



***Renal Sympathetic Nerve Ablation
for Resistant Hypertension:
Results of the US Pilot Trial***

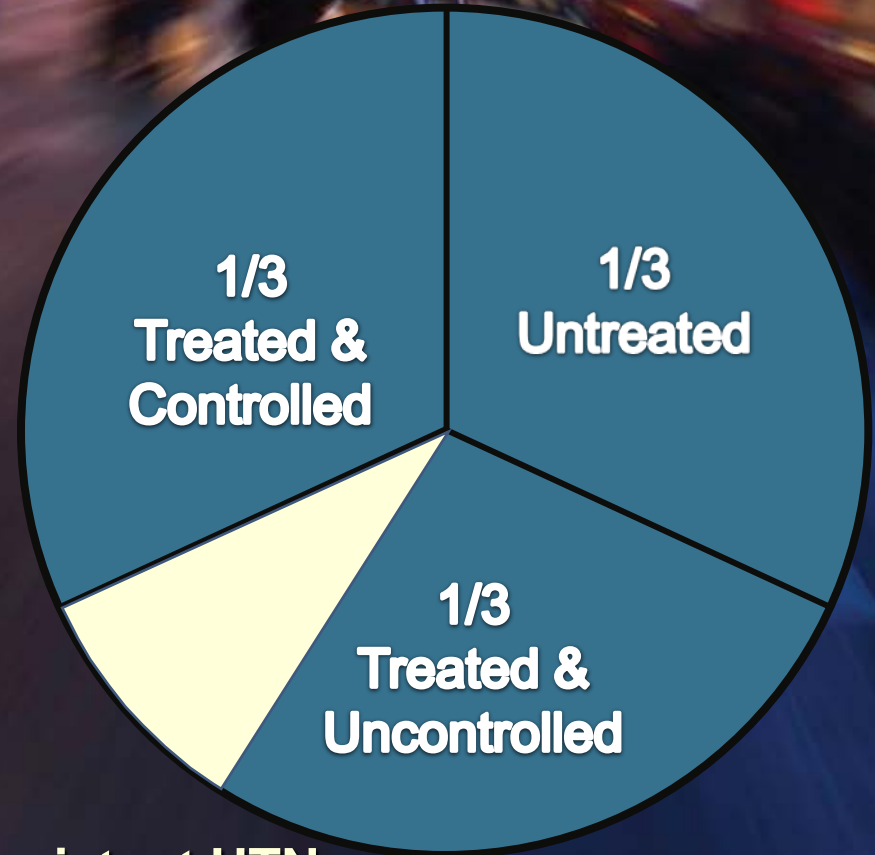
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Krishna Rocha-Singh, M.D.

- Research
 - Abbott Vascular
 - Gore
 - Spectranetics
 - Lumen
- Consultant/Advisory Board/Training
 - Cordis
 - Medtronic
 - ev3, Inc.
- Royalties/Financial Interest
 - None
- VIVA Board Member
- Medical Director PERC, salary
- I will discuss off-label use of vascular devices

Background: Hypertension

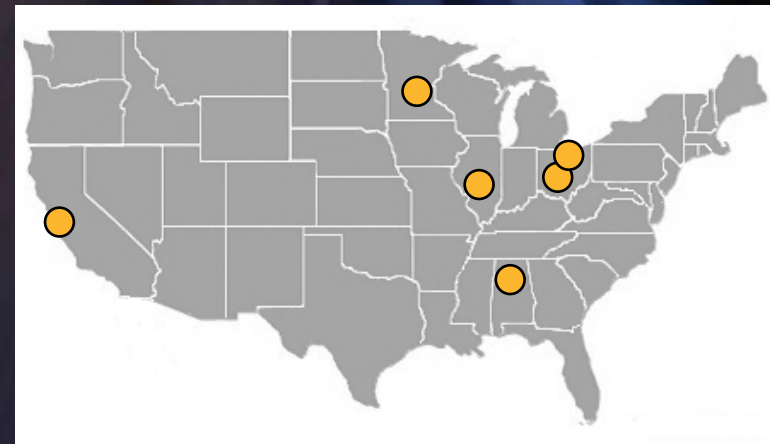
- 72 million in the US alone
- 1B Worldwide
- 2X cardiovascular mortality for every 20/10 mmHg increase over target
- The SNS and particularly the renal sympathetics are important to the progression of hypertension, CKD, and heart failure



