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Renal Denervation

What the Evidence Shows in 2026

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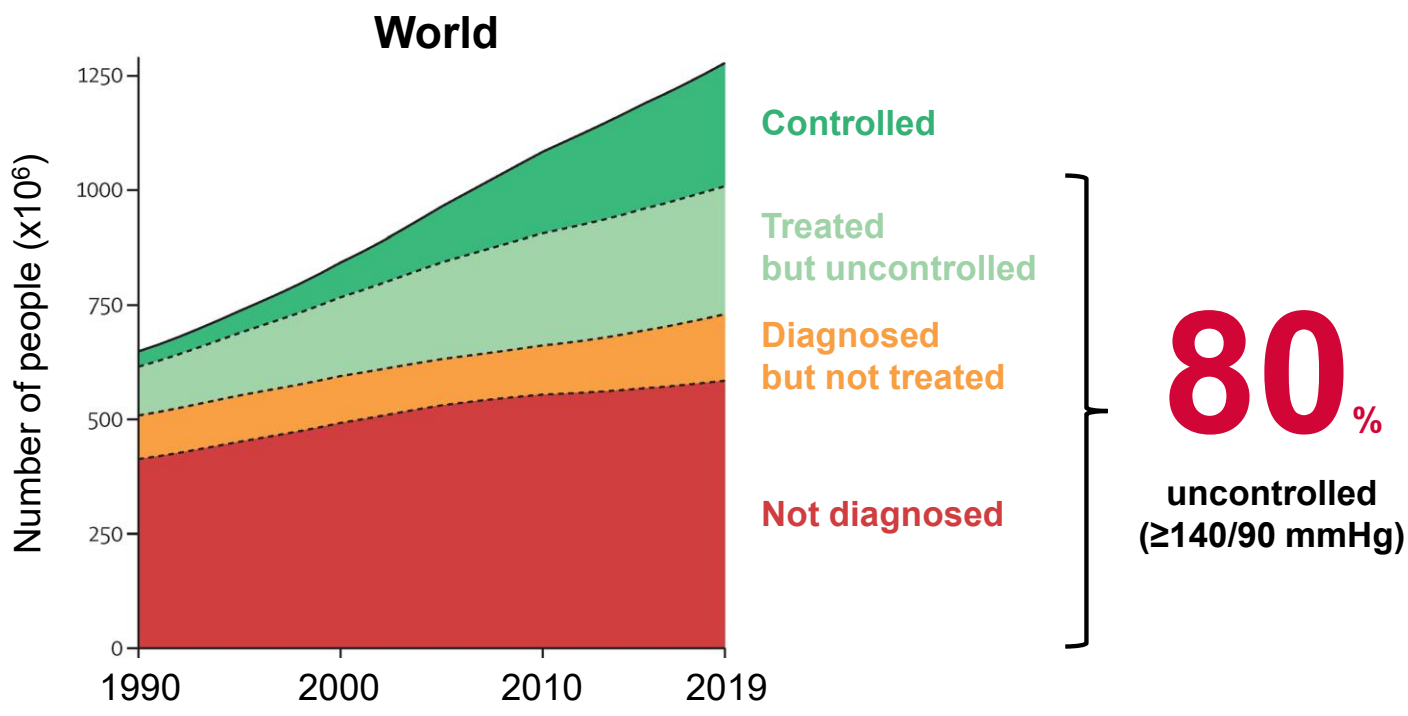
Disclosures

- **Speaker honoraria**
  - AstraZeneca, Medtronic, Novo Nordisk, Pfizer, Recor Medical, Sanofi, Servier
- **Consulting fees**
  - AstraZeneca, Biosensors International, Idorsia, Medtronic, Pfizer, Recor Medical
- **All payments were made to the institution**

- **Non-financial interests**
  - Nucleus member, ESC Council on Hypertension
  - Co-author, 2024 ESC Guidelines for the management of elevated blood pressure and hypertension
  - Deputy chair/ chair elect, DGK Working Group on Hypertension
  - Co-chair, ESH Working Group on Device-Based Therapies for Hypertension

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Four in Five People With Hypertension Are Uncontrolled

