

18th ANGIOPLASTY SUMMIT-TCTAP 2013  
Seoul, Korea, April 23-26, 2013

---

# Devices and Long-Term Outcomes of Renal Denervation for Hypertension

Horst Sievert, Ilona Hofmann, Laura Vaskelyte,  
Stefan Bertog, Simon Lam, Sameer Gafoor

CardioVascular Center Frankfurt - CVC

Frankfurt, Germany

18th ANGIOPLASTY SUMMIT-TCTAP 2013  
Seoul, Korea, April 23-26, 2013

---

**Devices** and  
Long-Term Outcomes of Renal  
Denervation for Hypertension

Horst Sievert, Ilona Hofmann, Laura Vaskelyte,  
Stefan Bertog, Simon Lam, Sameer Gafoor

CardioVascular Center Frankfurt - CVC

Frankfurt, Germany

# New devices

- Radiofrequency catheters
  - St. Jude Medical
  - Cordis
  - Medtronic
  - Angiocare – Terumo
  - Verve
- Radiofrequency balloons
  - Maya - Covidien
  - Vessix - Boston
- Nano particles
  - Apex Nano
- Drugs
  - Mercator
  - Ablative Solutions
  - Northwind
  - Kiprokration Hospital, Athens
- Radiation
  - Best Medical Int.
- Ultrasound
  - Recor Medical
  - CardioSonic
  - Sound Interventions
  - Kona

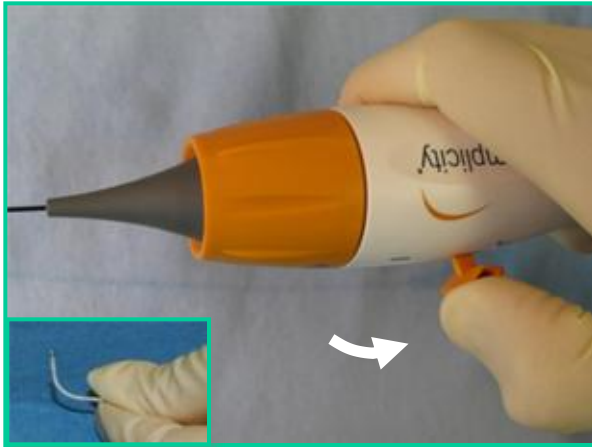
# SJM: EnligHTN Renal Artery Ablation Catheter

- Multi-electrode catheter
  - 4 monopolar electrodes
- Deflectable tip
- Two basket sizes:
  - 16 mm length; 6 mm
  - 18 mm length; 8 mm
- Good for arteries 4-8mm
- 8F guide compatible
- Ablation time 90 sec per electrode