Resistant HTN
(~10%)

Pilot U.S. Resistant HTN Study

- **Study Aim:** To perform a U.S.-based pilot evaluation of the safety and blood pressure-lowering efficacy of percutaneous renal sympathetic denervation in patients with resistant hypertension
- **20 patients enrolled – 15 with qualifying anatomy**
- **Enrollment from Sept. 2008 to July 2009**
- **Sites:**
 - Prairie Heart Institute, Springfield, IL
 - Hennepin County Medical Center, Minneapolis, MN
 - MetroHealth, Cleveland, OH
 - El Camino Hospital, Mountain View, CA
 - The Ohio State University Medical Center, Columbus, OH
 - Birmingham VA Medical Center, Birmingham, AL



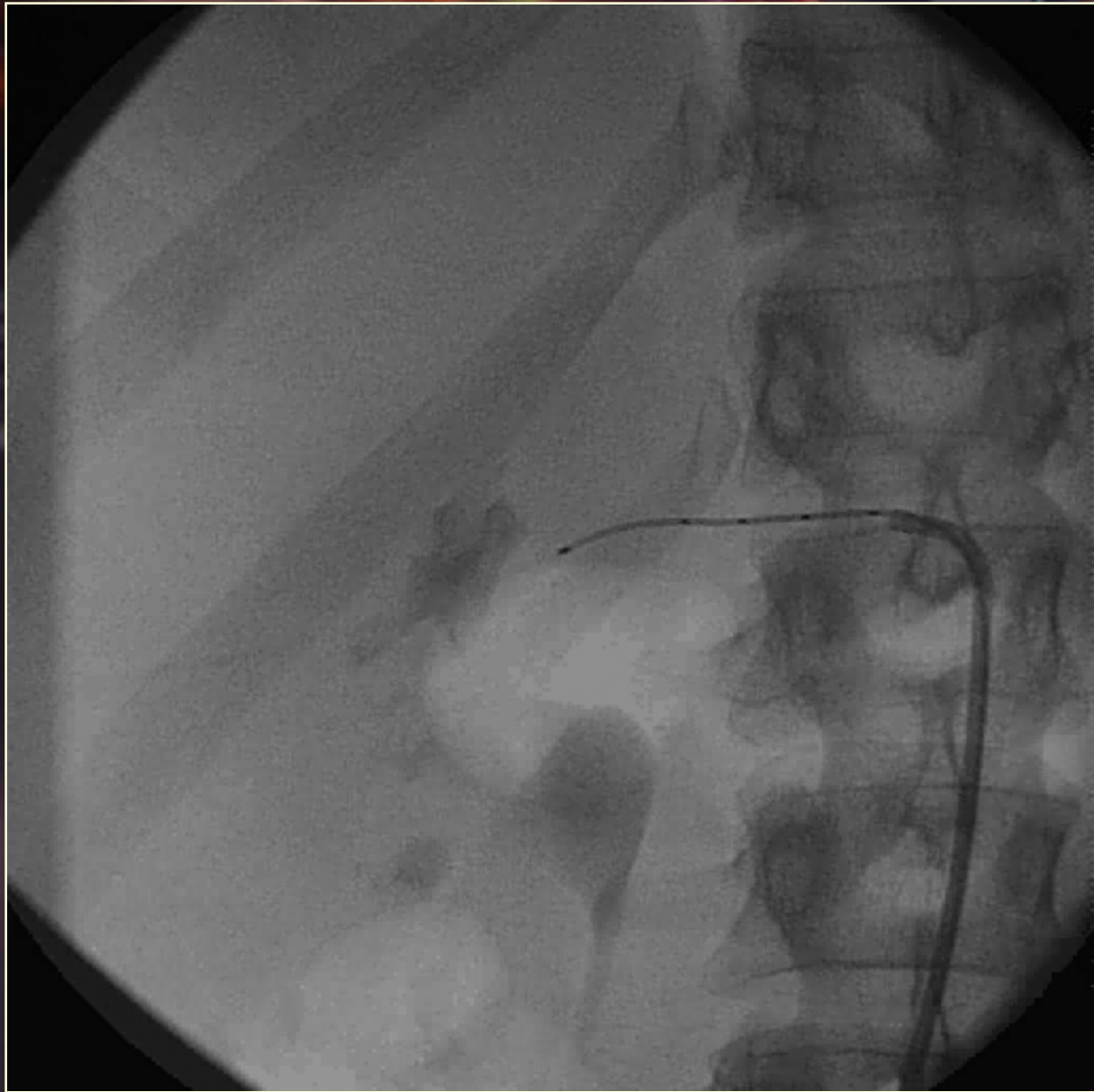
Inclusion/Exclusion Criteria

Key Inclusion Criteria

- Office SBP ≥ 160 mmHg despite 3+ anti-hypertensive medications (including diuretic)
- eGFR (MDRD formula) of ≥ 45 mL/min/1.73m²

Key Exclusion Criteria

- Renovascular abnormalities: significant renal artery stenosis, prior renal stenting or angioplasty, dual renal arteries
- Known secondary cause of hypertension other than sleep apnea
- Type I diabetes mellitus
- Hemodynamically significant valvular disease
- Currently taking clonidine, rilmenidine, systemic corticosteroids, or warfarin
- Pregnancy