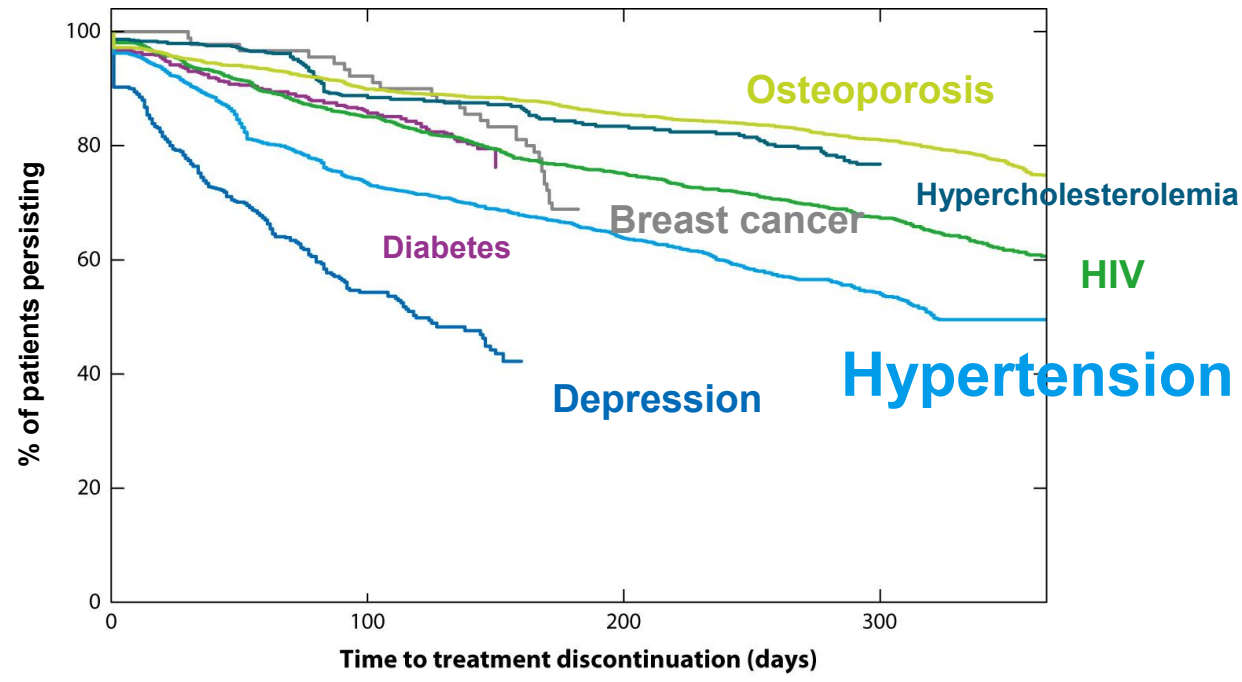


NCD Risk factor collaboration. Lancet. 2021;398:957-980.

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Persistence With Antihypertensive Drugs Declines Over Time

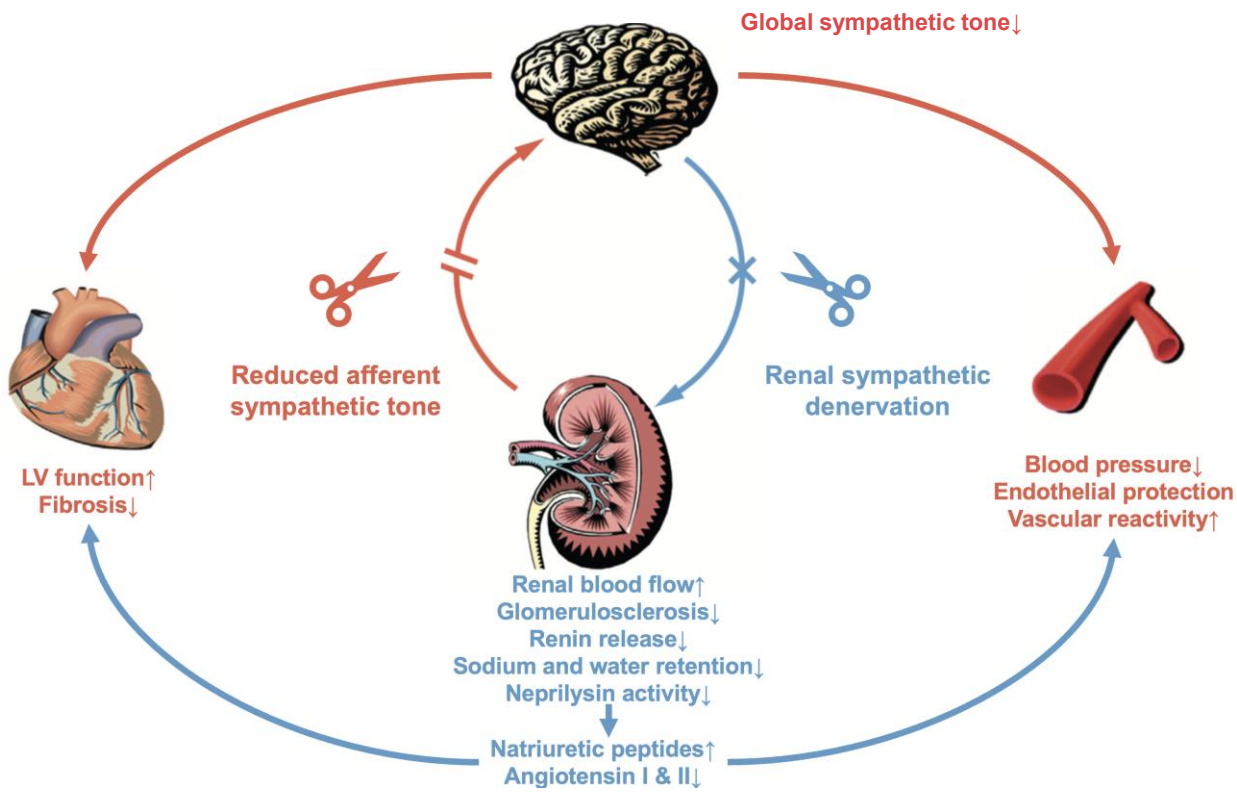
iAdherence database: 16,907 patients from 95 studies



Blaschke T et al. Annu Rev Pharmacol Toxicol. 2012;52:275-301.

