Endovascular Ultrasound Renal Denervation to Treat Uncontrolled Hypertension: Primary Results of the Randomized, Sham-Controlled RADIANCE II Pivotal Trial

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Disclosure Statement of Financial Interest

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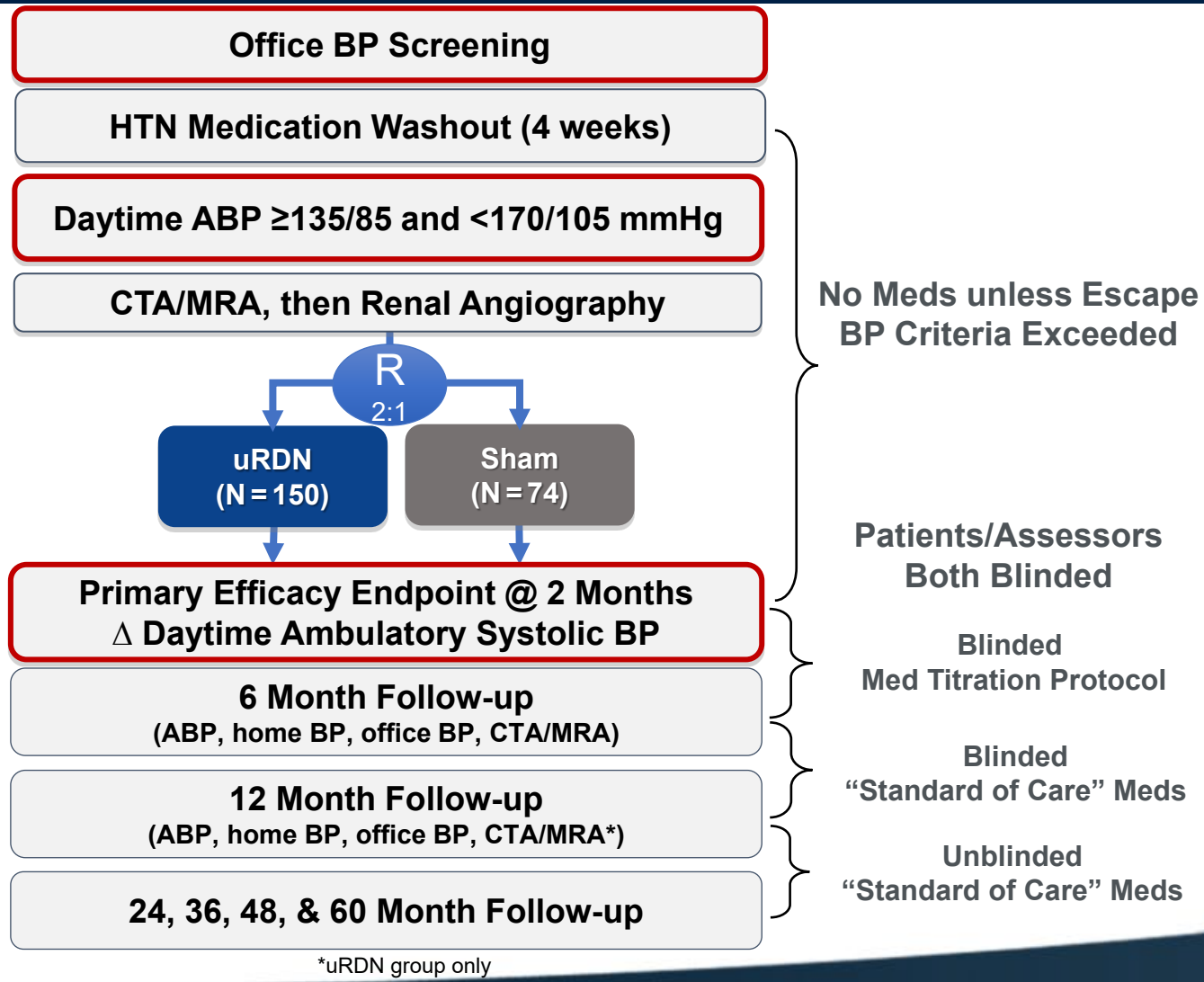
RADIANCE II: Study Design
Blinded, Sham-Controlled, Powered to Demonstrate BP Lowering Effectiveness at 2M

Key Entry Criteria:

- Age 18-75 years
- Uncontrolled HTN with a history of medication treatment on 0-2 anti-HTN meds
- Off-med daytime ABP≥135/85 & <170/105 mmHg
- No prior CV or cerebrovascular events
- No Type I or uncontrolled Type II diabetes
- eGFR ≥ 40mL/min/m^2
- Eligible renal artery anatomy

Escape BP criteria:

- Home BP≥170/105 mmHg / Office BP≥180/110 mmHg with clinical symptoms



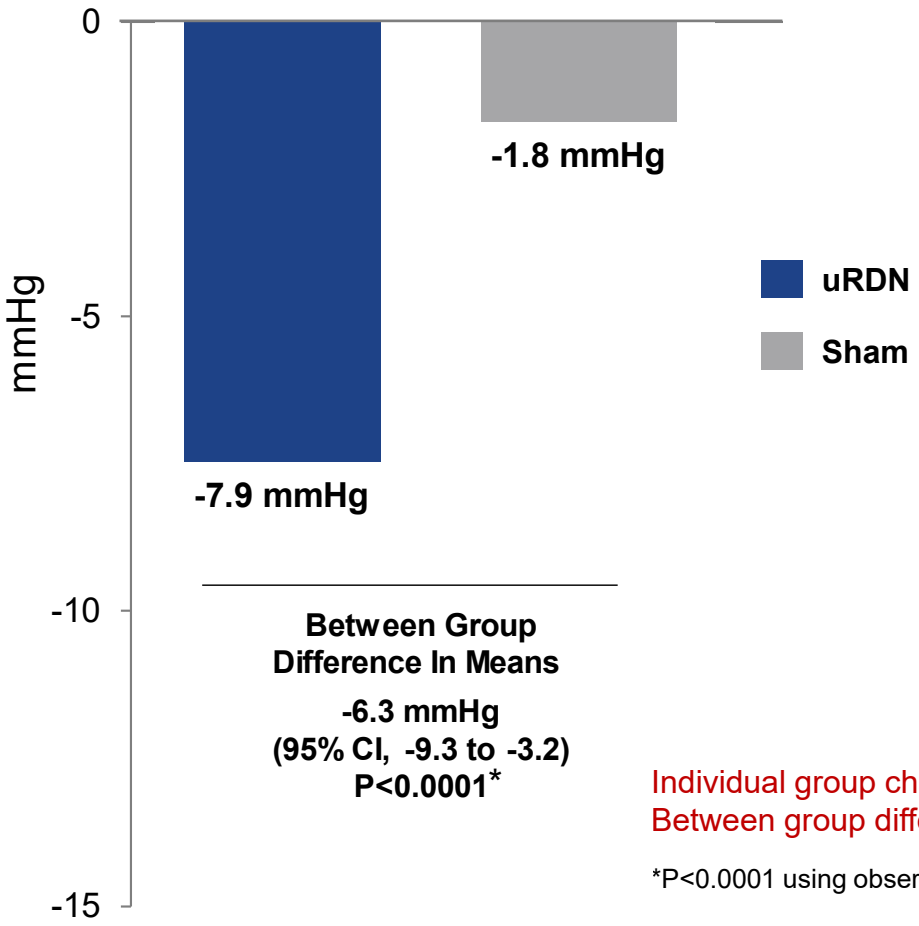
*uRDN group only

Baseline Blood Pressures:
After 4-week Washout Period (off Anti-Hypertensive Medications)

	uRDN (N=150)	Sham (N=74)
ABPM		
Daytime SBP (mmHg)	150.3 ± 8.6	151.2 ± 9.0
Daytime DBP (mmHg)	93.8 ± 5.2	93.2 ± 5.5
Nighttime SBP (mmHg)	132.2 ± 12.5	134.1 ± 13.3
Nighttime DBP (mmHg)	79.9 ± 8.2	80.5 ± 8.4
24-h SBP (mmHg)	143.4 ± 8.9	144.6 ± 9.6
24-h DBP (mmHg)	88.4 ± 5.8	88.3 ± 5.9
Home BP		
SBP (mmHg)	152.6 ± 9.6	150.1 ± 10.4
DBP (mmHg)	98.0 ± 6.5	96.0 ± 7.5
Office BP		
SBP (mmHg)	156.9 ± 13.1	156.3 ± 12.8
DBP (mmHg)	102.3 ± 7.6	101.0 ± 7.5