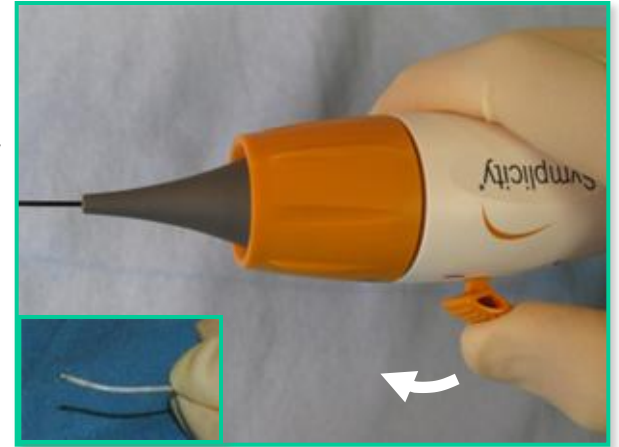


# Symplicity Catheter: Handle Features

Deflect tip by pulling lever towards back of handle



Straighten tip by pushing lever towards front of handle

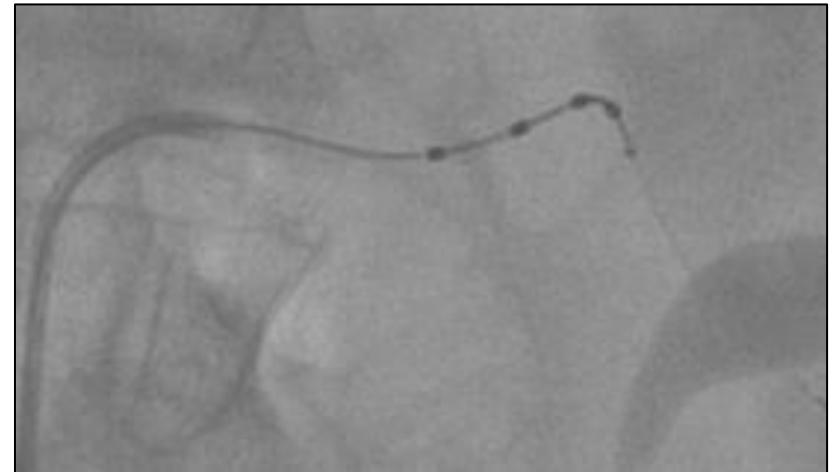
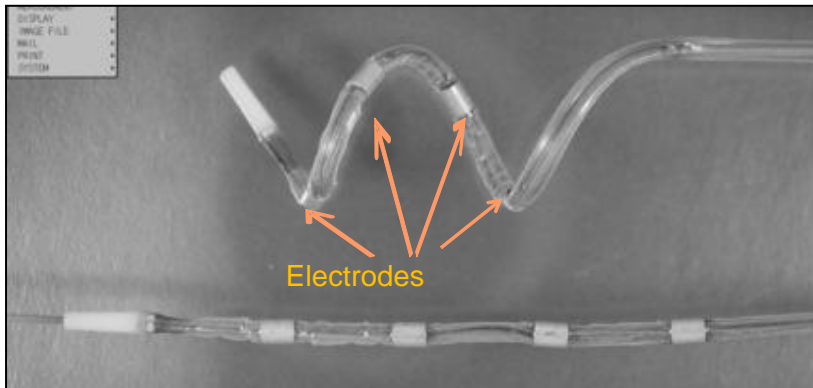