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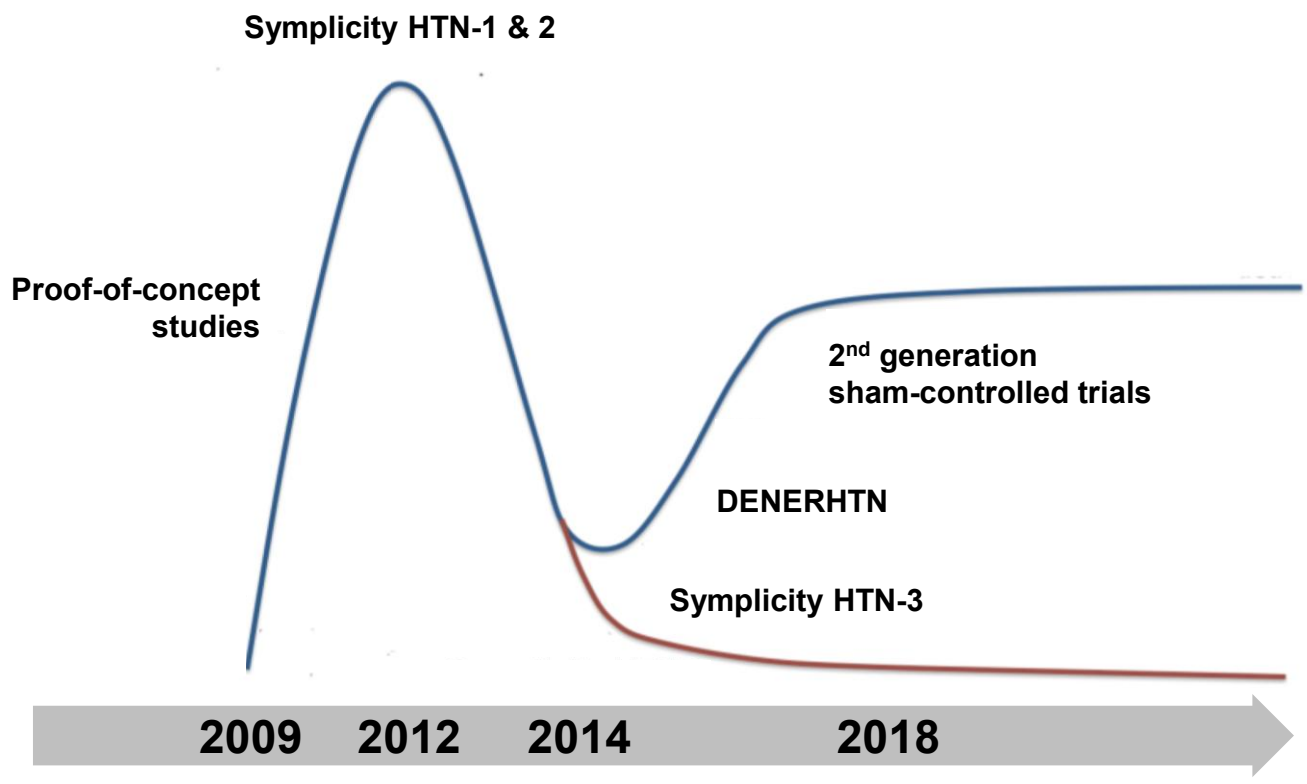
RDN Interrupts Renal Sympathetic Signaling



Lauder L et al. JACC Cardiovasc Interv. 2025;18(15):1833-1847.

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Renal Denervation Recovered After Symplicity HTN-3



Modified from: Mahfoud F et al. Eur Heart J. 2018;39(47):4144-4149.

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Symplicity HTN-3 Had Important Design Limitations



Medication
39% medication changes
No adherence testing

Study population
Isolated systolic hypertension
Secondary hypertension?

Procedure
Unexperienced proceduralists
6% bilat. circumferential ablation
Single-electrode catheter
Main renal artery only

Kandzari D et al. Eur Heart J. 2015;36:219-227.

Current Renal Denervation Systems

Catheter	Design	Access site	Ablation sites	Efficacy confirmed in sham-controlled trial?	
Radiofrequency					
Symplicity Spyral (Medtronic)	Multielectrode (4 monopolar gold electrodes), helical design, rapid exchange monorail catheter, 60 seconds per ablation cycle	F (6 Fr)	Main and accessory arteries, including branches (diameter 3-8 mm)	Yes, multiple trials	FDA
Netrod (Shanghai Golden Leaf Medtec)	Multielectrode (6 electrodes), basket-shaped tip, 120 seconds per ablation cycle	F (8 Fr)	Main and accessory arteries, including branches (diameter 3-12 mm)	Yes, single study (EuroPCR 2023, publication pending)	CE
Iberis 2nd-generation (AngioCare and Terumo)	Multielectrode (4 monopolar electrodes), helical design, over-the-wire catheter, 60 seconds per ablation cycle, 90 cm catheter length for transfemoral and 160 cm for transradial RDN	F/R (6 Fr)	Main and accessory arteries, including branches (diameter 3-8 mm)	Yes, single study (CIT Congress 2023, publication pending)	CE
SyMapCath I	Steerable monoelectrode stimulation and ablation catheter, stimulation time 20-120 seconds, 120 seconds per ablation cycle	F (6-7 Fr)	Main renal arteries	Yes, single study	
Ultrasound					
TIVUS (SoniVie)	Unidirectional steerable or multidirectional, over-the-wire, 30 seconds per emission	F (6 Fr)	Main and accessory arteries (diameter ≥4 mm)	No	CE
Paradise (ReCor Medical)	Piezoelectric ceramic transducer within a fluid-cooled, low-pressure balloon, over-the-wire, 7 seconds per emission	F (7 Fr)	Main and accessory arteries (different catheter sizes for diameters of 3-8 mm)	Yes, multiple studies	FDA
Neurolysis					
Peregrine (Ablative Solutions)	3 extendable microneedles	F (7 Fr)	Main and accessory arteries (4-7 mm)	No, TARGET-BP I ongoing	CE