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

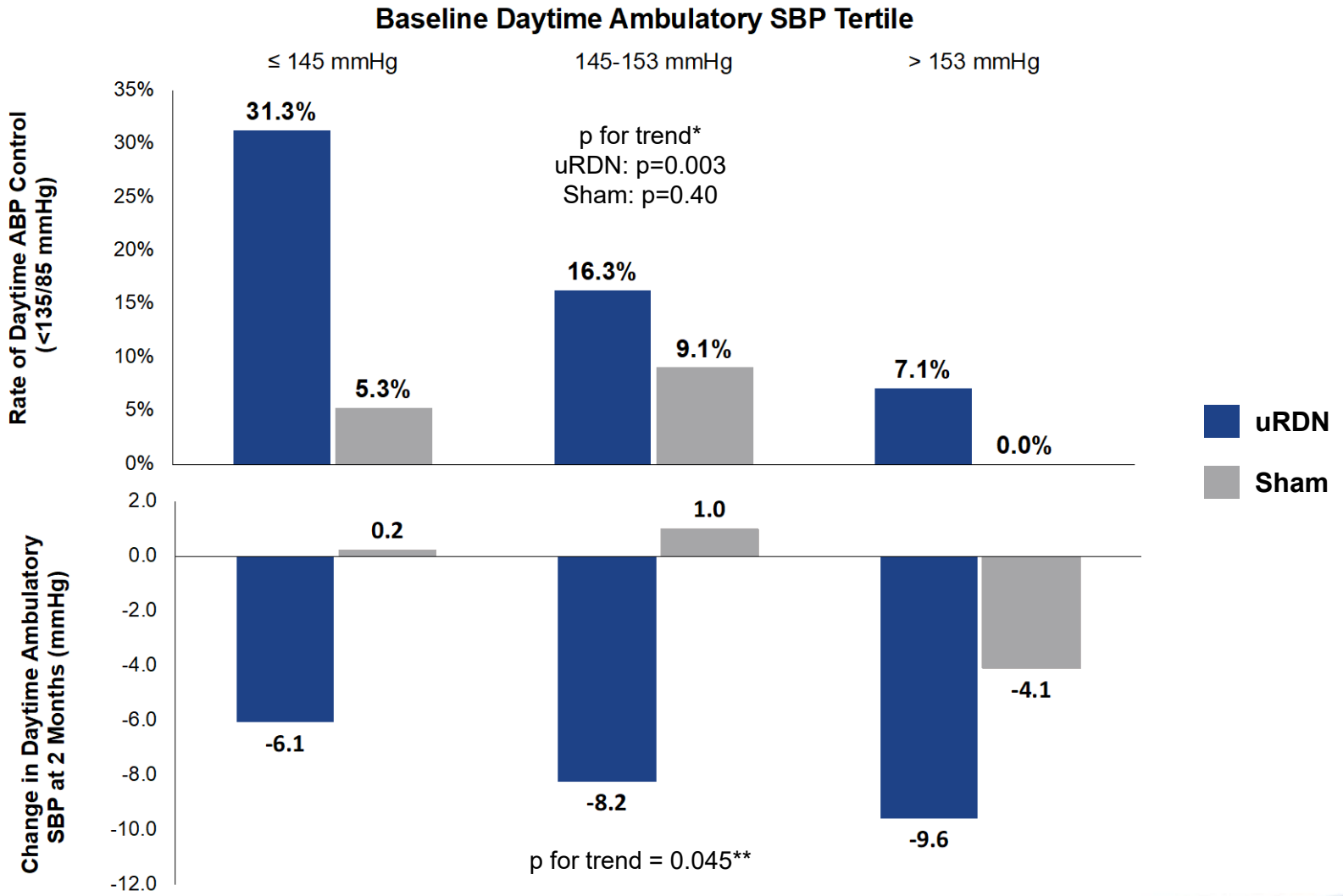
Baseline-Adjusted Change in Daytime Ambulatory SBP



Individual group changes are based on observed values
Between group difference includes multiple imputation for missing values

