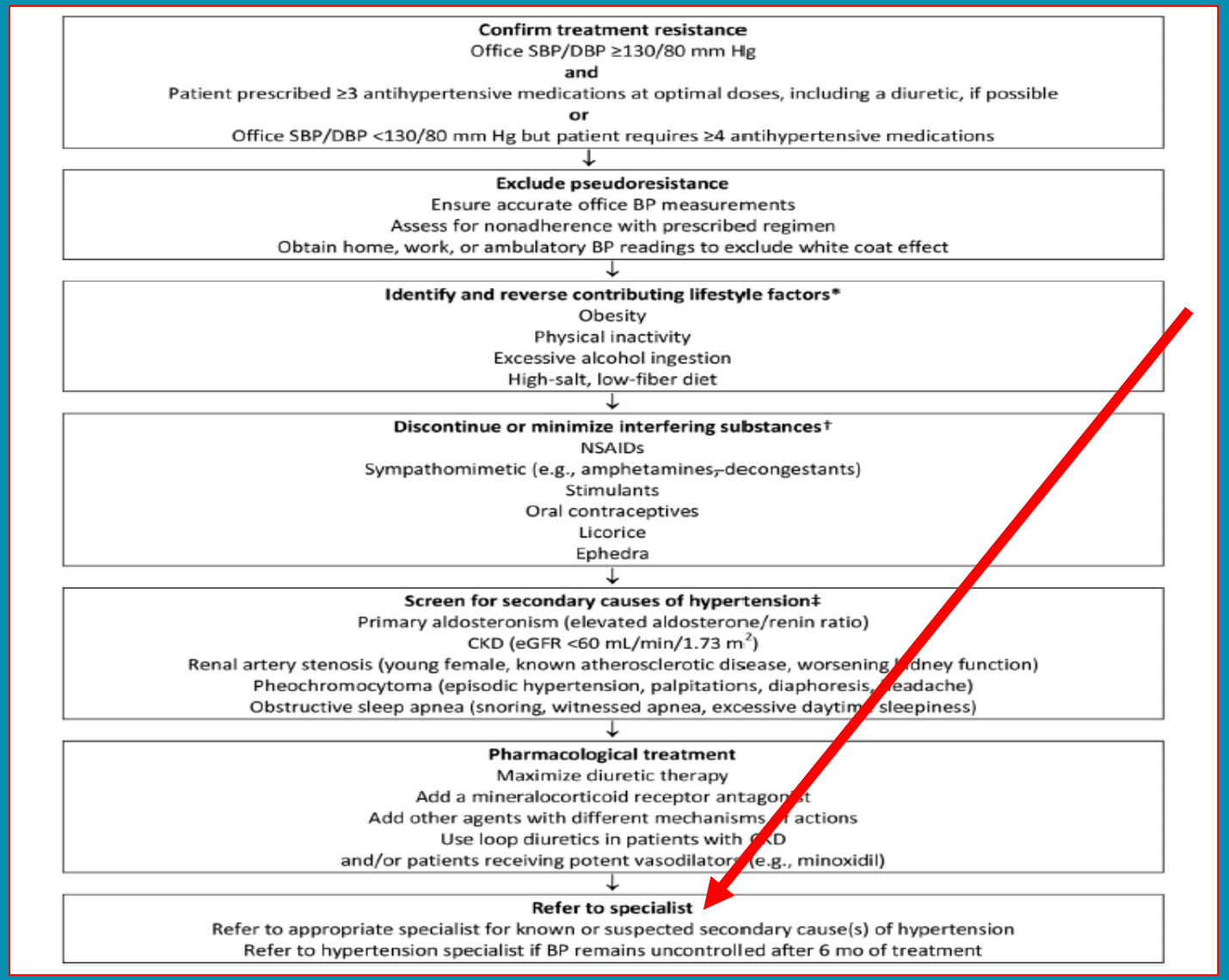
*Combined United Kingdom and Czech populations (N=1348)
Adherence determined by urine and blood biochemical analysis. Patients whose baseline serum analysis by LC-MS/MS did not detect at least one of the prescribed antihypertensive medications were classified as nonadherent.

Conclusions:

- HTN remains the #1 cause of global disease burden
- Prevalence of HTN is increasing (? related to DM and obesity)
- Extensive evidence that BP control reduces CV events
- A significant % of known hypertensives are not controlled on Rx
- Current rates of control are actually declining (again, ? related to HTN/DM)
- Non-adherence to antihypertensive Rx remains a huge problem

2023 Cors at the Shore

Resistant/Uncontrolled HTN: A Role for Renal Denervation?



Cors at the Shore 2023

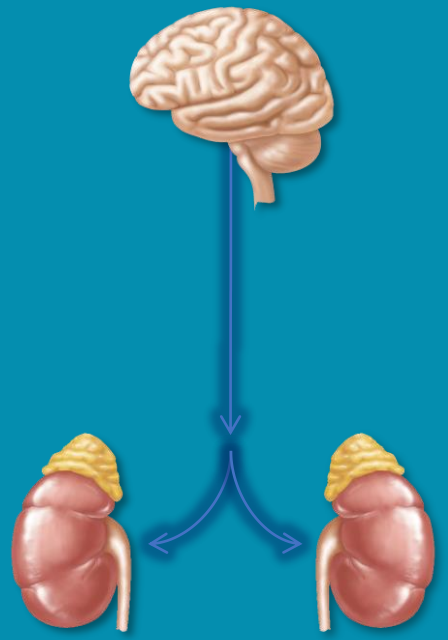
Renal Denervation Update

(RDN is not dead!!)

Cors at the Shore 2023

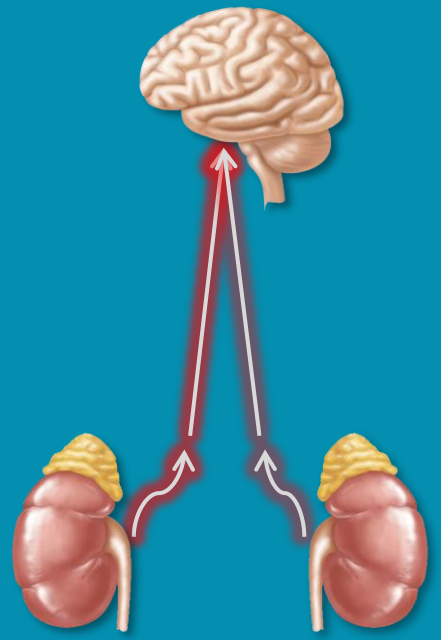
Renal Nerves and the SNS

Effect of Efferent Renal Nerves on Sympathetic Activity



Sympathetic signals
from the CNS
modulate the physiology of the kidneys

Effect of Afferent Renal Nerves on Sympathetic Activity



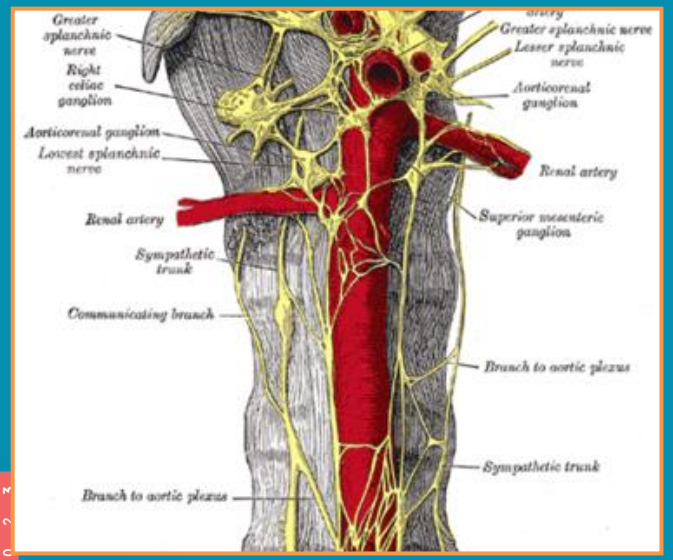
The kidney is a source of
central sympathetic activity,
sending signals to the CNS

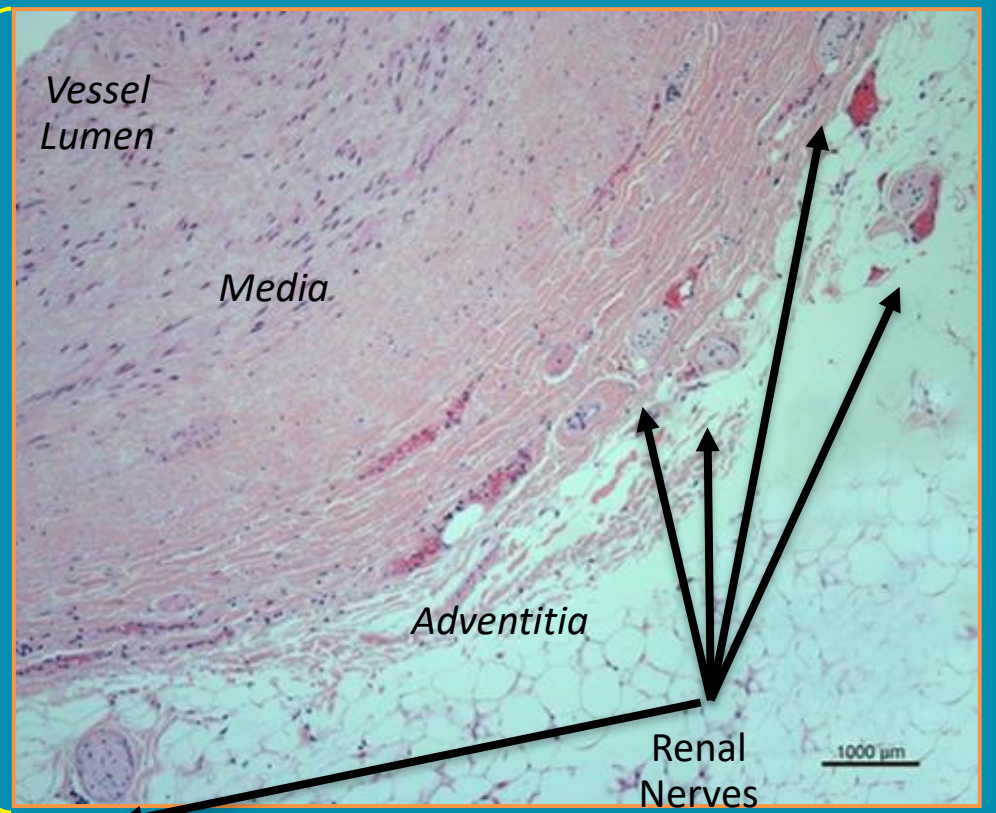
Cors at the Shore 2023

Adapted from Schlaich MP, et al. *Hypertension*. 2009;54:1195-1201.