Lauder L et al. EuroIntervention. 2024;20(8):e467-e478.

Renal Denervation Procedure

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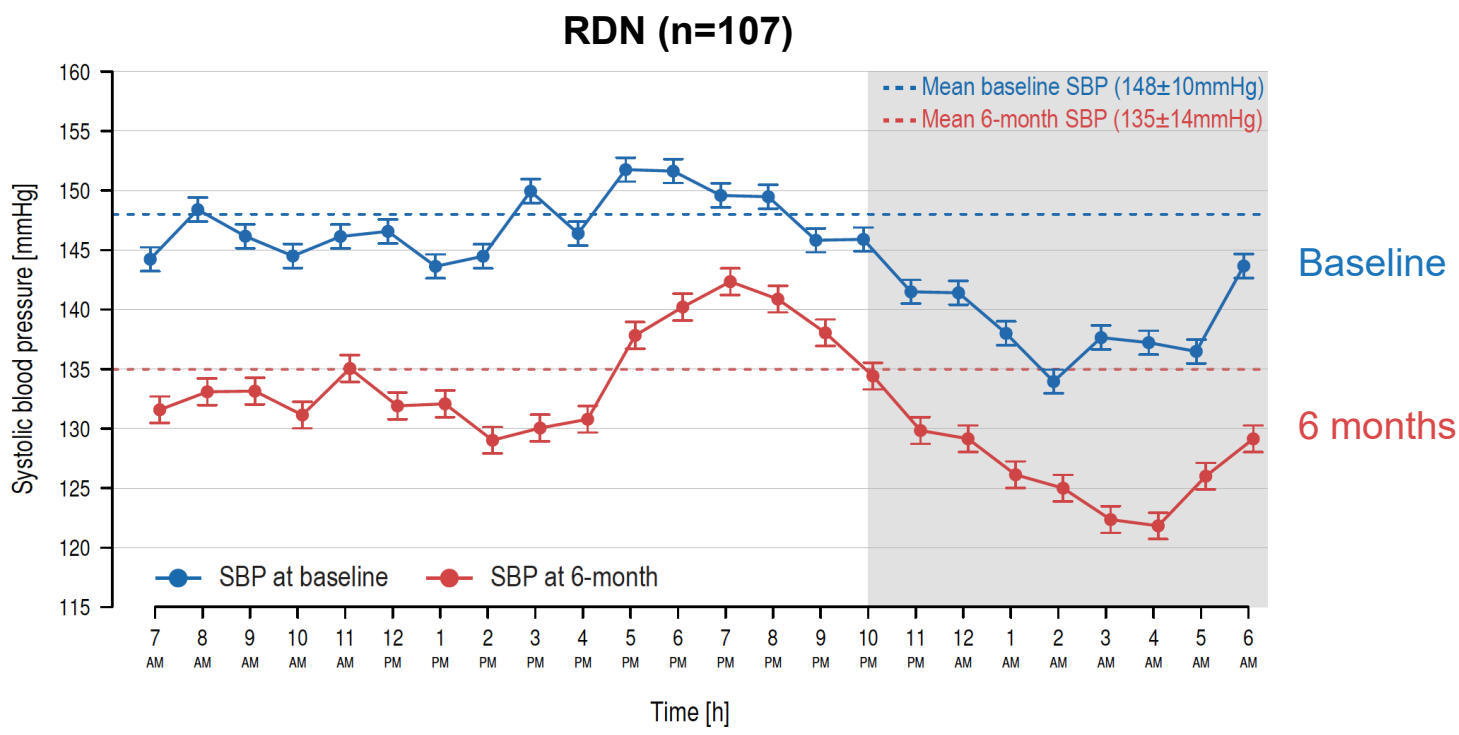
RDN Lowers 24-h Systolic BP Compared With Sham

Böhm M et al. Lancet 2020; Kandzari DE et al. Lancet. 2018; Kandzari DE et al. JACC 2023; Azizi M et al. Lancet. 2018; Azizi M et al., Lancet. 2021; Azizi M et al. JAMA 2023;

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RDN Lowers BP Around the Clock

Iberis-HTN: RF-RDN for uncontrolled hypertension on valsartan, amlodipine, and HCT