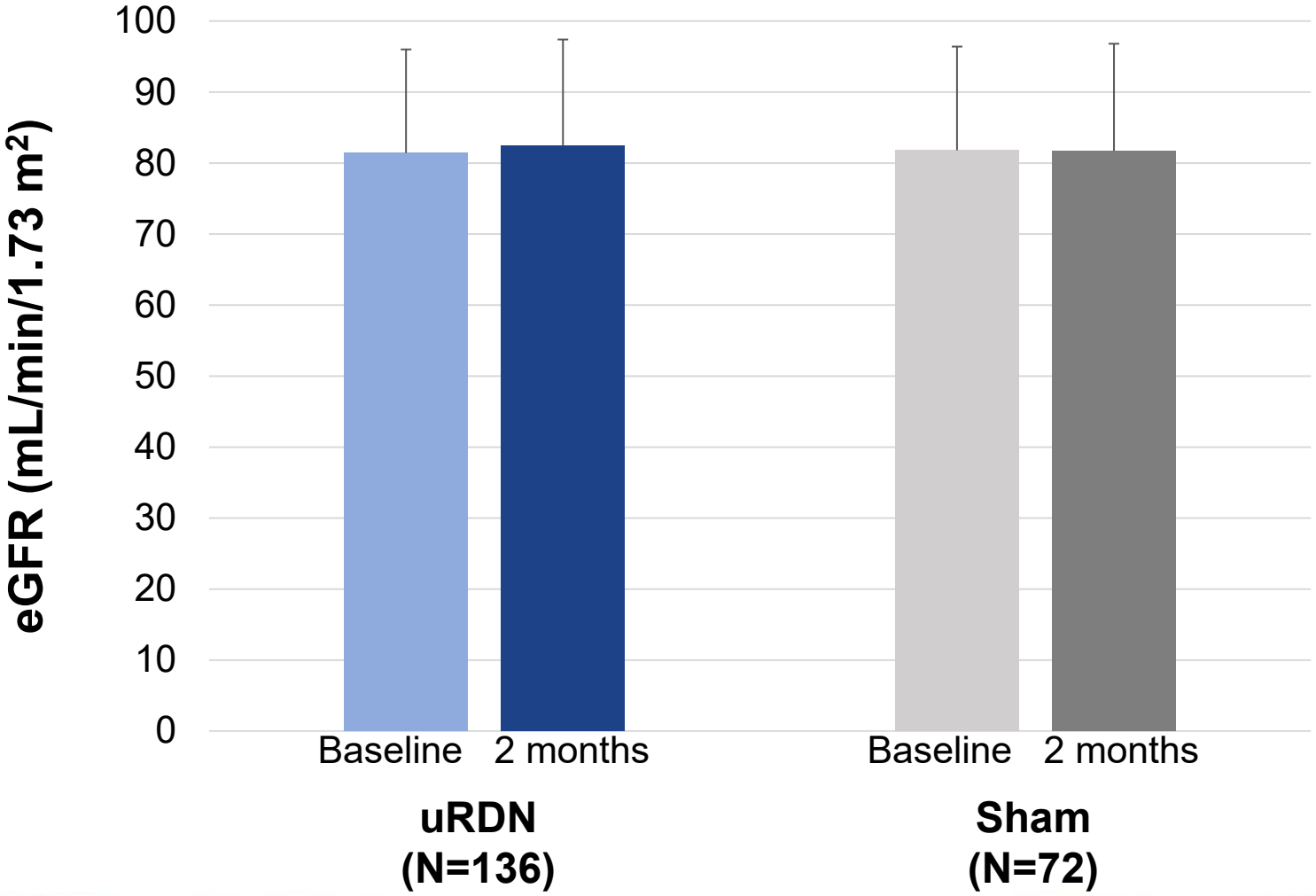
*P<0.0001 using observed values or multiple imputation

Daytime ABP Control Rates and SBP Change at 2 Months Stratified by Starting Daytime Ambulatory SBP



ITT population with observed values, excluding all subjects that started medications prior to 2 months (uRDN N=133 and Sham N=63)

eGFR at 2 Months
(Matched data at baseline and 2 months)



Data are mean ± SD

Major Adverse Events (Complete through 30 days)

	uRDN (N=150)	Sham (N=74)
30-day events		
All-cause mortality	0 (0.0%)	0 (0.0%)
New onset ESRD (eGFR<15 mL/min/m^2 or need for renal replacement therapy)	0 (0.0%)	0 (0.0%)
Significant embolic event resulting in end-organ damage	0 (0.0%)	0 (0.0%)
Renal artery perforation or dissection requiring an invasive intervention	0 (0.0%)	0 (0.0%)
Major vascular complications requiring surgical repair, interventional procedure, thrombin injection, or blood transfusion	0 (0.0%)	0 (0.0%)
Hospitalization for hypertensive or hypotensive crisis	0 (0.0%)	0 (0.0%)
Hospitalization for major cardiovascular or hemodynamic related events	0 (0.0%)	0 (0.0%)
New onset stroke	0 (0.0%)	0 (0.0%)
New onset myocardial infarction	0 (0.0%)	0 (0.0%)
6-month events		
New onset renal artery stenosis >70%, confirmed by CTA or MRA*	0 (0.0%)	0 (0.0%)

*At the time of analysis, 162 patients (117 RDN and 45 Sham) had completed the 6-month CTA/MRA

Conclusions

- **The RADIANCE II pivotal trial is the largest individually powered randomized trial to demonstrate superiority of endovascular uRDN in lowering blood pressure compared with a sham procedure**
- The trial met primary/secondary efficacy BP lowering endpoints at 2 months, showing statistically and clinically significant reductions in:
  - **Daytime ambulatory SBP (↓7.9 mmHg from baseline, Δ6.3 mmHg vs. sham)**
  - 24-h, nighttime, home and office SBP (Δ5-7 mmHg vs. sham)
- There were no major adverse events at 30 days
- These results are concordant with those of RADIANCE-HTN SOLO and RADIANCE-HTN TRIO, confirming that uRDN lowers blood pressure across the spectrum of hypertension