Handle rotator has tactile "click" every 45 degrees



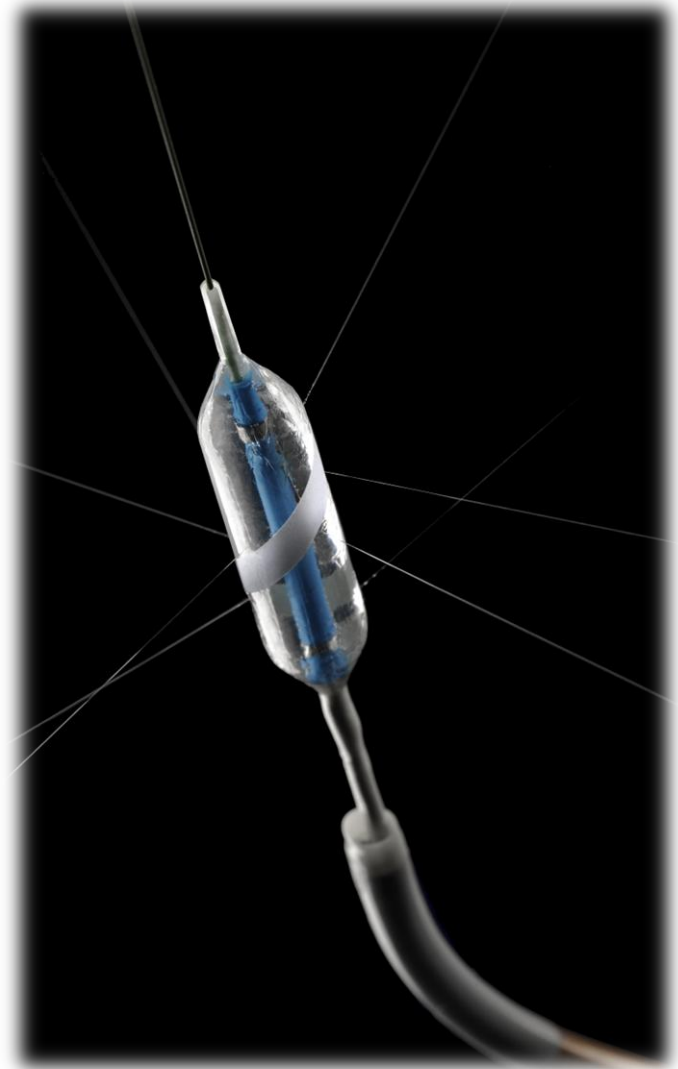
# Medtronic's Multi-Electrode

- 4 electrodes
- Monorail
- 6F guide compatible
- 60 second per artery



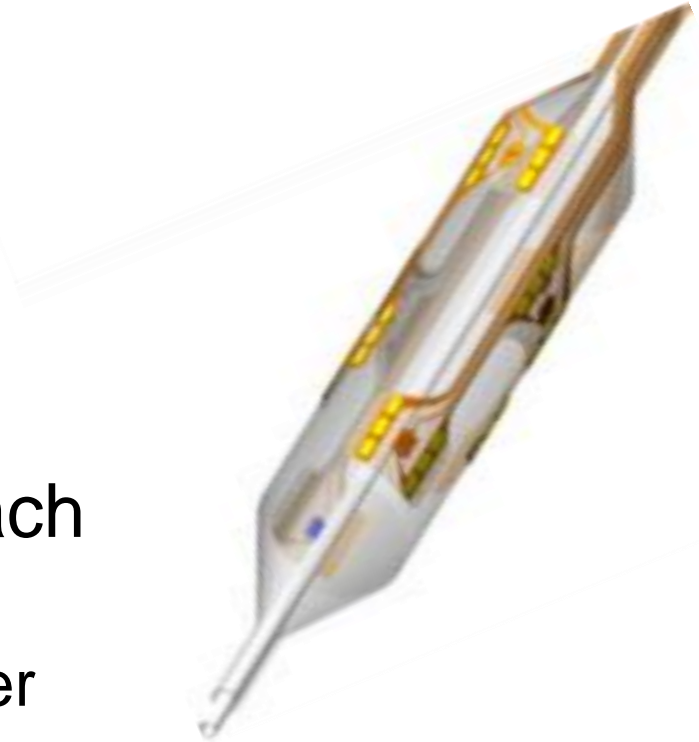
# Covidien OneShot™ Renal Denervation System

- Balloon with spiral electrode
  - 20 mm long
  - 5, 6 and 7mm diameter
  - Low pressure (<1atm)
  - 0.014" guidewire
  - 8F guide compatible
- Cooling by irrigation holes



# Vessix Vascular - Boston V2 Renal Denervation System

- Balloon catheter with gold bipolar RF electrodes
- 3-7 mm renal arteries
- Low pressure (<3 atm)
- Simultaneous energy delivery to all electrodes
- Temperature sensors at each electrode
  - independent titration of power
- 68°C
- 30 seconds
- < 1/2 to 1 watt





# Therapeutic Ultrasound

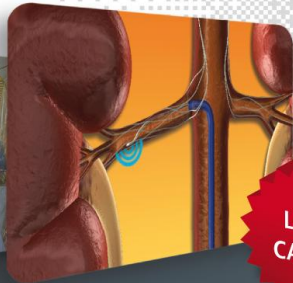
- As with RF energy, renal denervation is achieved by inducing thermal necrosis
- Ultrasound energy passes through the fluids and generates frictional heating in soft tissues
- Unlike RF, no direct tissue contact required

# Ultrasound: Recor Medical

- Ultrasound transducer mounted inside of a 6 F low pressure balloon
- Ultrasound creates heat within the surrounding structures and tissue
- Cooled water in the balloon protects the endothelium against heat
- 2<sup>nd</sup> gen device is OTW
- 30 seconds of circumferential heating