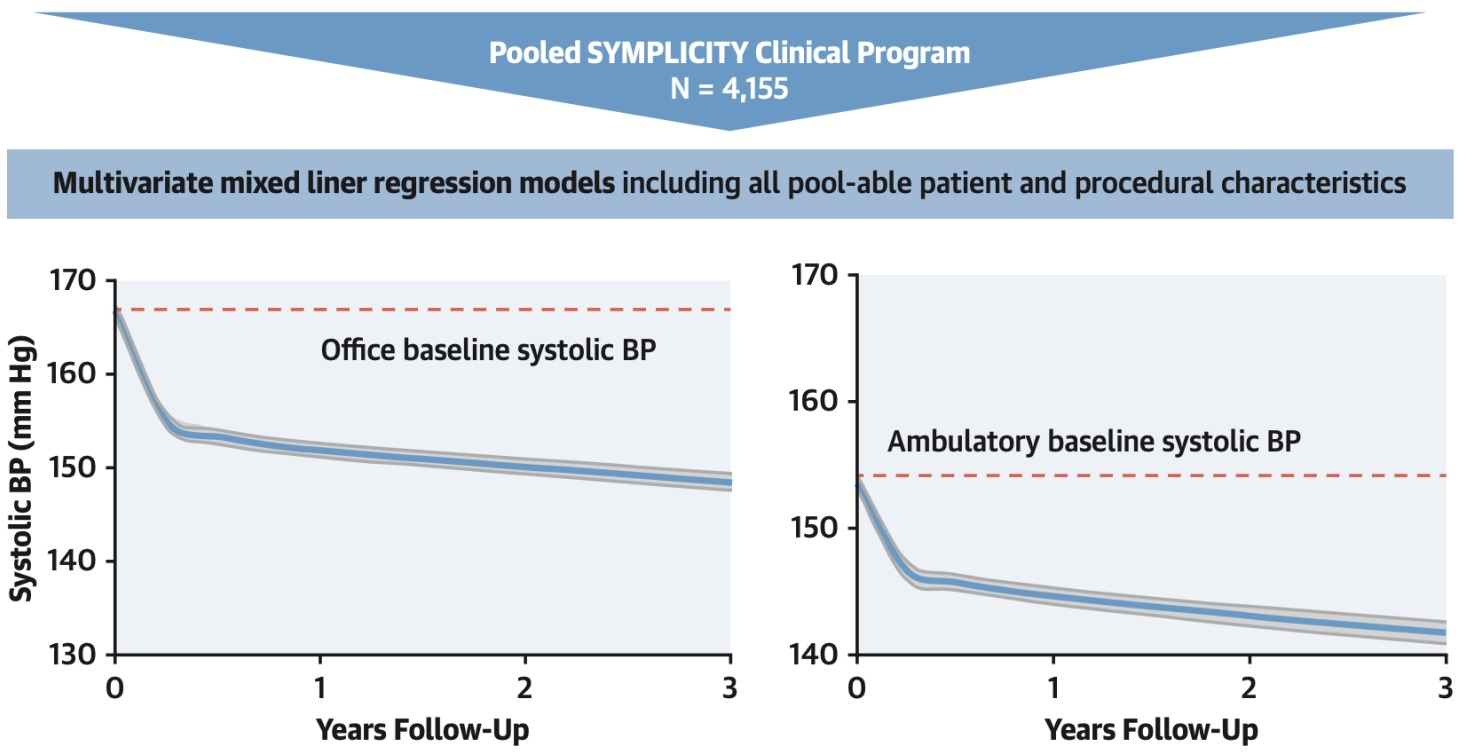


Jiang X, Mahfoud F, ... Lauder L et al. Circulation. 2024;150:1588-1598.

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Temporal Pattern of BP Reduction After RDN