Targeting Renal Nerves

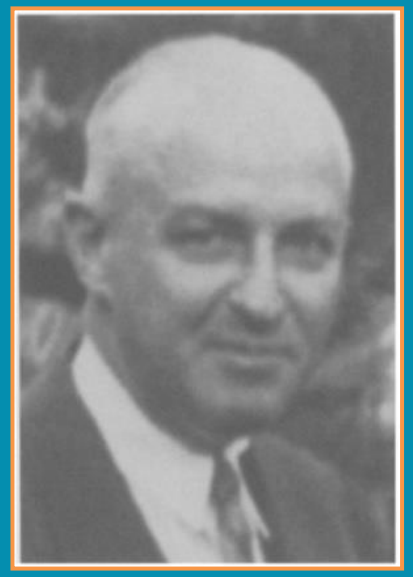
- Nerves arise from T10-L2
- The nerves arborize around the artery and primarily lie within the adventitia





Shore

Sympathectomy: An Early Surgical Option



Dr. Reginald H. Smithwick

THE JOURNAL

of the American Medical Association

Published Under the Auspices of the Board of Trustees

VOL. 152, NO. 16 — CHICAGO, ILLINOIS — AUGUST 15, 1953

SPLANCHNICECTOMY FOR ESSENTIAL HYPERTENSION

RESULTS IN 1,266 CASES

Reginald H. Smithwick, M.D.
and
Jesse E. Thompson, M.D., Boston

THE BRITISH JOURNAL OF SURGERY

1952

SYMPATHECTOMY IN THE TREATMENT OF BENIGN AND MALIGNANT HYPERTENSION*

A REVIEW OF 76 PATIENTS

BY C. J. LONGLAND AND W. E. GIBB

THE EFFECTS OF PROGRESSIVE SYMPATHECTOMY ON BLOOD PRESSURE

BRADFORD CANNON

From the Laboratories of Physiology in the Harvard Medical School

Received for publication March 24, 1931

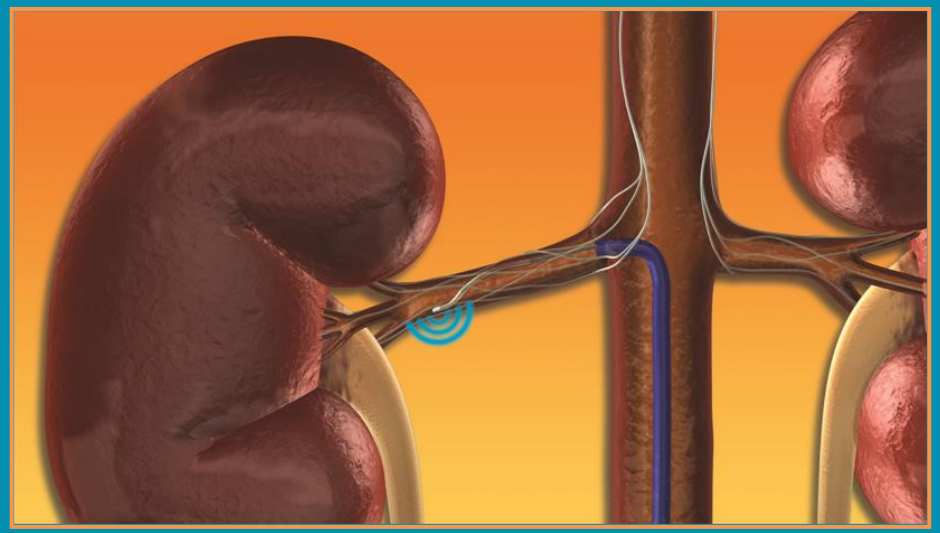
Cors at the Shore 2023

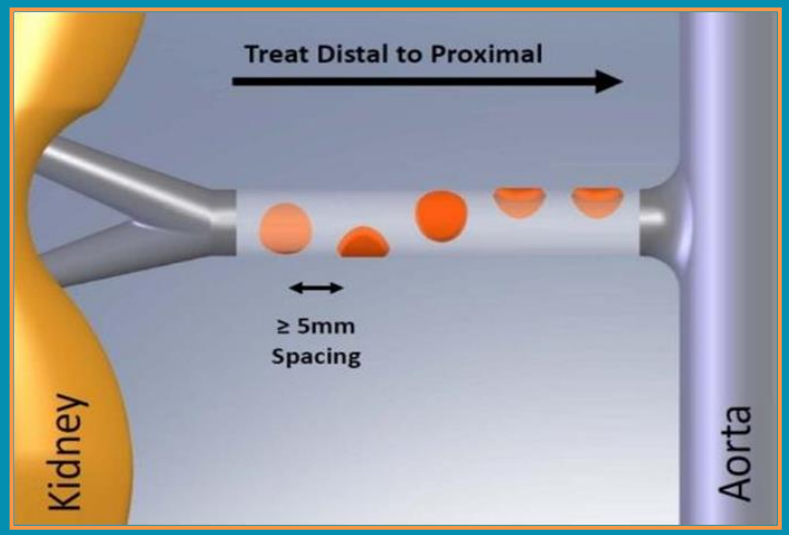
Photo of Dr. Smithwick reproduced with permission from *JAMA*.

Simplicity HTN 1

- 1st in man feasibility study
- Initial cohort of 50, expanded to 153

Catheter-Based Approach with RF Ablation: Simplicity Studies

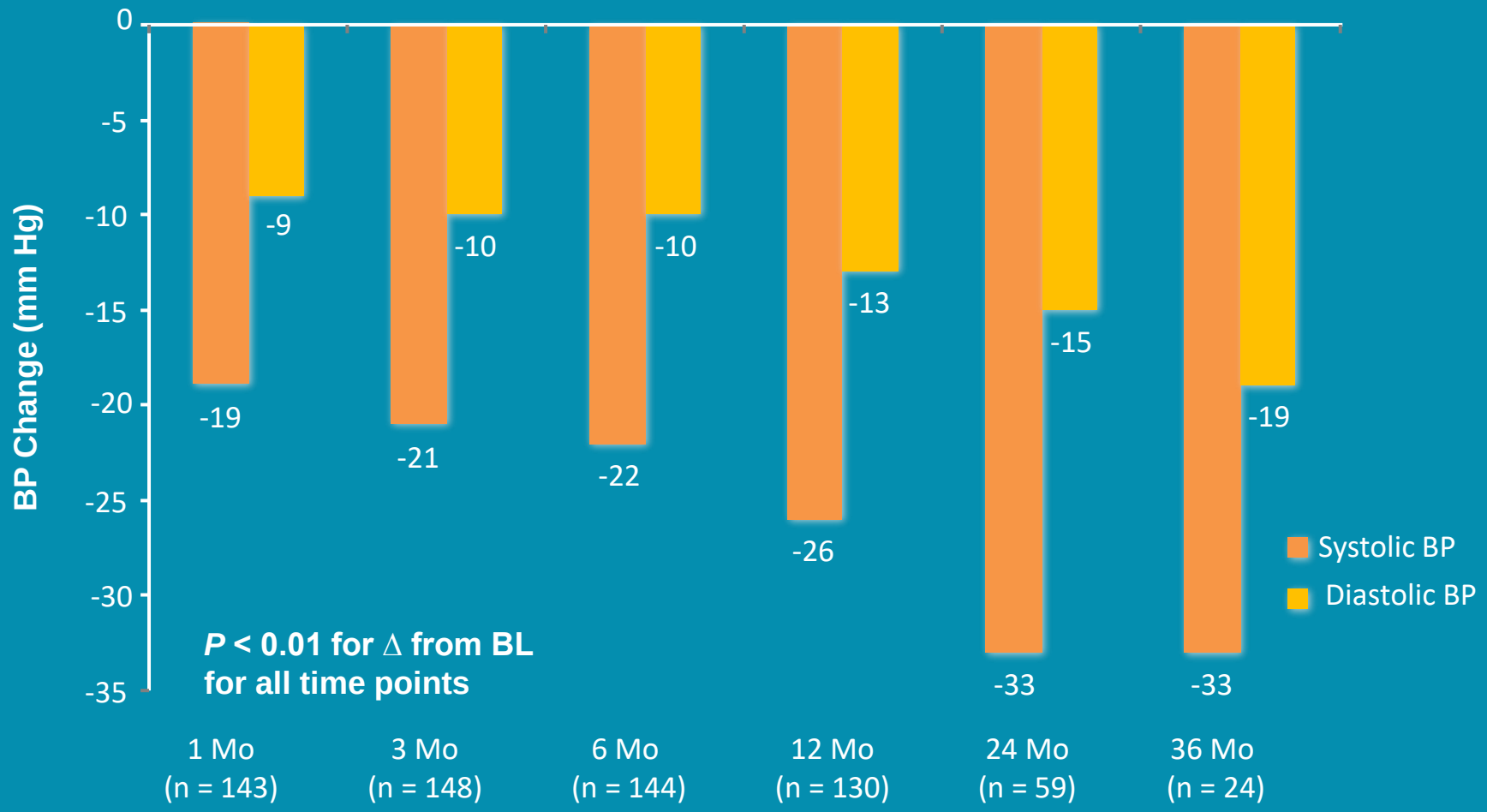




- Standard interventional technique
- 4-6 120-second treatments per artery

Cors at the Shore 2023

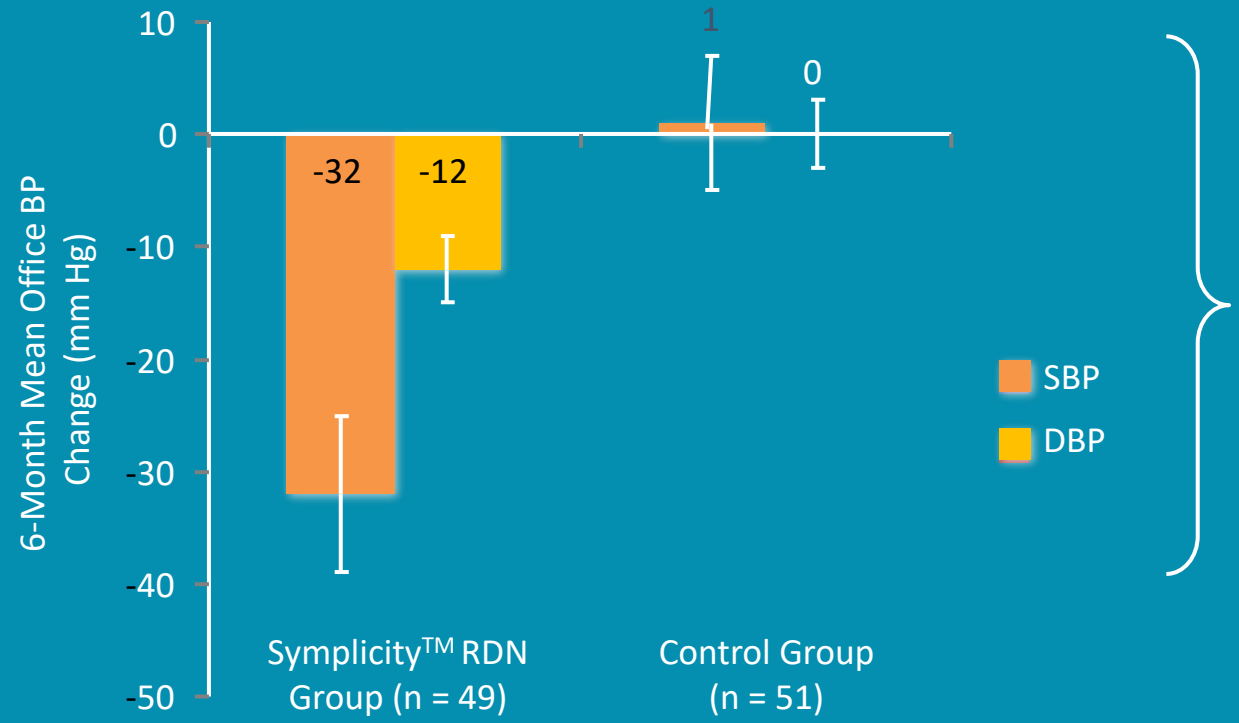
Symplicity HTN-1 Trial: 36-Month Results



Cors at the Shore 2023

Sobotka P. Symplicity HTN-1: Long-term follow-up of catheter-based renal sympathetic denervation for resistant hypertension confirms durable blood
pressure reduction. Presented at: ACC.12 61st Annual Scientific Session & Expo; March 25, 2012. Chicago, IL.

Symplicity HTN-2 Trial: 6-Month Office BP* (Primary Endpoint)



33/11 mm Hg difference between Symplicity™ RDN and control groups ($P < 0.0001$ for SBP and DBP)

- 84% of patients in the RDN group had ≥10 mm Hg reduction in SBP
- 10% of patients in the RDN group had no reduction in SBP

Cors at the Shore 2023

*Error bars represent 95% CIs.