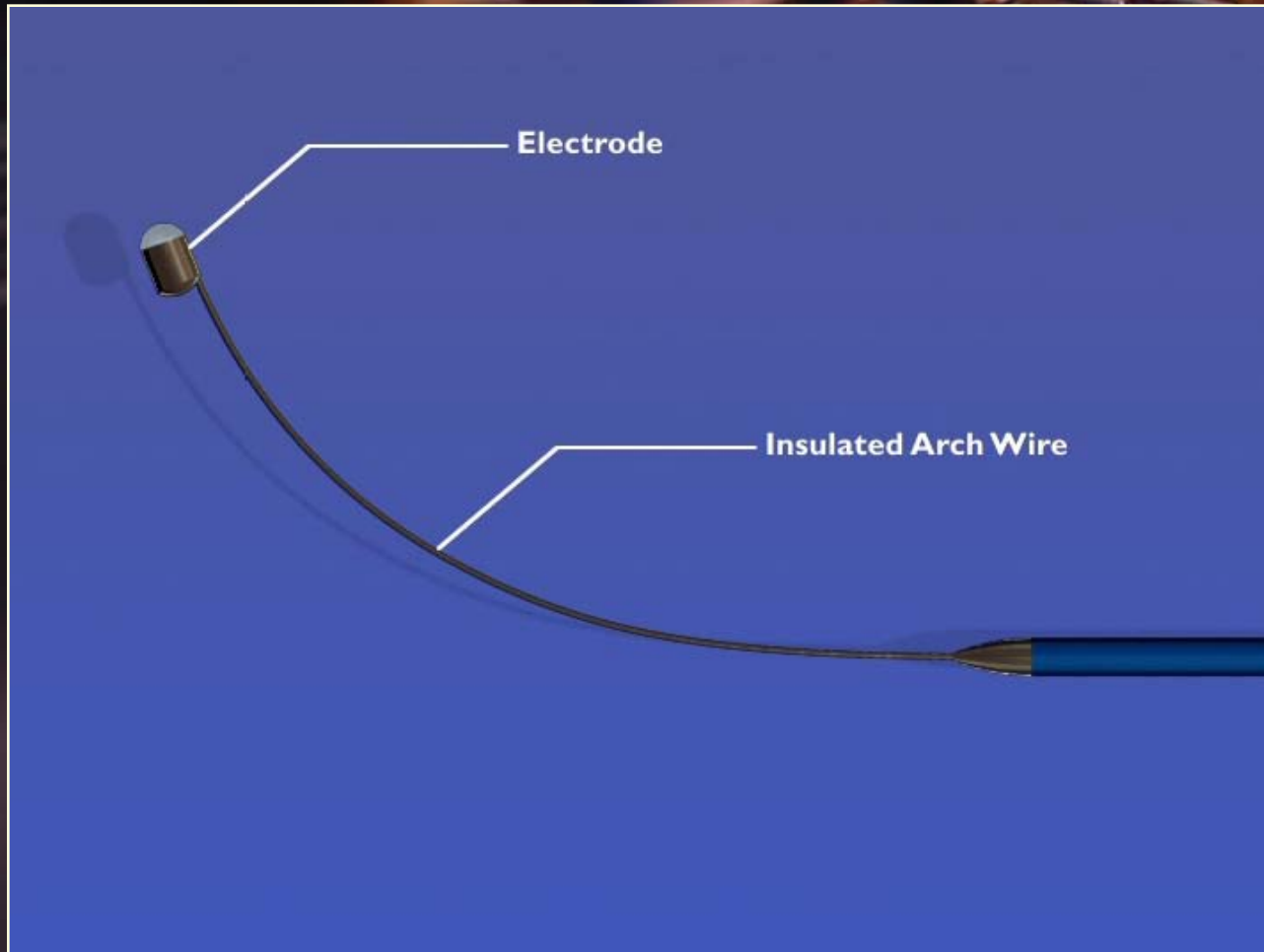




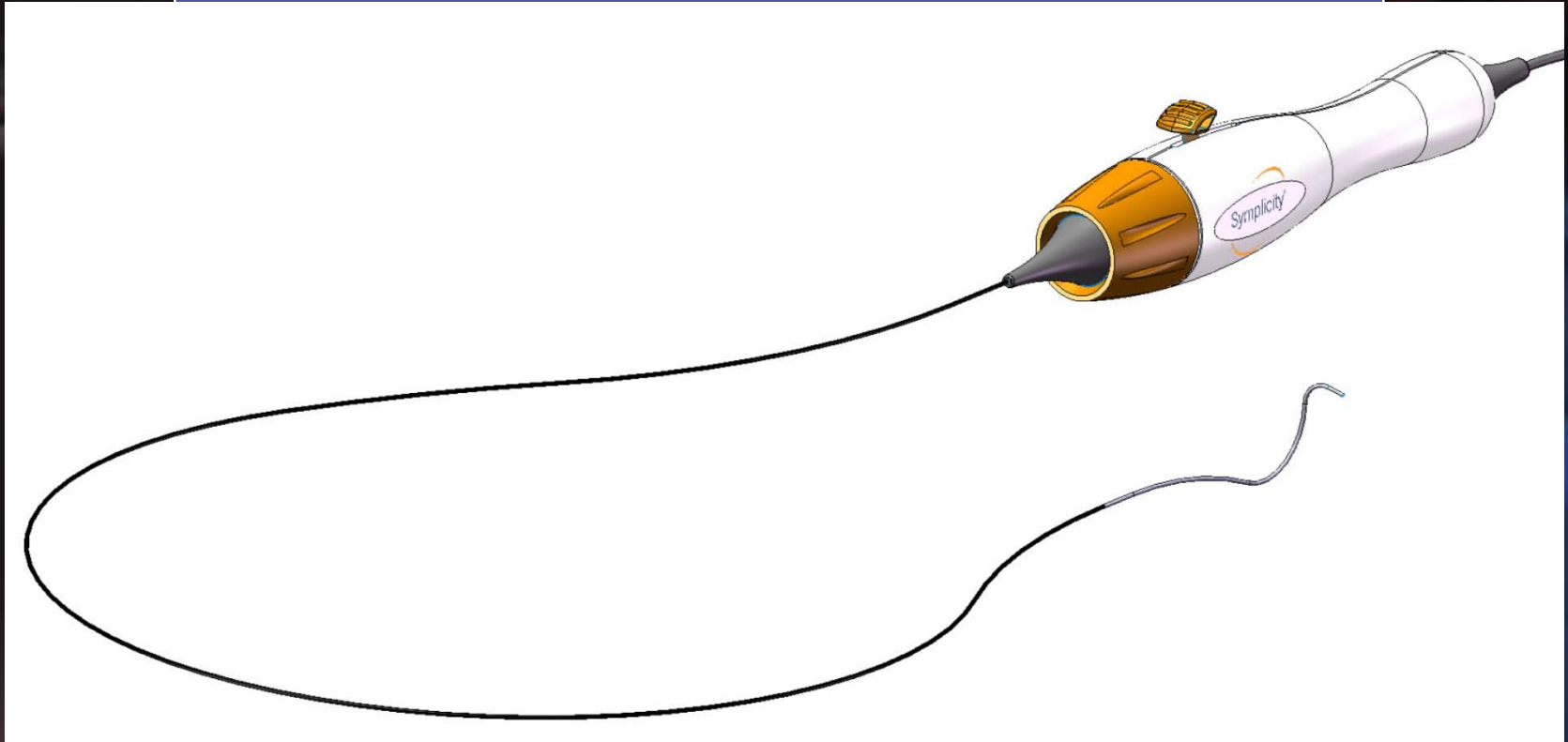


Symplicity[®]

RF Ablation for Renal Denervation



Symplcity® RF Ablation for Renal Denervation



In the United States: Caution: Investigational Device. Limited by U.S. law to investigational use.

Baseline Patient Characteristics

	Treated Patients (N=15)
Age (years)	51 ± 14
Gender (% female)	40%
Race (% non-Caucasian)	20%
Diabetes Mellitus II (%)	33%
CAD (%)	20%
Heart Rate (bpm)	75 ± 14
eGFR (mL/min/1.73m ²)	84 ± 21
BP (mmHg)	173/96 ± 12/15

Baseline Patient Characteristics

	Treated Patients (N=15)
Number of anti-HTN meds (mean)	5.2 ± 1.3
ACE/ARB (%)	67
Beta-blocker (%)	87
Calcium channel blocker (%)	87
Vasodilator (%)	33
Diuretic (%)	93