Pooled SYMPLICITY Clinical Program: 4,155 patients

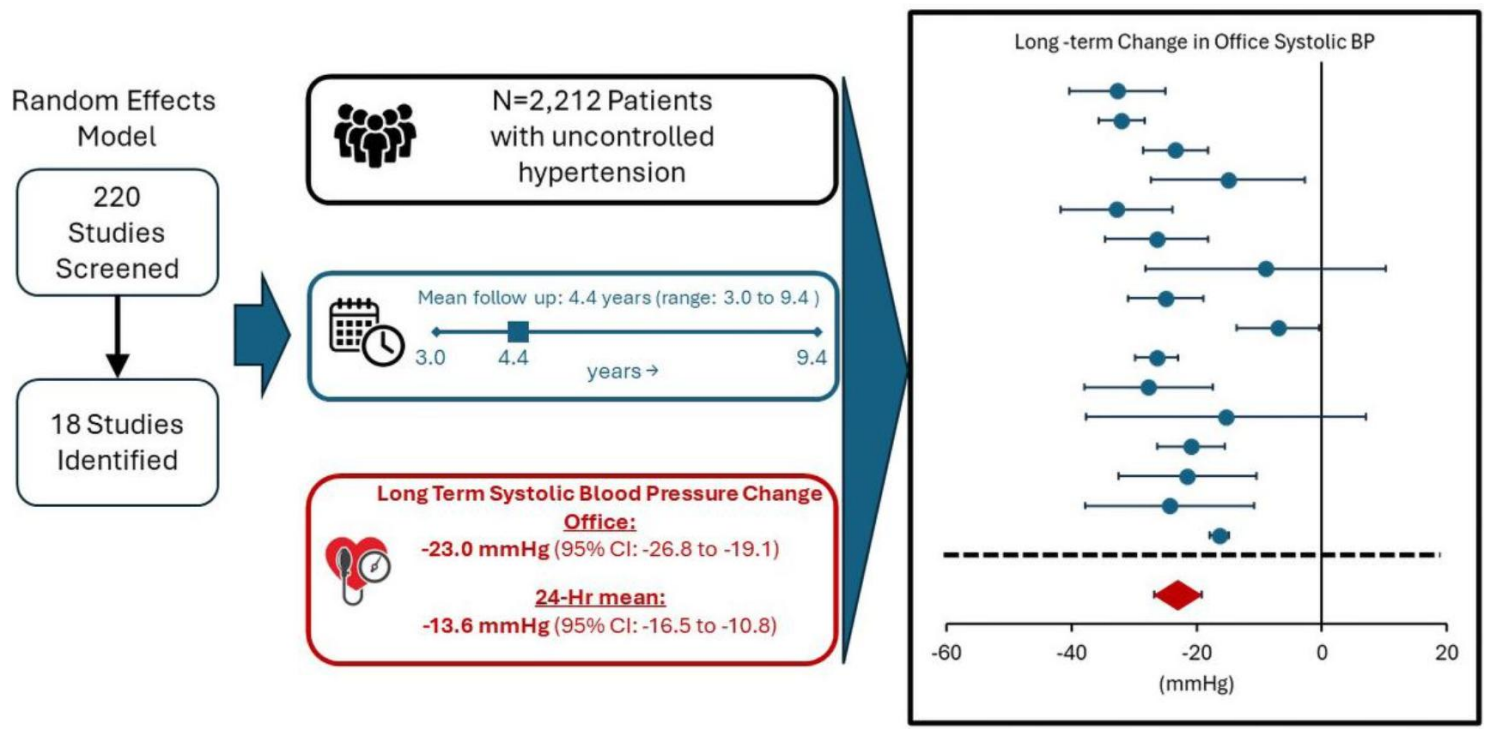


Mahfoud F *et al. JACC Adv* 2025;4(3):101606.

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BP Reductions Are Sustained for at Least 3 Years

Meta-analysis of 18 studies of RF-RDN with a follow-up of at least 3 years

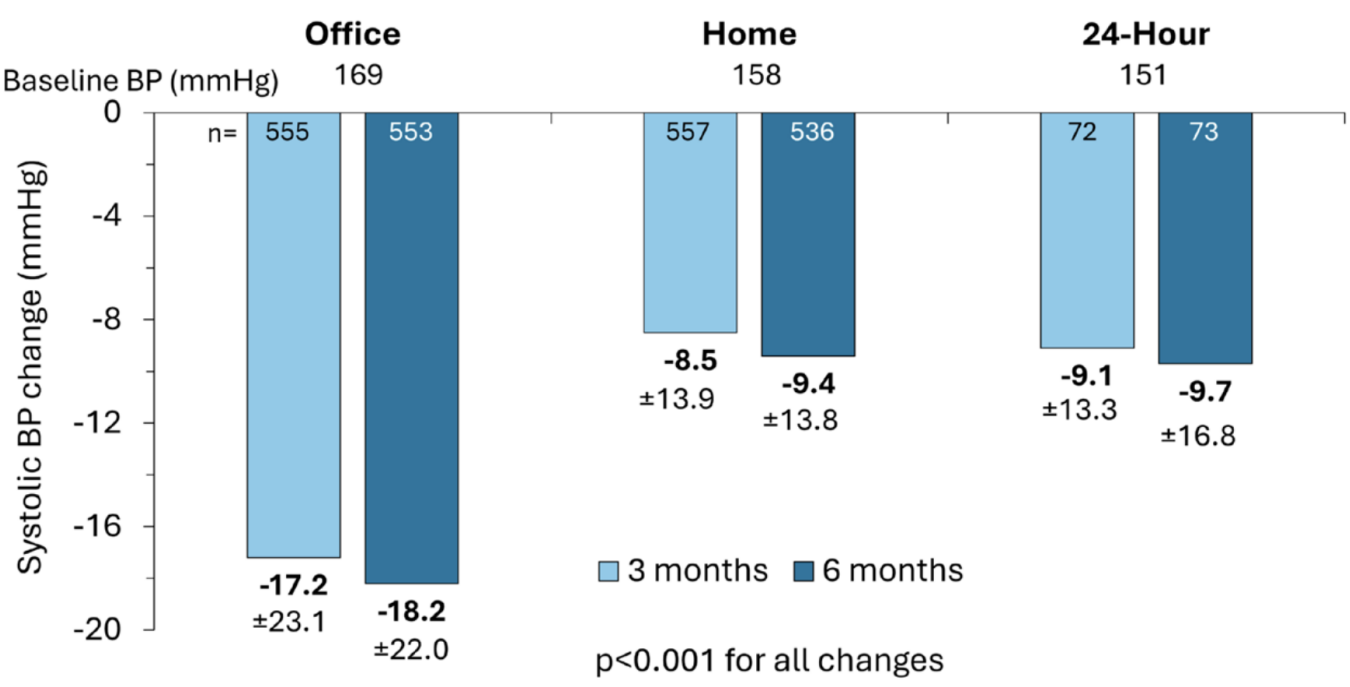


Mahfoud F et al. Eur J Prev Cardiol 2025 (online ahead of print).