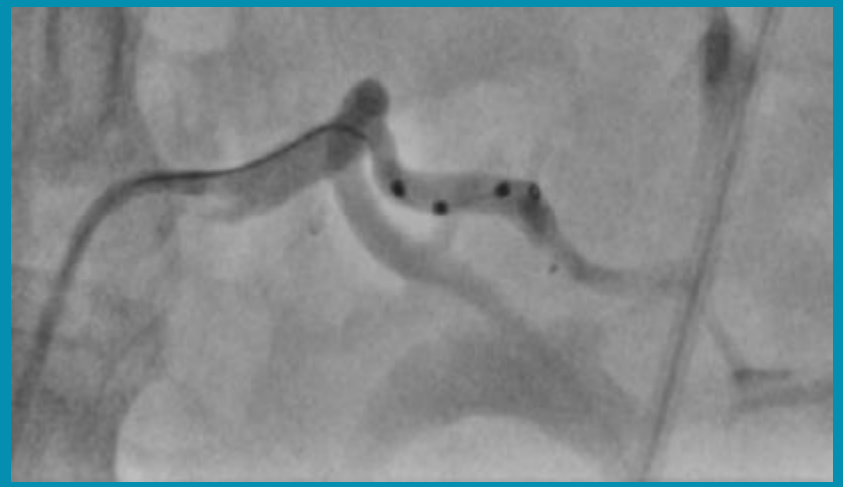
Symplicity HTN-2 Investigators. *Lancet*. 2010;376:1903-1909.

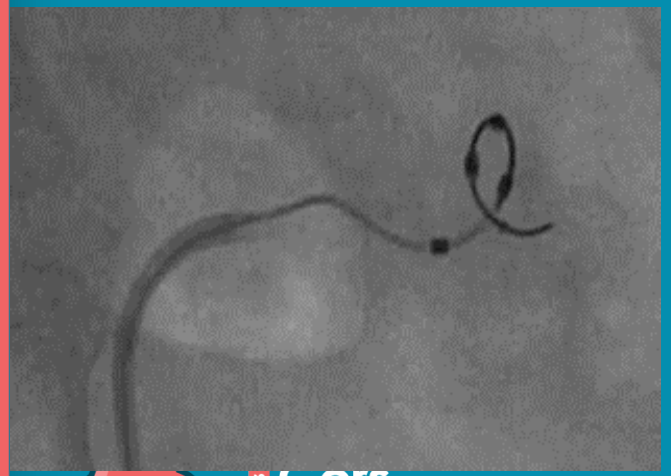
Simplicity 3: Results of 1 & 2 not Reproducible: Lessons Learned

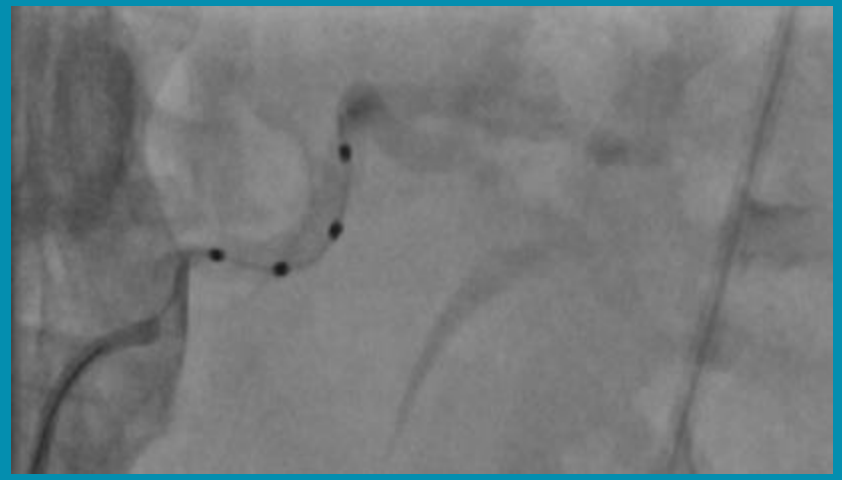
- Need Improved Technology
  - Better understanding of renal nerve anatomy
  - Robust preclinical science
- Need Reproducible Procedures
  - Safe, easy access, reduced operator variability
  - Consistent denervation
- Need Robust Clinical Study Design
  - Standardization of BP measures
  - Standardization of medication management
  - Need improved understanding of patient selection

New catheter design to reduce procedural variability

- **The Symplicity Spyral™ Catheter replaced the SYMPLICITY™ FLEX catheter**



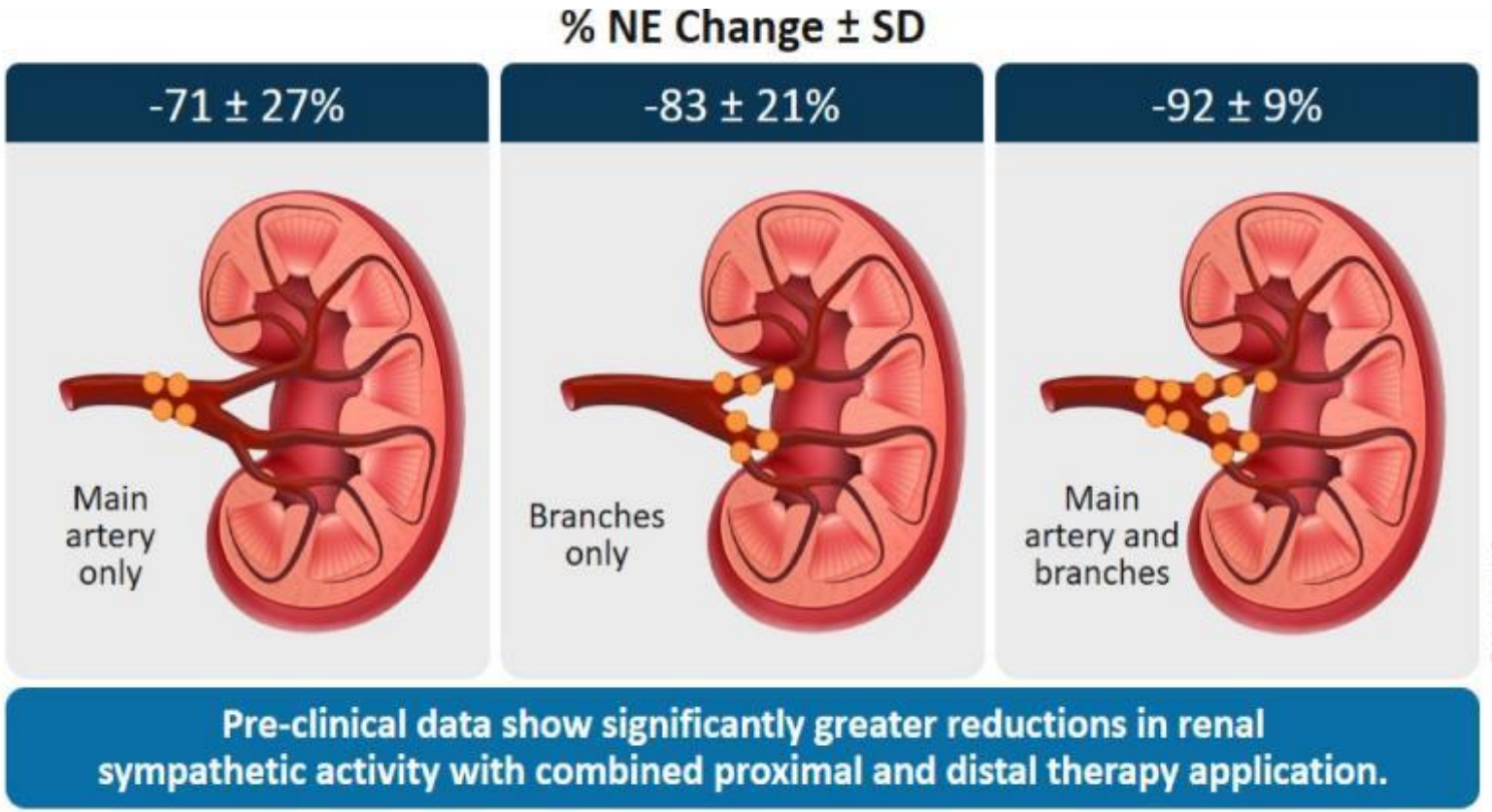




- **Unique design automatically positions electrodes to generate 360-degree ablations**
  - Consistent, repeatable four-quadrant ablation pattern
  - 60-second simultaneous energy delivery
  - Temperature and impedance feedback to control energy delivery
- **RF energy is delivered to the renal nerves through the artery wall, preferentially heating perivascular adipose tissue**
- **Vessel diameter range: 3–8 mm**
  - Able to treat distal main renal artery and its branches
- **Convenient to use**
  - 6 F guide catheter compatible
  - 0.014” rapid exchange delivery

SPYRAL HTN

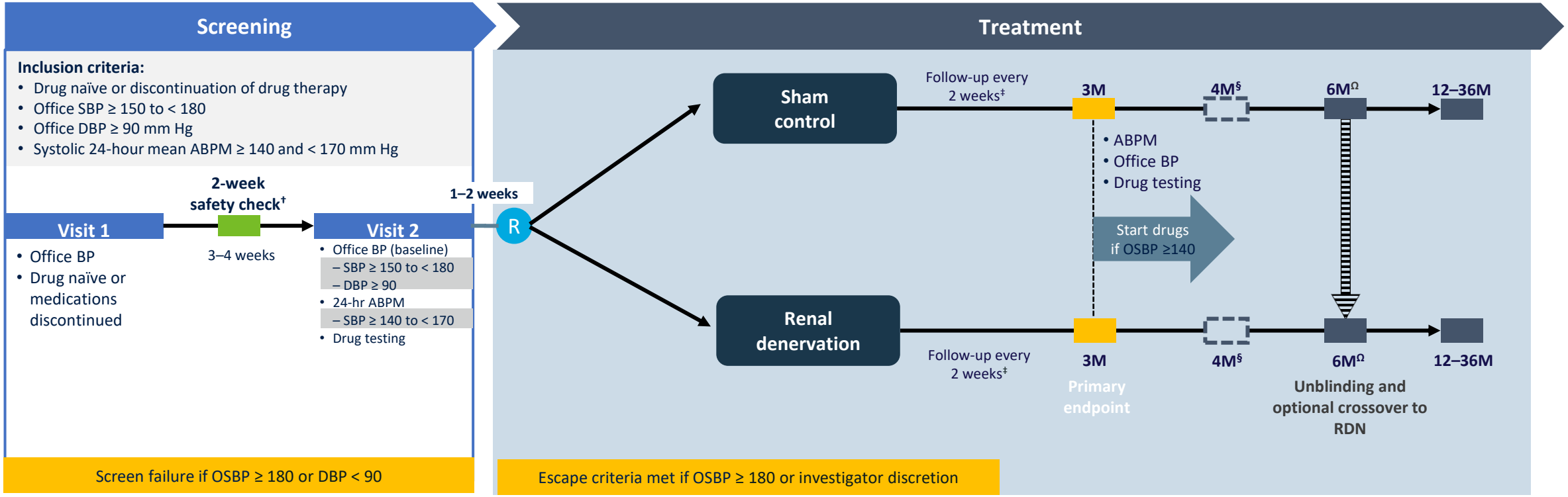
- Treatment of main artery, distal branches, and Accessories



Note: Preclinical data may not be representative of human data.
Mahfoud F, et al. *J Am Coll Cardiol*. 2015;66:1766-1775.