Procedure & Acute Procedural Safety

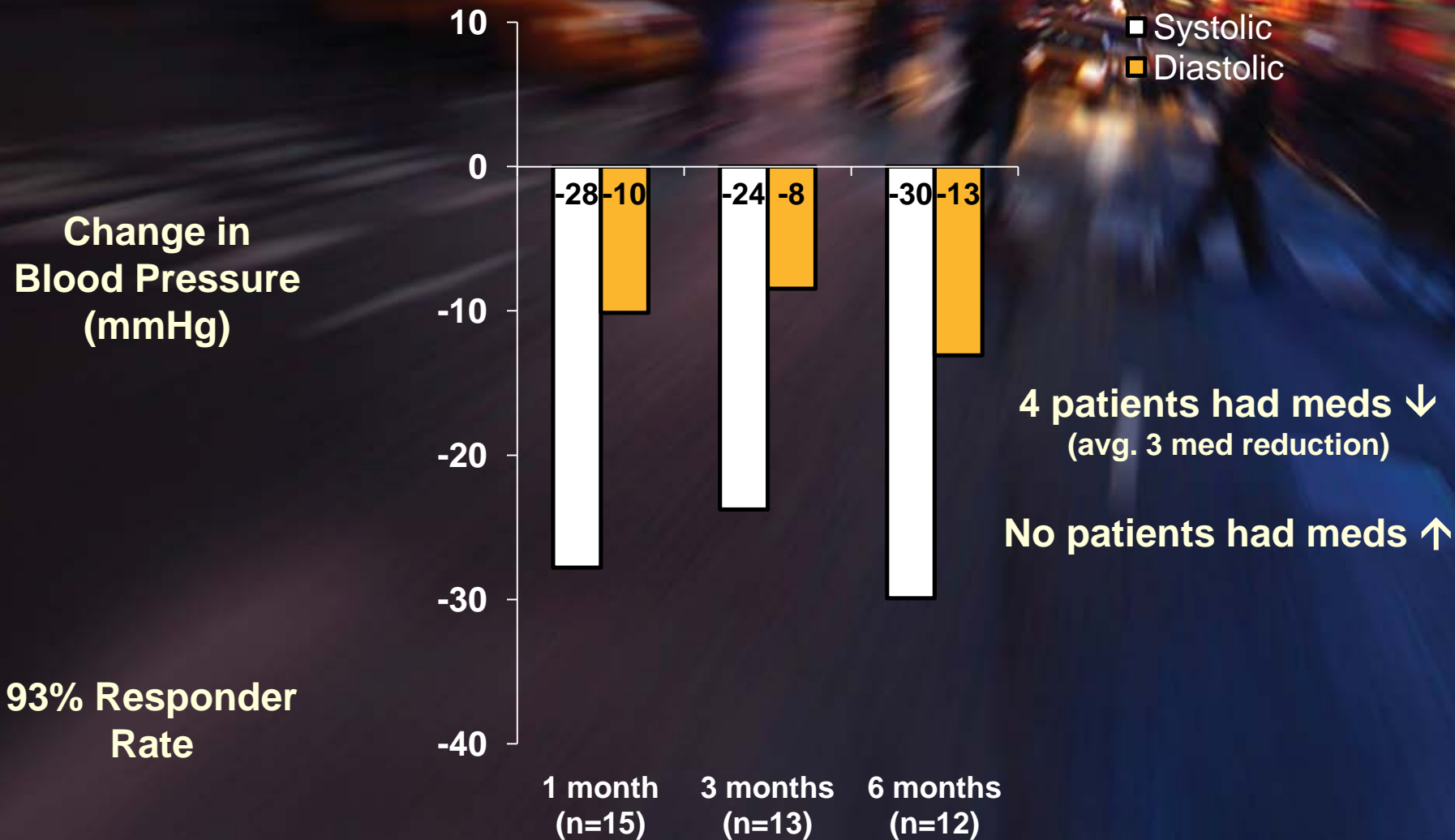
- Procedure time: median 43 (IQR 38-51) min
- Bilateral procedure:
 - Average of 4.4 treatments in each renal artery
- Intravenous narcotics & sedatives used to manage pain during delivery of RF energy
- Treatment delivered without complication in 14 of 15 patients:
 - 1/15 developed a pseudoaneurysm at the groin access site that was treated without further sequelae

Chronic Procedural Safety

- **No chronic RF related vascular complications**
 - One progression of a pre-existing renal artery stenosis (40%→80%), possibly related to catheter manipulation, successfully stented.
- **No chronic renal (Δ eGFR) complications**
- **No orthostatic or electrolyte disturbances**