# www.CSI-TRENDS.org



LIVE  
CASES

## TRENDS 2013 ASIA-PACIFIC

SEPTEMBER 14, 2013 | TAIPEI, TAIWAN

Renal Denervation ... Device Based Treatment of Hypertension ...  
Neurohumoral Interventions ... [www.csi-trends.org](http://www.csi-trends.org)



LIVE  
CASES

## TRENDS 2014

Neurohumoral Interventions  
Catheter and Device Based Treatment of Hypertension and Heart Failure  
Transcatheter Renal Denervation

[www.csi-trends.org](http://www.csi-trends.org)

18th ANGIOPLASTY SUMMIT-TCTAP 2013  
Seoul, Korea, April 23-26, 2013

---

# Devices and **Long-Term Outcomes** of Renal Denervation for Hypertension

Horst Sievert, Ilona Hofmann, Laura Vaskelyte,  
Stefan Bertog, Simon Lam, Sameer Gafoor

CardioVascular Center Frankfurt - CVC

Frankfurt, Germany

# Symplicity HTN-1

## THE LANCET

Volume 373 · Number 9671 · Pages 1273-1310 · April 11-17, 2009

www.thelancet.com

Catheter-based renal sympathetic denervation for resistant hypertension: a multicentre safety and proof-of-principle cohort study

Henry Krum, Markus Schlaich, Rob Whitbourn, Paul A Sobotka, Jerzy Sadowski, Krzysztof Bartus, Boguslaw Kapelak, Anthony Walton, Horst Sievert, Suku Thambar, William T Abraham, Murray Esler

*Lancet.* 2009;373:1275-1281

### Initial Cohort – Reported in the *Lancet*, 2009:

- First-in-man, non-randomized
- Cohort of 45 patients with resistant HTN (SBP  $\geq$ 160 mmHg on  $\geq$ 3 anti-HTN drugs, including a diuretic; eGFR  $\geq$  45 mL/min)
- 12-month data

## Hypertension

Celebrating 30 Years: 1979 to 2009

JOURNAL OF THE AMERICAN HEART ASSOCIATION

Catheter-Based Renal Sympathetic Denervation for Resistant Hypertension

Durability of Blood Pressure Reduction Out to 24 Months

Symplicity HTN-1 Investigators\*

*Hypertension.* 2011;57:911-917.

### Expanded Cohort – initially reported in *Hypertension*, 2011, updated

- n=153
- 24 and 36 -month follow-up

# Baseline Patient Characteristics (n=153)

<b>Demographics</b>	Age (years)	57 ± 11
	Gender (% female)	39%
	Race (% non-Caucasian)	5%
<b>Co-morbidities</b>	Diabetes Mellitus II (%)	31%
	CAD (%)	22%
	Hyperlipidemia (%)	68%
	eGFR (mL/min/1.73m <sup>2</sup> )	83 ± 20
<b>Blood Pressure</b>	<b>Baseline BP (mmHg)</b>	<b>176/98 ± 17/15</b>
	<b>Number of anti-HTN meds (mean)</b>	<b>5.1 ± 1.4</b>
	Diuretic (%)	95%
	Aldosterone blocker(%)	22%
	ACE/ARB (%)	91%
	Direct Renin Inhibitor	14%
	Beta-blocker (%)	82%
	Calcium channel blocker (%)	75%
	Centrally acting sympatholytic (%)	33%
	Vasodilator (%)	19%
	Alpha-1 blocker	19%

# Periprocedural Adverse Events

- 1 renal artery dissection during catheter delivery (prior to RF energy)
  - no sequelae
- 3 access site complications
  - treated without further sequelae