SPYRAL HTN-OFF MED pivotal trial

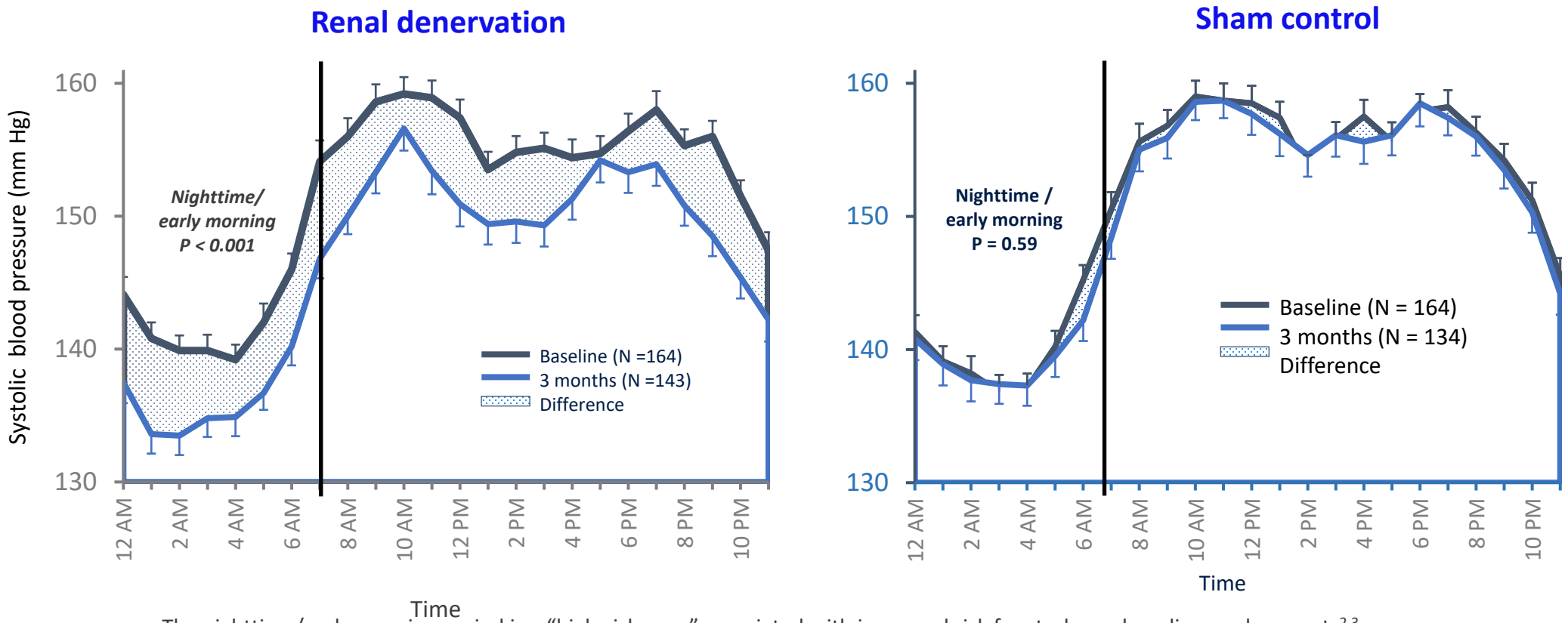
- **Randomized, sham-controlled trial**



- †Only for patients discontinuing antihypertensive medications.
- ‡Optional follow-up at weeks 6 and/or 10 if the patient is not controlled.
- §Only for patients with BP ≥ 140 mm Hg at 3 months.
  Ω6- and 12-month renal imaging.
- NCT02439749
- [1] Böhm M, et al. *Clin Res Cardiol*. 2020;109:289-302. Erratum in: Böhm M, et al. *Clin Res Cardiol.* 2020;109:653.

RDN demonstrated an “always on” effect on 24-hour BP lowering[1]

- **Spyral HTN-OFF MED pivotal: 24-hour systolic ABPM trend at 3 months**

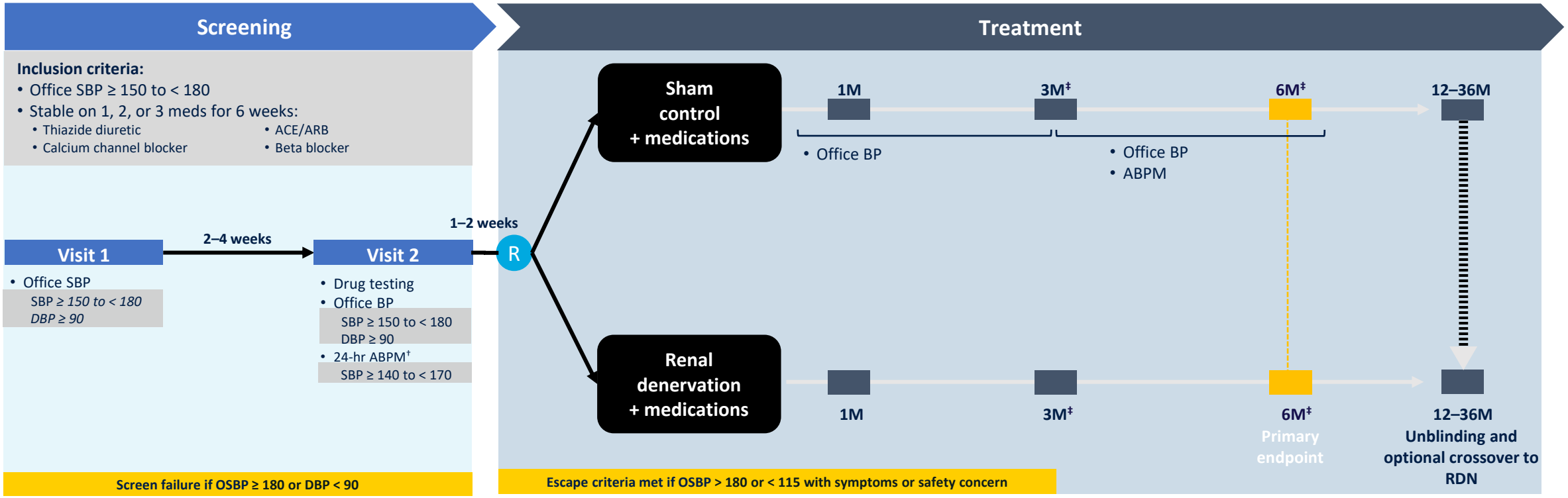


The nighttime/early morning period is a “high-risk zone” associated with increased risk for stroke and cardiovascular events[2,3]

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

SPYRAL HTN-ON MED pilot study design

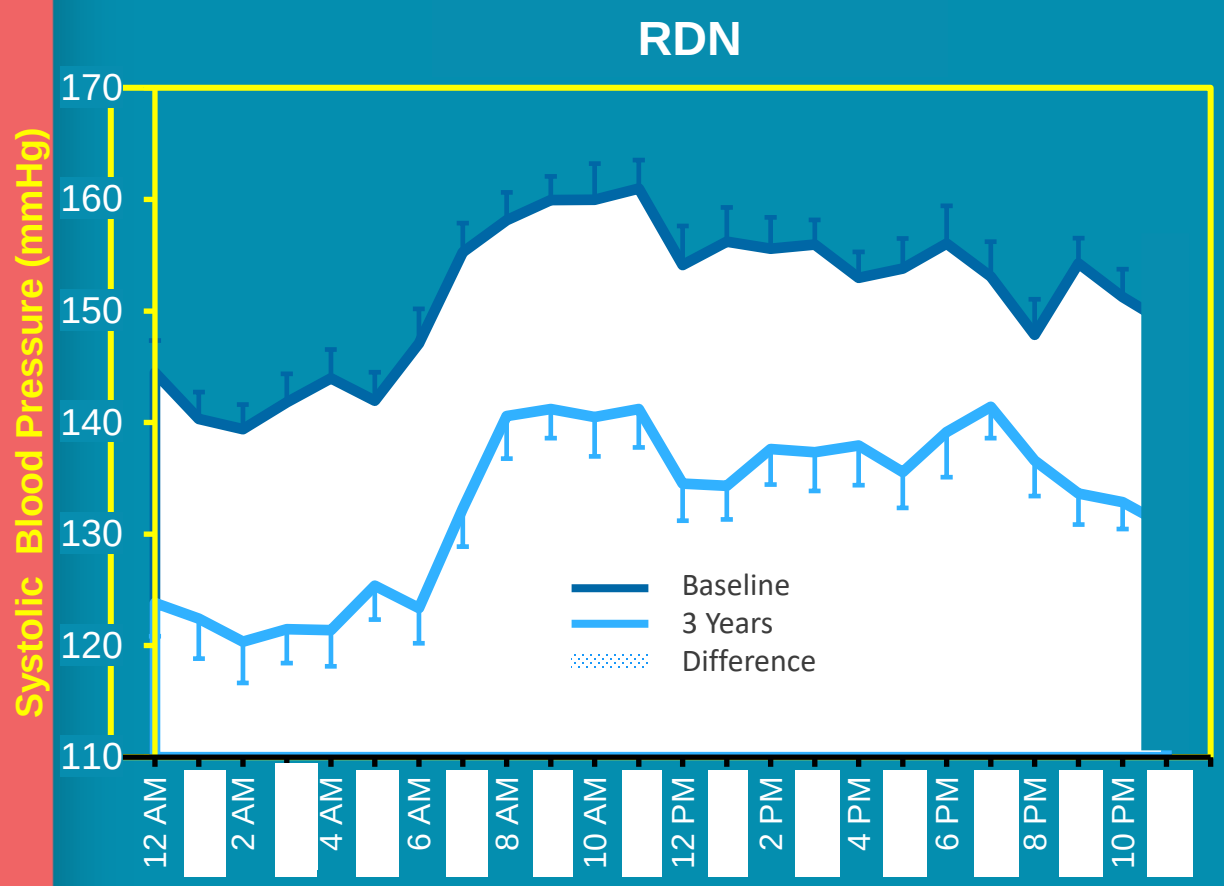
- **Randomized, sham-controlled trial[1]**

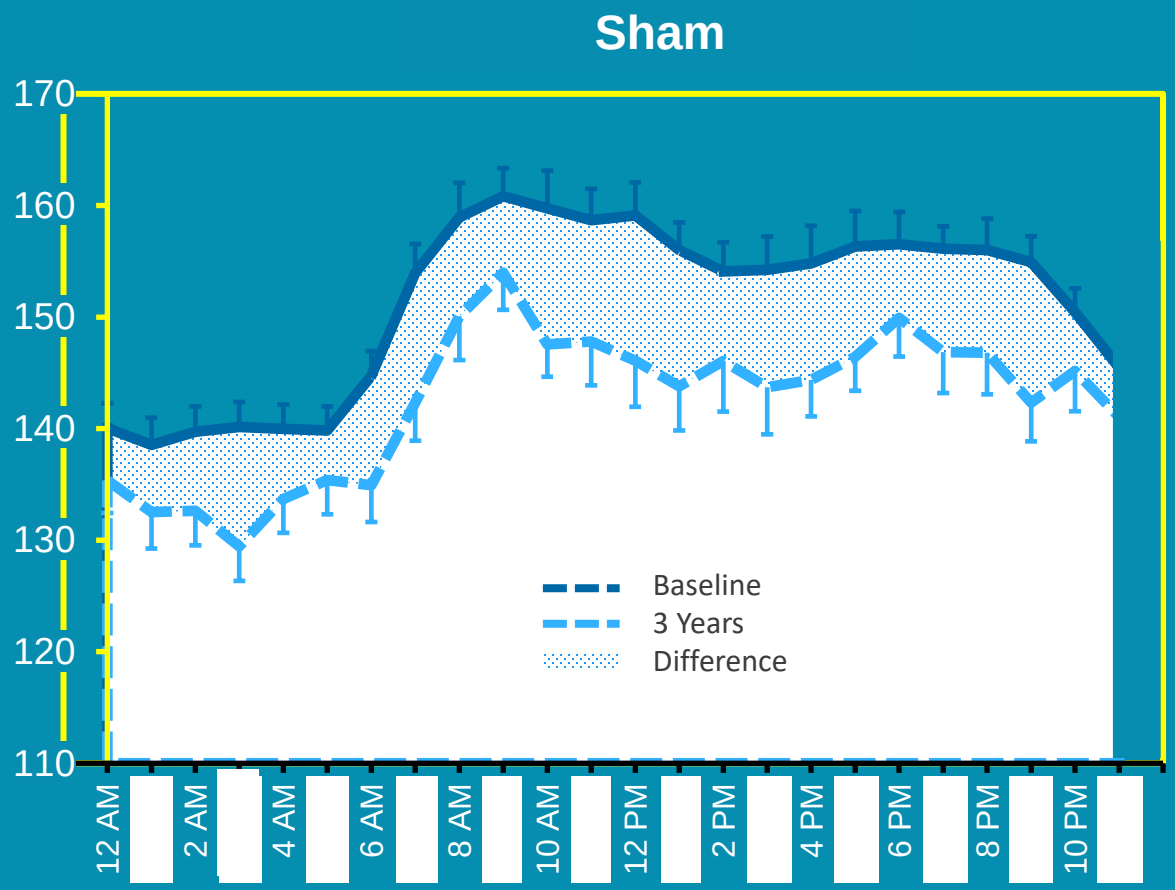


- †Measurement started after witnessed drug ingestion.
- ‡Drug testing.
- NCT02439775.
- [1] Kandzari DE, et al. *Am Heart J*. 2016;171:82–91.