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RDN Lowers BP in a Broad US Population

SPYRAL AFFIRM (postapproval): 594 patients (56 years, 45% women, OBP ≥140/90 mmHg, home SBP ≥135 mmHg) from 73 US sites



Mean of 3.6 antihypertensive medications at each visit

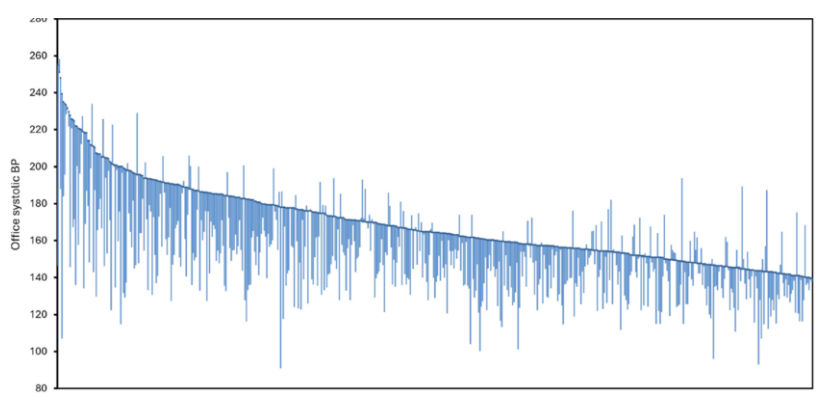
Kandzari DE et al. Circ Cardiovasc Interv. 2026;19:e017422.

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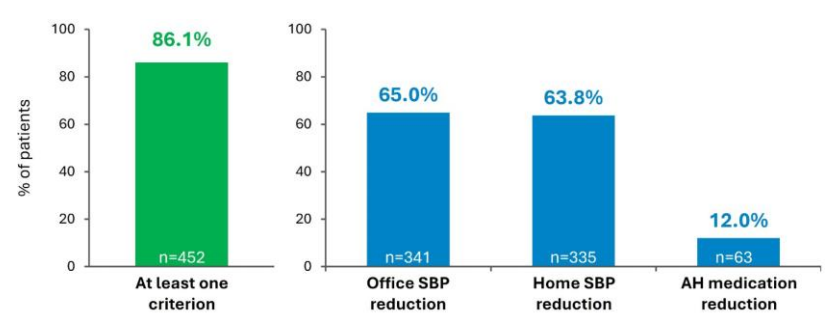
Nearly 9 in 10 Patients Show Clinical Benefit at 6 Months

SPYRAL AFFIRM: 525 US patients with office BP, home BP, and medication data at 6 months

Office SBP per patient, baseline to 6 months



Clinical benefit at 6 months



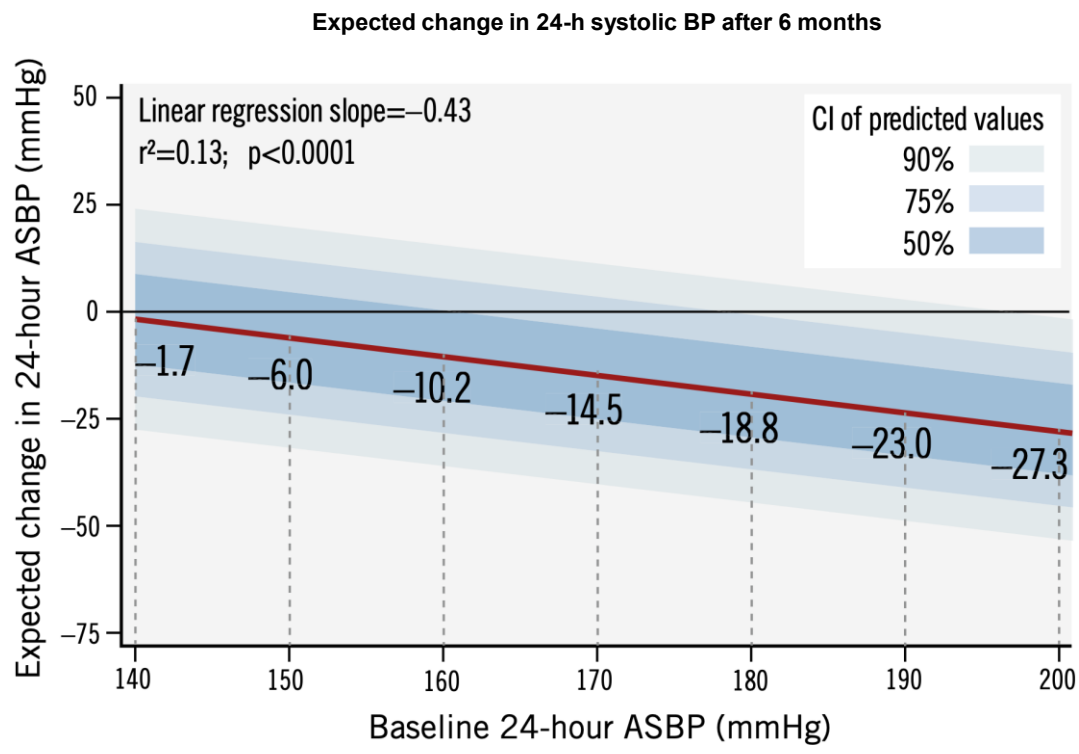
Benefit: office SBP reduction ≥10 mmHg, home SBP reduction ≥5 mmHg, or ≥1 fewer drug