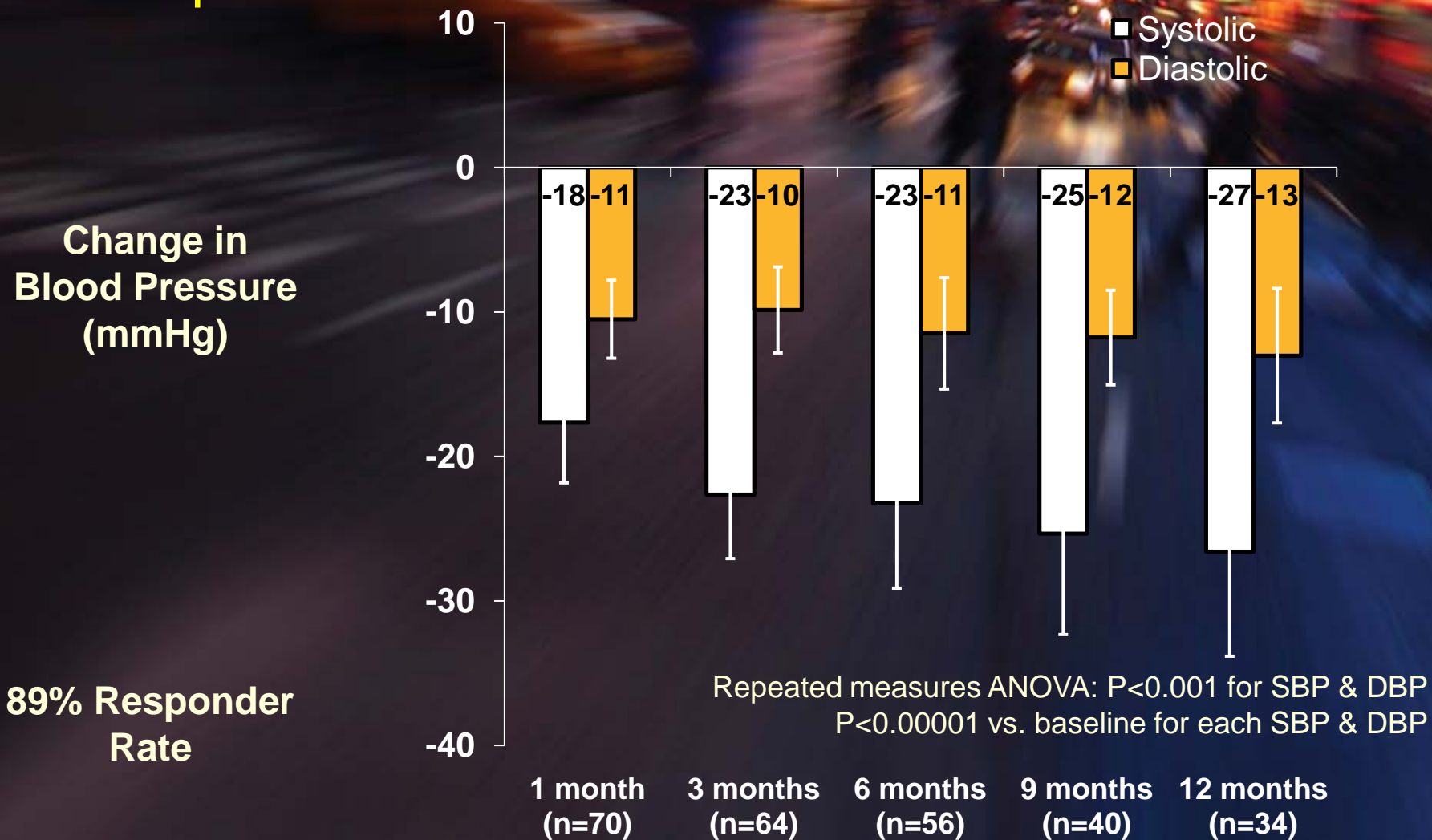
Blood Pressure Response

US Cohort



Blood Pressure Response

Full Experience



Summary/Conclusions

- **Percutaneous, catheter based, therapeutic renal sympathetic denervation is simple and safe**
- **Significant and sustained reductions in blood pressure were achieved in patients with multi-drug resistant hypertension**

Conclusion/Summary

- This US experience independently confirms data reported from studies in Europe and Australia
- Prospective RCT data required to definitively determine the role of this therapy in patients with refractory hypertension
 - European/Australian RCT currently underway (Symplicity HTN-2)
 - Plan to conduct US RCT following Symplicity HTN-2