RDN demonstrated an “always on” effect on 24-hour BP lowering

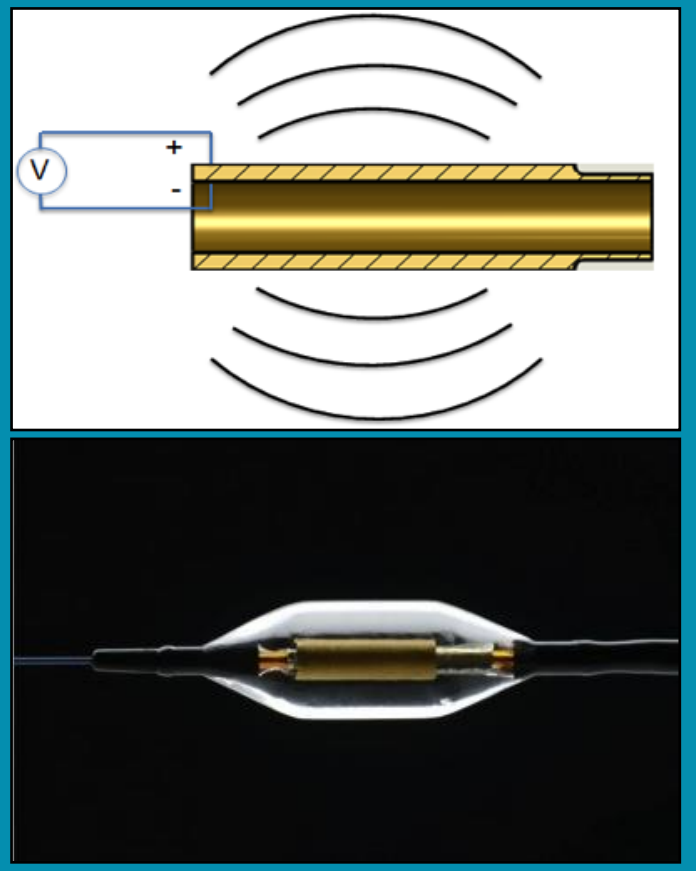
- Baseline and 3 Years





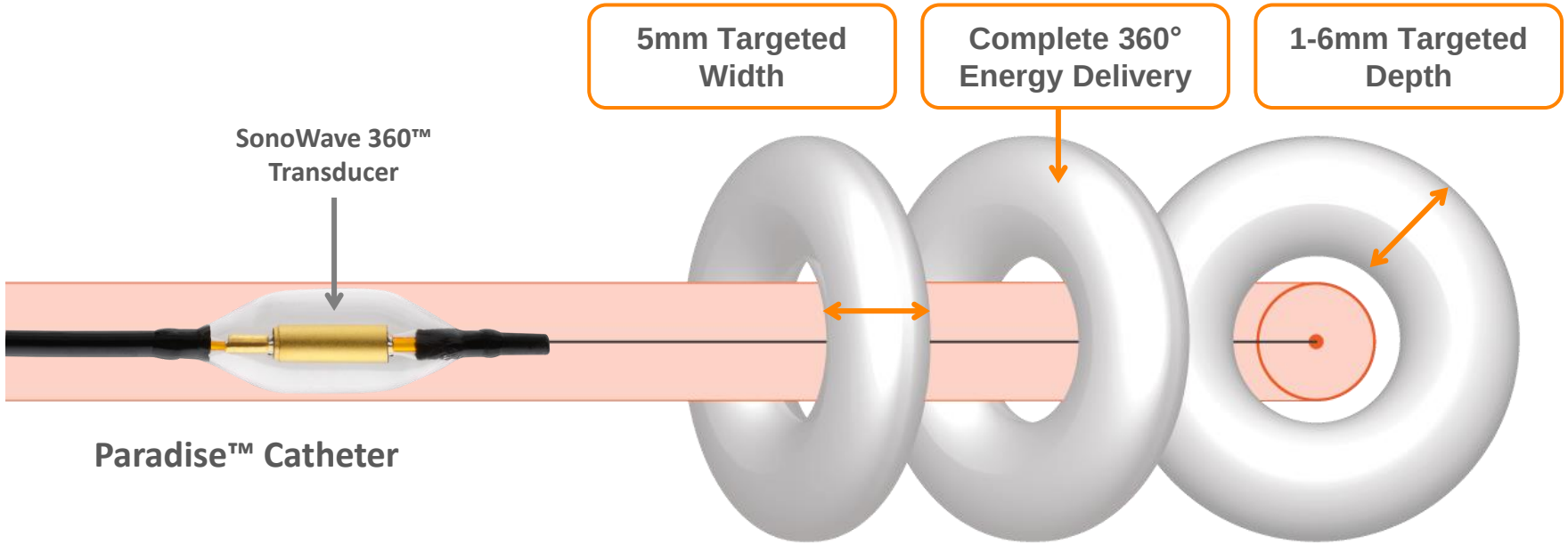
Ultrasound Technology for Renal Denervation

- Therapeutic ultrasound energy consists of high-frequency sound waves that generate frictional heating in soft tissues
  - Direct tissue contact with the ultrasound source is not required for energy transmission
- Cylindrical ultrasound source creates uniform toroidal lesions
- Piezoelectric Ultrasound Transducer
  - expands and contracts when a voltage is applied, create acoustic pressure waves.
  - Acoustic pressure waves generate heat in tissue.



Paradise (ReCor Medical) RDN System

Complete 360° energy delivery in single sonication to target 5mm width and 1-6mm depth



CIRCUMFERENTIAL SONICATION

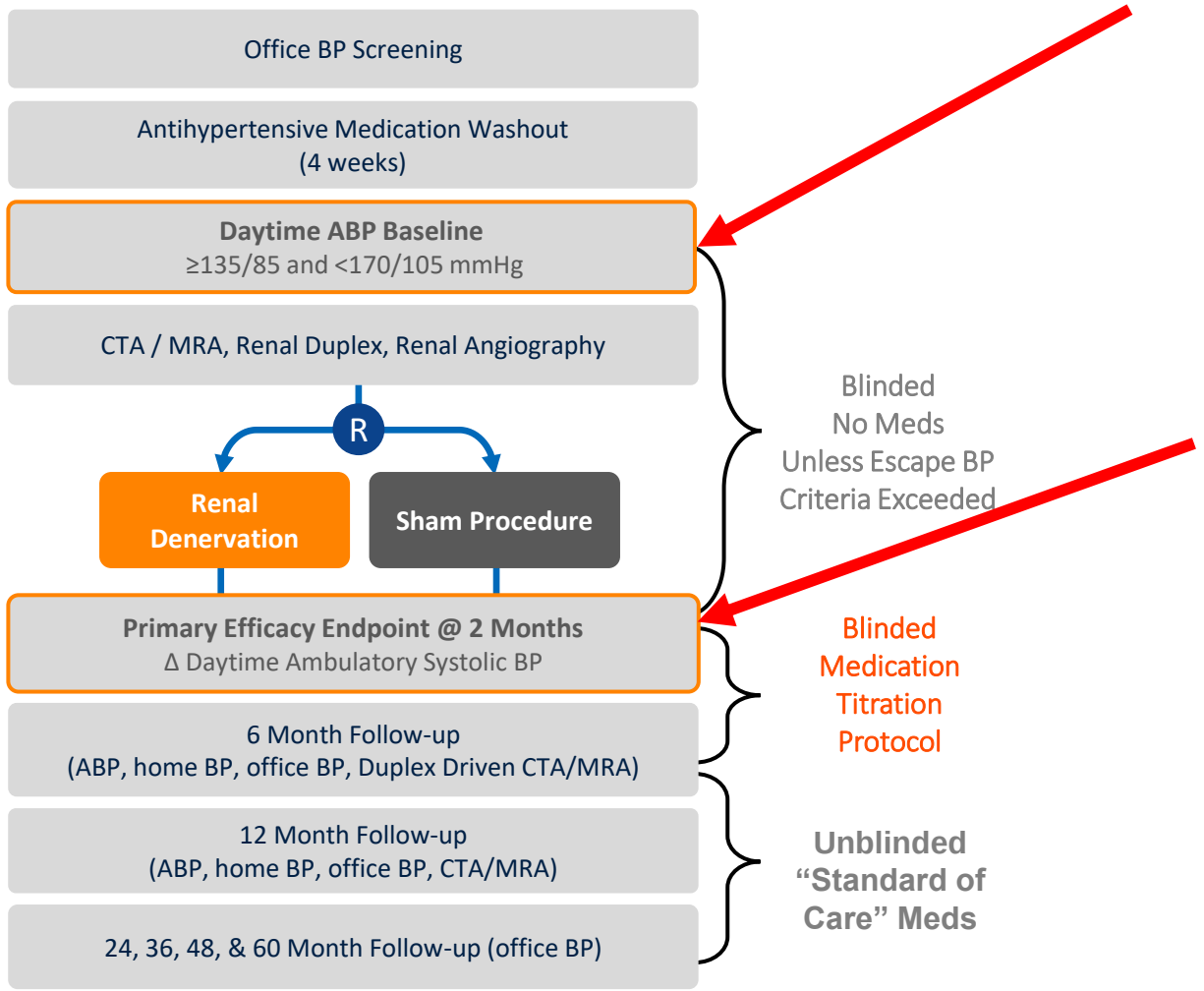
- Complete 360° energy delivery
- 1-6mm targeted depth from the arterial wall
- 5mm targeted width

RADIANCE-HTN SOLO

Blinded, Sham-Controlled, Powered to Demonstrate BP Lowering Effectiveness at 2M.