Kandzari DE et al. Circ Cardiovasc Interv. 2026;19:e017422.

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Higher Baseline BP Predicts Greater BP Reduction

IPD meta-analysis of 3,377 patients from the SYMPLICITY and SPYRAL program



Schmieder R et al. EuroIntervention. 2025;21(21):e1281-e1287.

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RDN Has a Favorable Safety Profile

Meta-analysis of 10 sham-controlled trials including 2,478 patients

End point	No. of studies with documented end point	No. of studies that specifically reported end point	RDN n (%)	Sham n (%)	Effect estimate (OR with 95% CI)
Vascular complication	7	13	8/1598 (0.5%)	2/1197 (0.17%)	1.69, 0.57–5.0, *P*=0.34
Renal artery stenosis >70%	1	12	1/1424 (0.07%)	0/1029 (0%)	1.50, 0.06–36.97, *P*=0.80
Renal artery reintervention	0	10	0/1377 (0%)	0/1040 (0%)	NA
Hypertensive crisis/ emergency	5	9	14/1248 (1.12%)	13/915 (1.42%)	0.65, 0.30–1.38, *P*=0.26
Stroke	4	8	4/1160 (0.34%)	5/823 (0.60%)	0.54, 0.15–1.91, *P*=0.34
Hospitalization for HF	1	6	9/847 (1.06%)	3/582 (0.51%)	1.47, 0.39–5.50, *P*=0.57
All-cause death*	3	11	4/1476 (0.27%)	1/1070 (0.08%)	1.76, 0.34–9.20, *P*=0.50
Embolic event	1	9	1/1270 (0.07%)	0/930 (0%)	1.45, 0.06–36.12, *P*=0.82
New-onset ESRD	0	8	0/1316 (0%)	0/914 (0%)	NA

Vukadinovic D, Lauder L et al. Circulation. 2024;150(20):1599-1611.

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Guidelines Support RDN in Uncontrolled and Resistant Hypertension

	Shared decision-making	Multidisciplinary hypertension team	Experienced specialized centers	eGFR ≥40 ml/min/1.73 m²

	2023 ESH	2024 ESC	2025 ACC/AHA
Uncontrolled hypertension	Can be considered if drugs elicit side effects or poor QoL IIa B	May be considered if CV risk is increased IIb A	May be reasonable if drugs elicit side effects 2b B
Resistant hypertension	Can be considered IIa B	May be considered IIb B	May be reasonable 2b B

Lauder L et al. JACC Cardiovasc Interv. 2025;18(15):1833-1847.

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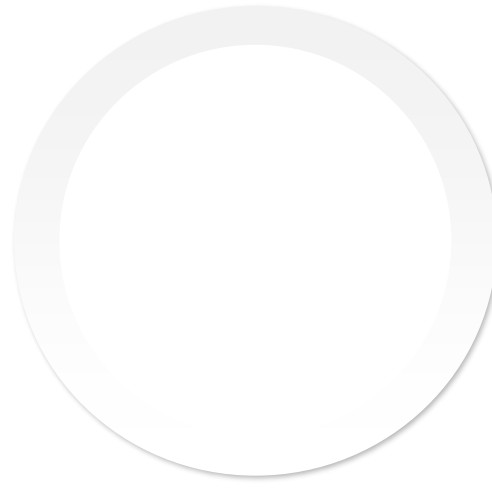
Many Patients Prefer a Device-Based Therapy

US (n=400)	**Germany** (n=1,011)	**Japan** (n=2,392)
15-31%	**28-38%**	**32%**

Schmieder R et al. Clin Res Cardiol. 2019;108:1331-1342.
Kario K et al. Hypertens Res. 2022;45:232-240.
FDA Panel Aug 2023

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Challenges and Future Directions

Identifying responders	**Expanding clinical indications**	**Multiorgan denervation**
		

Barbato E et al. Eur Heart J. 2023;44:1313-1330.
Barbato E et al. EuroIntervention. 2023;18:1227-1243.

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Take-Home Messages

- Hypertension is the leading CV risk factor, yet remains poorly controlled
- **RDN has demonstrated safety & efficacy** in sham-controlled trials
- **Always-on effect:** Independent of PK/PD and adherence
- Most patients still need antihypertensive drugs after RDN.
- Guidelines support RDN as an option in **uncontrolled HTN**
- **Multidisciplinary hypertension team** & **shared decision making** are recommended

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Thank you

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