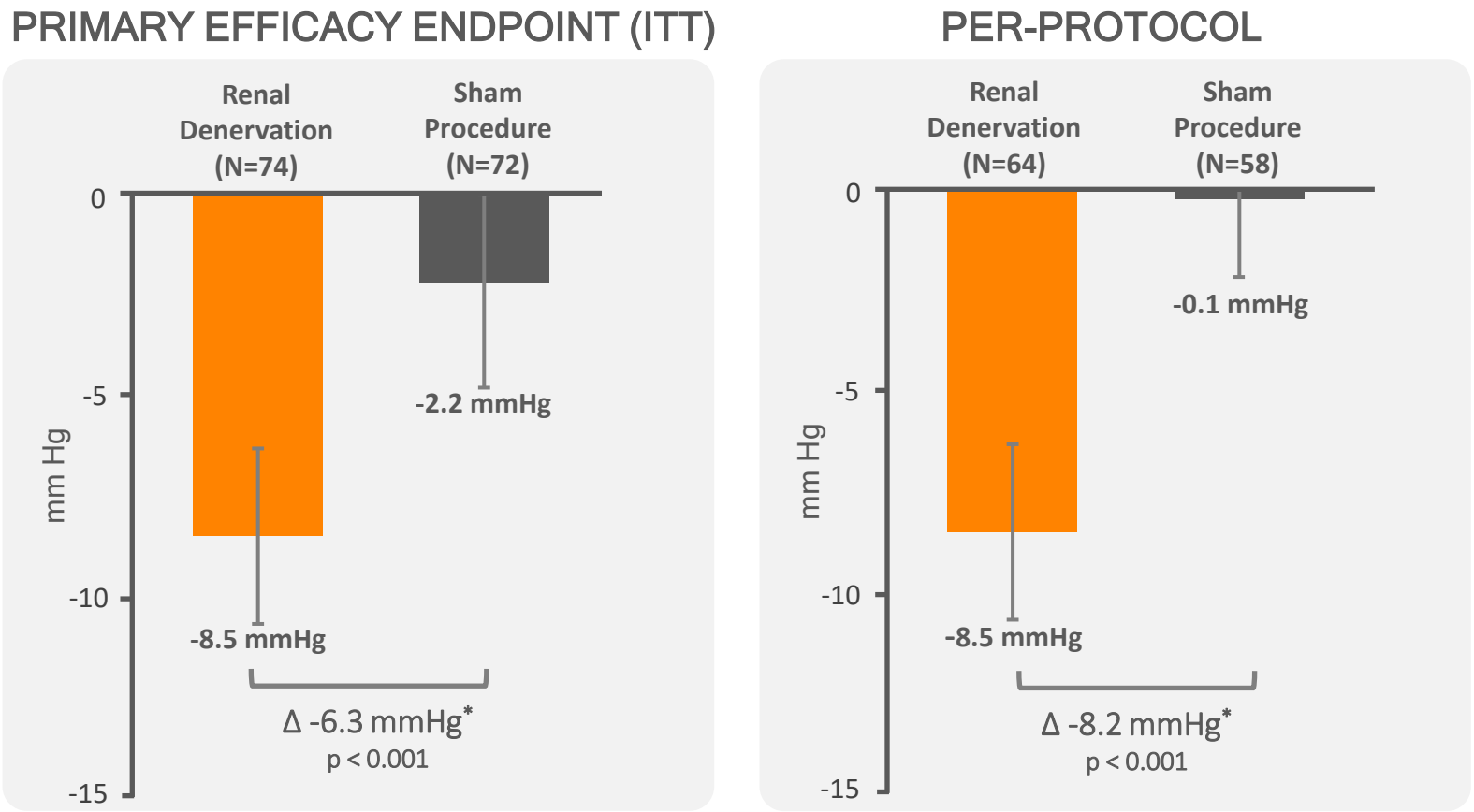
Key Entry Criteria:

- **Hypertension controlled on 1-2 anti-HTN meds or uncontrolled on 0-2 meds**
- Off-medication daytime ABP ≥135/85 and <170/105 mmHg
- Age 18-75 years
- No prior cardiovascular or cerebrovascular events
- No Type I or uncontrolled Type II diabetes
- eGFR ≥40mL/min/m^2
- Eligible renal artery anatomy (bilateral diameter 4-8mm, length ≥25mm, and no stenosis ≥30%)



RADIANCE-HTN SOLO Primary Endpoint

Change in Daytime Ambulatory Systolic BP at 2 Months



8.5 mmHg reduction in ABP in the RDN group at 2 months

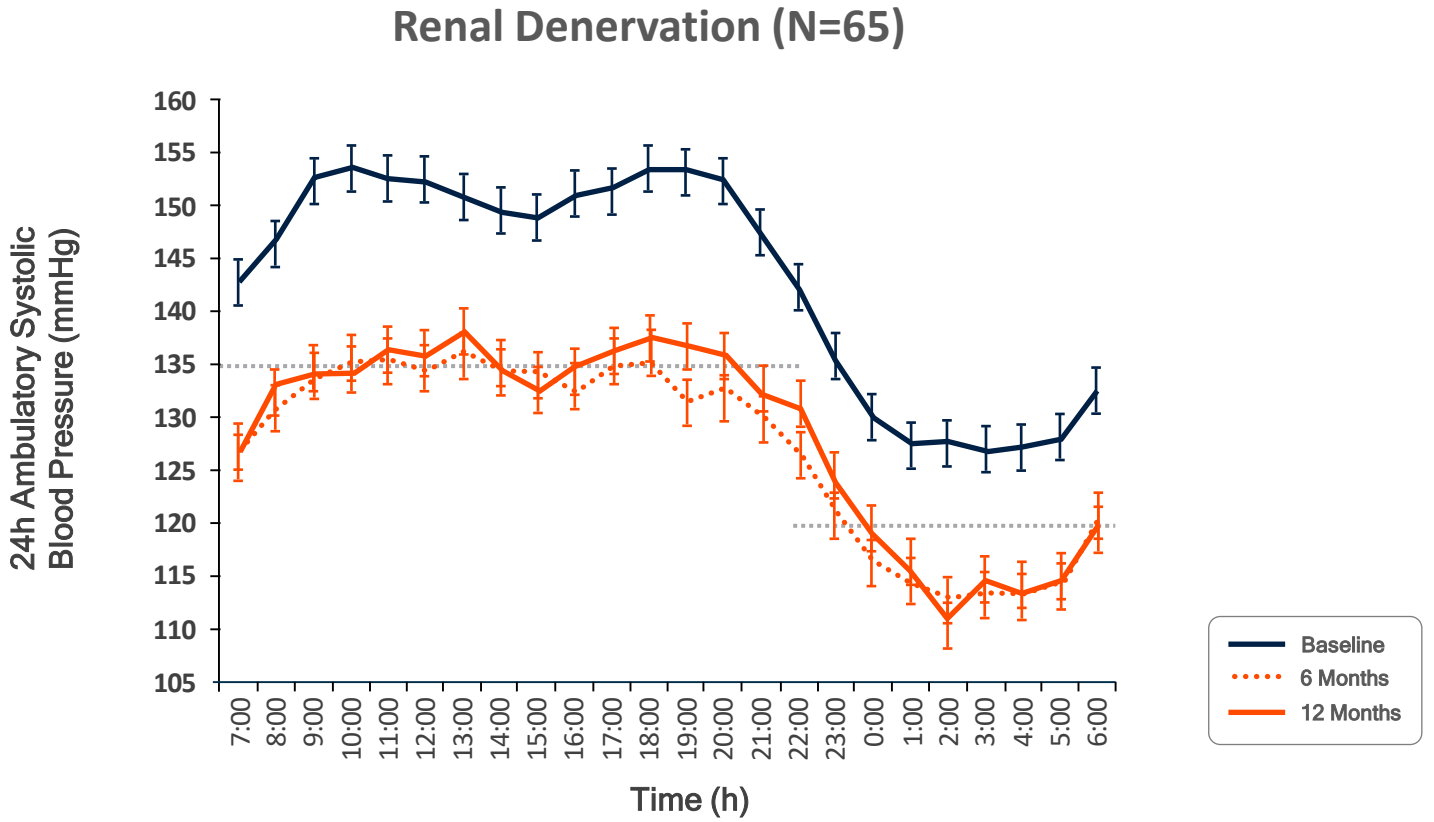
* Between group difference adjusted for baseline blood pressure

Azizi et al. *Lancet*. 2018 Jun 9;391(10137):2335-2345.

RADIANCE-HTN SOLO – Durable Efficacy

Change in 24h ABPM Systolic BP at 12 Months

No adverse safety signals @ 12 mo



Reduction in Ambulatory SBP from Baseline was Sustained at 12 months

Azizi et al. *JACC Cardiovasc Interv*. Dec 28;13(24):2922-2933.

ACHIEVE Study Overview

Single-arm on med

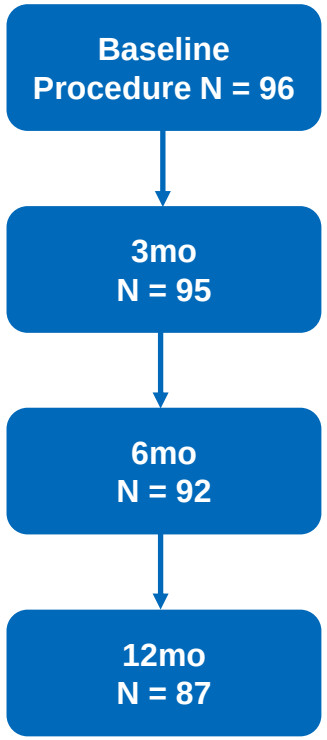
Key Entry Criteria:

- **Uncontrolled hypertension on 3+ medications including a diuretic**
- Age ≥ 18
- Systolic ABP ≥ 130 mmHg and office systolic BP ≥ 160 mmHg
- Renal arteries 4-8 mm diameter & ≥ 20 mm length
- No pre-existing renal stenosis
- Moderate and severe renal insufficiency excluded

Outcomes:

Follow-ups at 3, 6, and 12 months

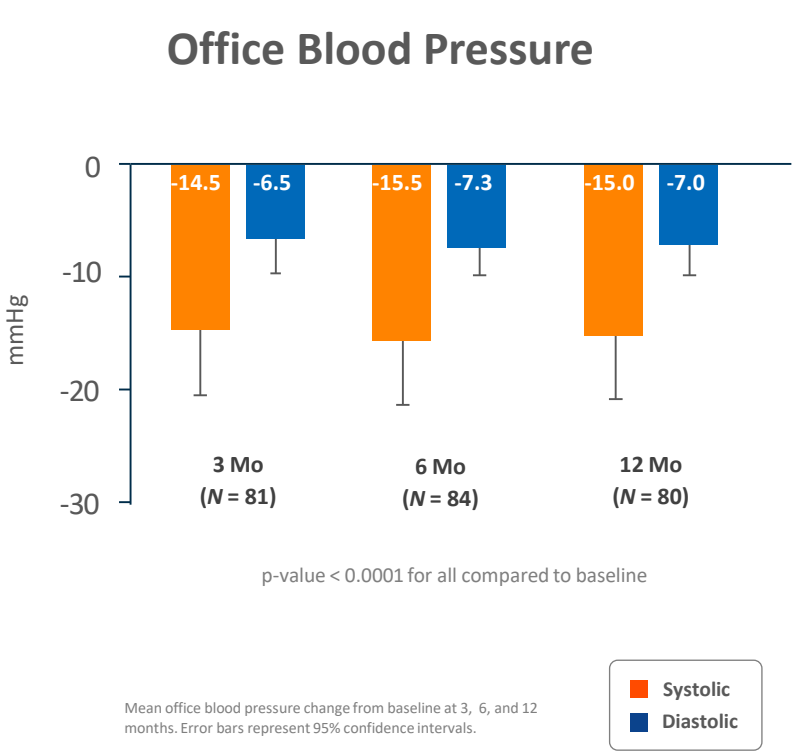
- Office BP
- 24-hour Ambulatory BP
- BP Medications

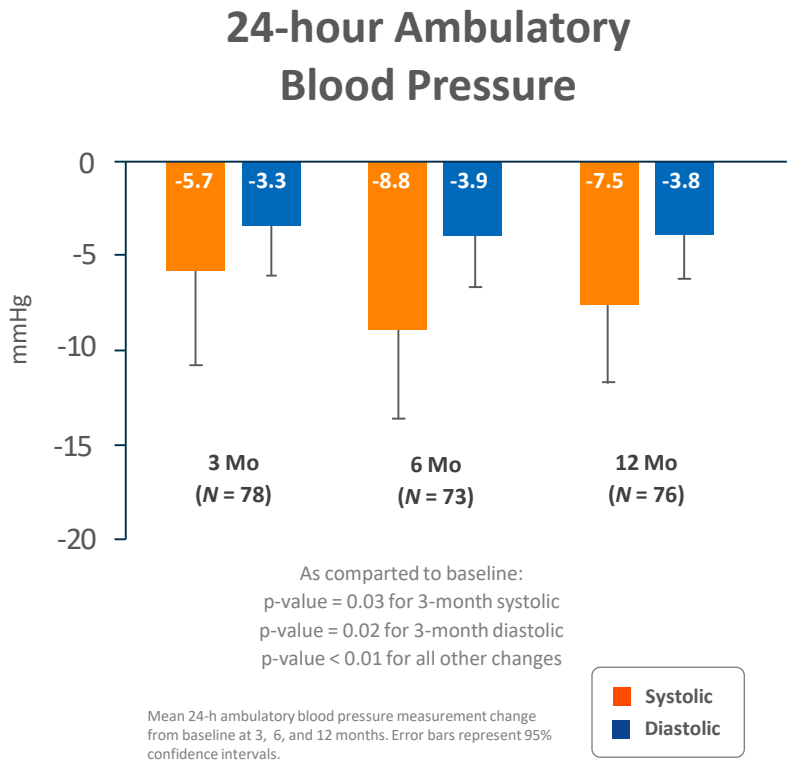


ClinicalTrials.gov Identifier: NCT01789918

Daemen et al. *J Hypertens*. 2019 Sep;37(9):1906-1912.

ACHIEVE - Durable Efficacy





ACHIEVE Study demonstrated 12-month durable efficacy

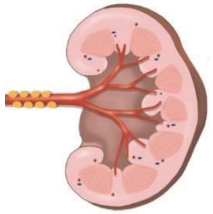
Daemen et al. *J Hypertens*. 2019 Sep;37(9):1906-1912.

RADIOSOUND-HTN

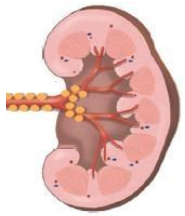
Study Overview

Prospective, single blind, single center, randomized trial

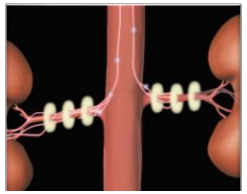
1. Radiofrequency Main Renal Artery Ablation



2. Radiofrequency Main and Branch Renal Artery Ablation

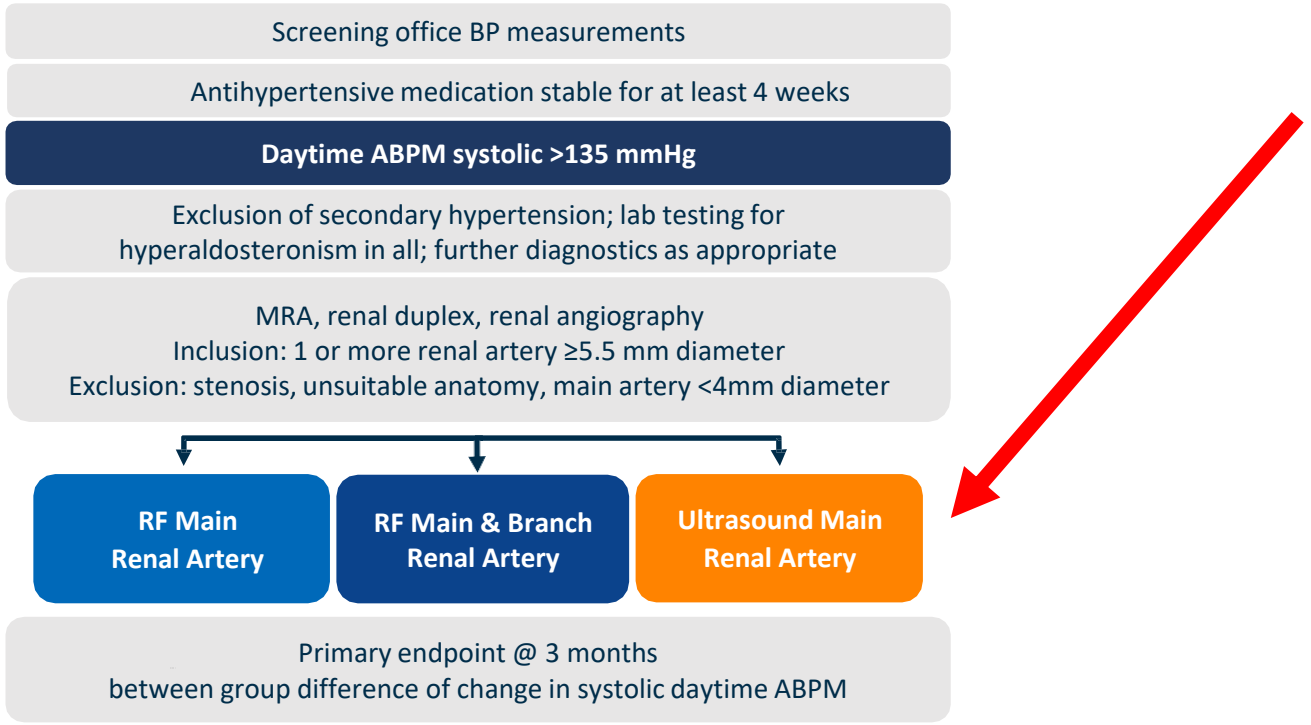


3. Ultrasound Main Renal Artery Ablation



Objective: To compare the effects of renal denervation using 3 treatments in patients with resistant hypertension

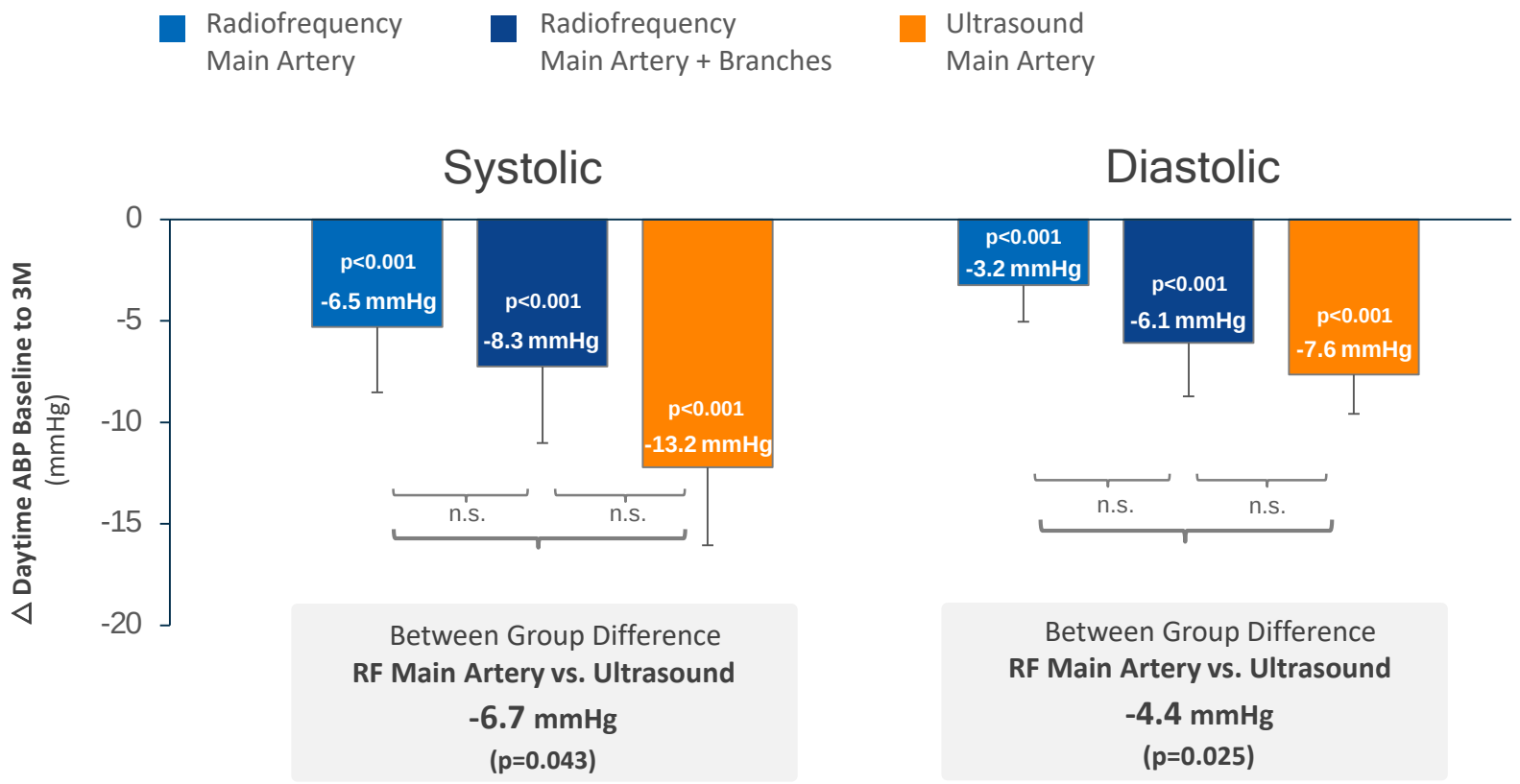
- DESIGN: Prospective, single-blind, single-center, three-arm randomized trial (1:1:1)
- POPULATION: Patients aged 18-75 years with resistant hypertension despite treatment with ≥3 drug classes at ≥50% maximum dosage including ≥1 diuretic
- PRIMARY ENDPOINT: Between-group difference in 3 Mo Δ in Daytime Systolic APBM



Fengler et al. *Circulation*. 2019 Jan 29;139(5):590-600.

RADIOSOUND-HTN

Primary Endpoint



Lurz et al. TCT 2018.

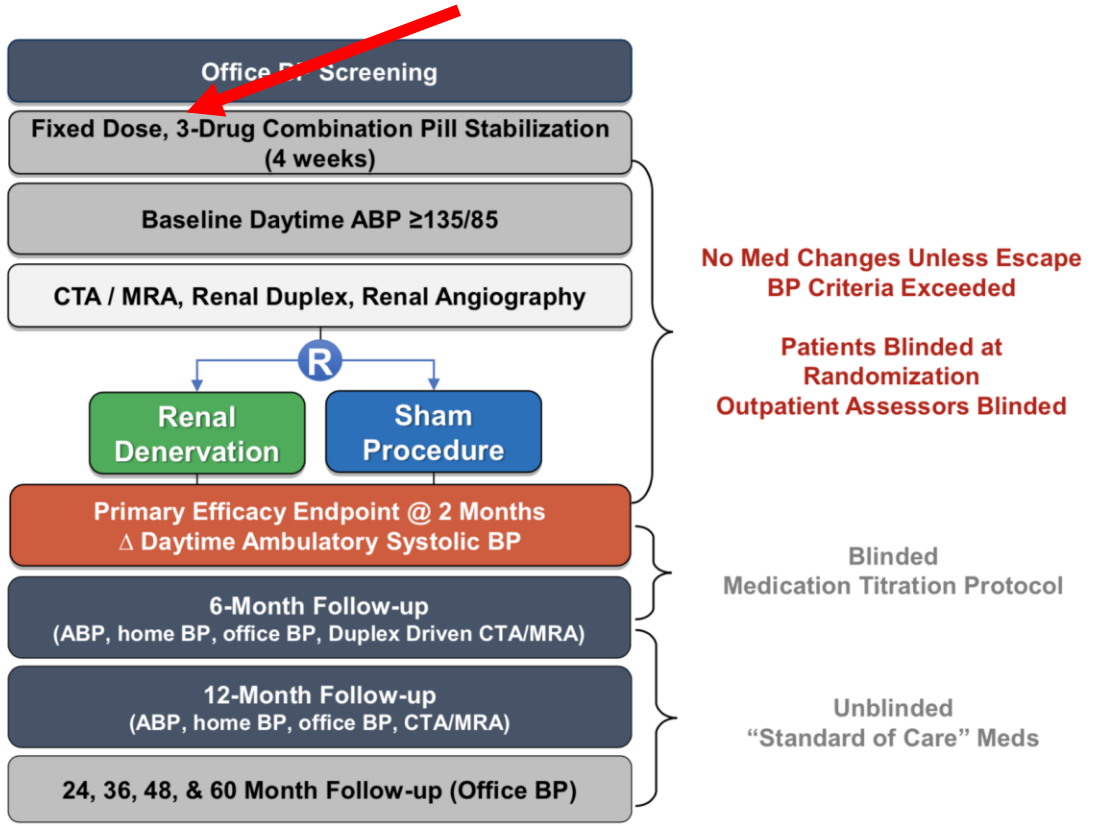
Fengler et al. *Circulation*. 2019 Jan 29;139(5):590-600.

Radiance Trio: ACC 2021: Ajay J Kitrane, MD

RADIANCE-HTN TRIO Design:
Blinded, Sham-Controlled, Powered to Demonstrate BP Lowering Effectiveness at 2M

Key Entry Criteria:

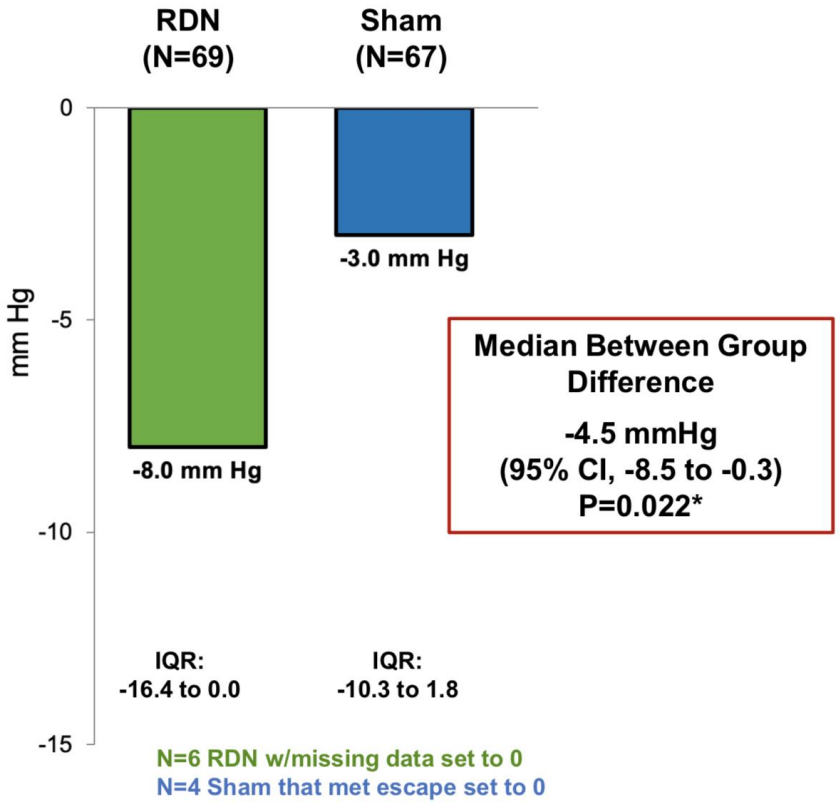
- Office BP ≥140/90 on 3+ anti-HTN meds
- Daytime ABP ≥135/85 on a fixed-dose, 3-drug combination pill
- Age 18-75 years
- No secondary hypertension aside from OSA
- No CV or cerebrovascular events within the prior 3M
- No Type I or uncontrolled Type II diabetes
- eGFR ≥40 mL/min/m^2
- Eligible renal artery anatomy



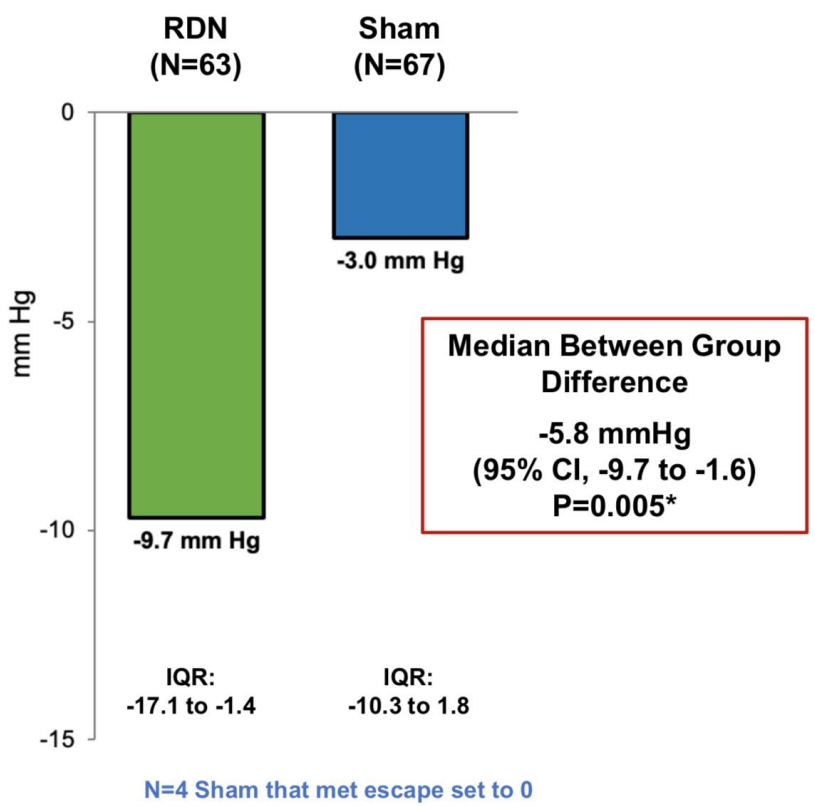
Cors at the Shore 2023

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

Intent-To-Treat Population



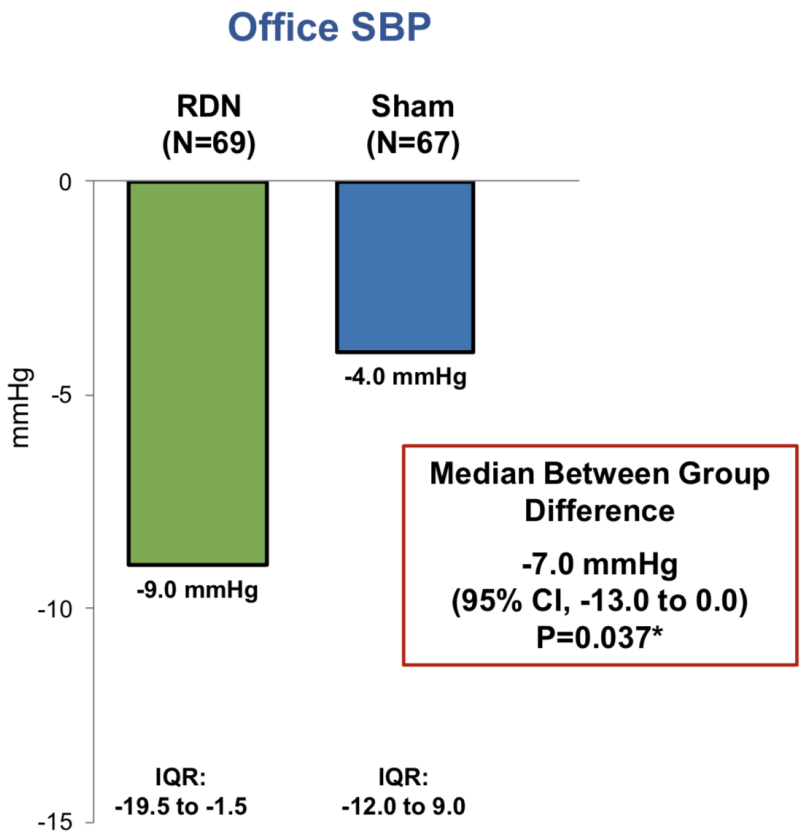
Complete ABPM Population

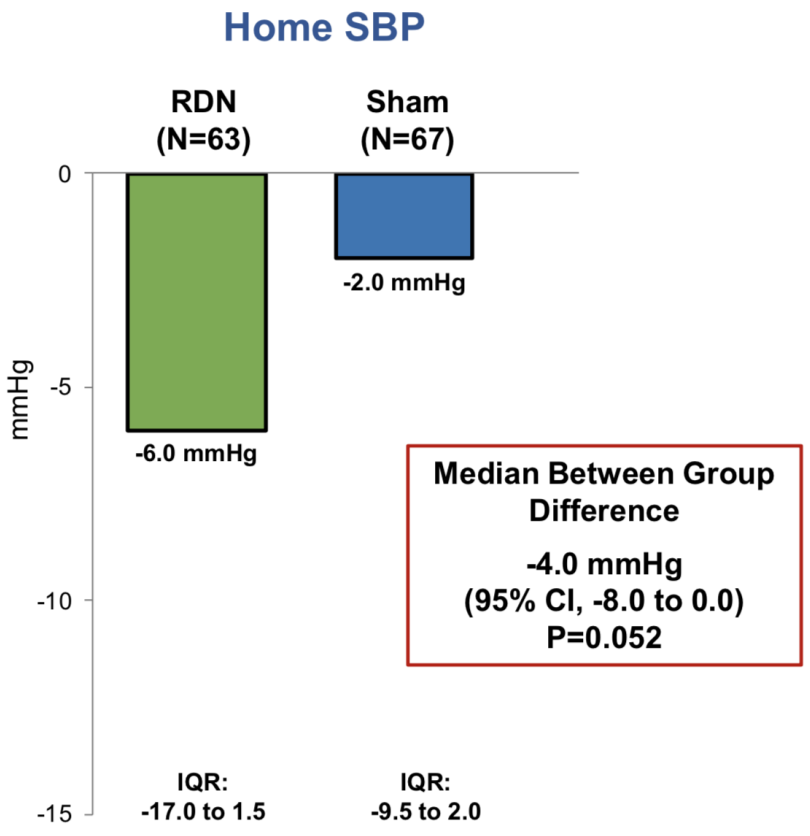


*Baseline-adjusted ANCOVA on the ranks due to non-normality of distribution

Cors at the Shore 2023

Change in Office and Home SBP at 2 Months





*Baseline-adjusted ANCOVA on the ranks due to non-normality of distribution

Putting These #s in Perspective:

- Most BP meds have received FDA approval for a reduction of only 2 mm Hg in their office or ambulatory BP measurements

Closing Thoughts

- Future studies testing the safety and efficacy of Renal Denervation are needed.
- The concept of renal denervation is sound. Better devices and recent studies have continued to demonstrate proof of concept.
- Comprehensive and global management of HTN remains an elusive target, but is absolutely essential for reduction in the incidence of cardiovascular events and mortality.
- Renal denervation appears to be at least as effective as pharmacologic therapy as a primary therapy, or at the very least as an adjunctive treatment for those with drug resistant or uncontrolled HTN

2023 Cors at the Shore

Thank You!

Cors at the Shore 2023

Deborah®

Guidelines Medical Therapy For Hypertension
(Where Does Renal Denervation Fit In)

Richard C Kovach, MD, FACC, FSCAI, FACP

Division Director, Interventional Cardiology
Medical Director, Cardiac Catheterization Laboratory
Assistant Director, Interventional Cardiology Fellowship Program
Deborah Heart and Lung Center, Browns Mills, New Jersey

Course Co-Director
NCVH-New Jersey

Associate Interventional Fellows Course Director
Cardiovascular Institute of Philadelphia

Cors at the Shore 2023