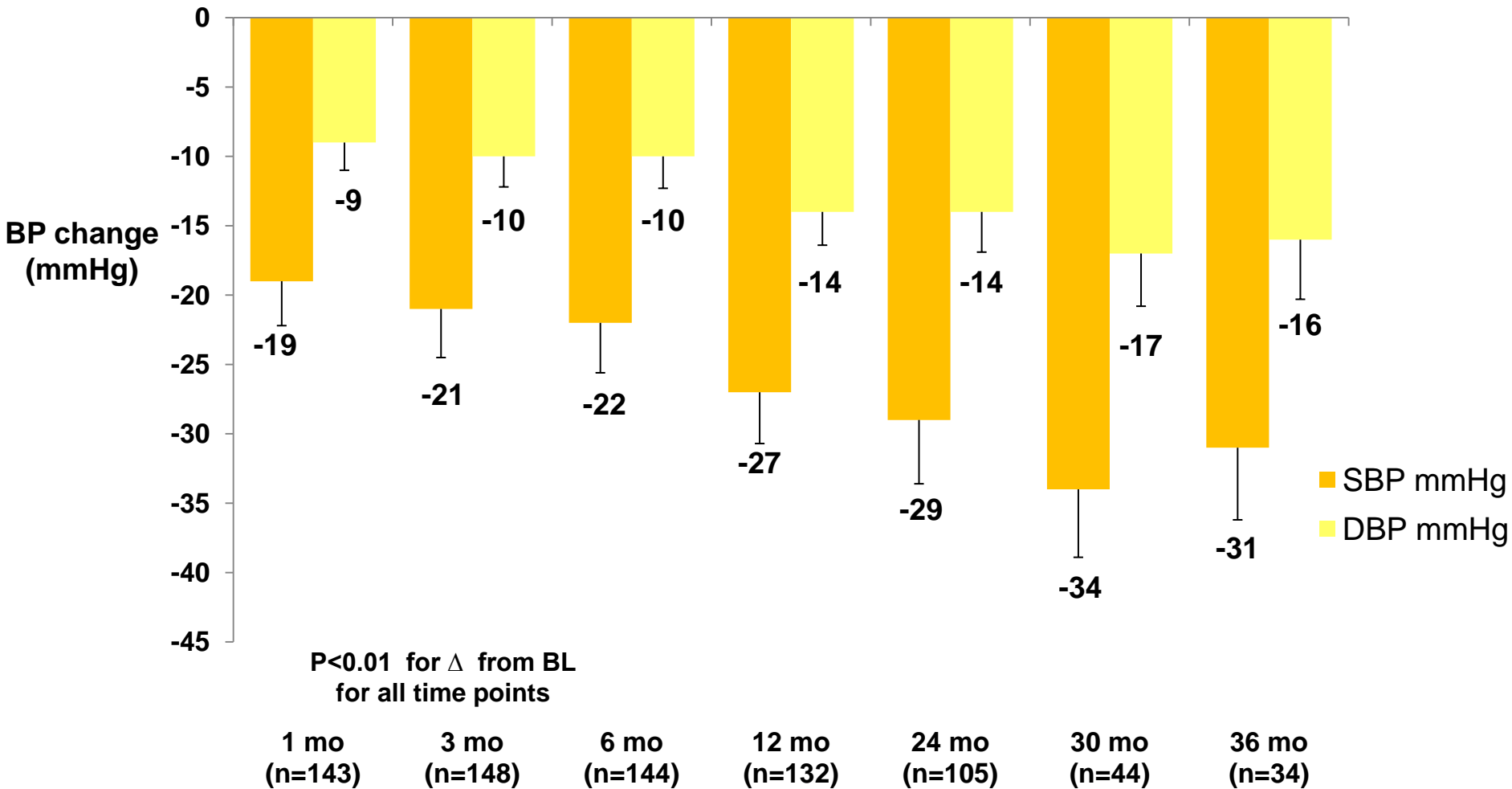
# Adverse Events Out to 36 months\*

- One progression of a pre-existing stenosis unrelated to RF treatment (stented without further sequelae)
- One new moderate stenosis, no treatment
- Hypotension and Renal Failure (18 m) n=1
  - Due to sepsis, resolved
- Hypotension and Renal Failure (24 m) n = 1
  - Post-operative acute renal failure
  - resolved
- Hypotension Episode (n = 1)
  - No treatment, resolved
- 3 deaths, unrelated to procedure
  - Myocardial Infarction - After 3-day visit
  - Sudden death (cardiac) - After 6 months
  - Cardio-respiratory arrest - After 18 months

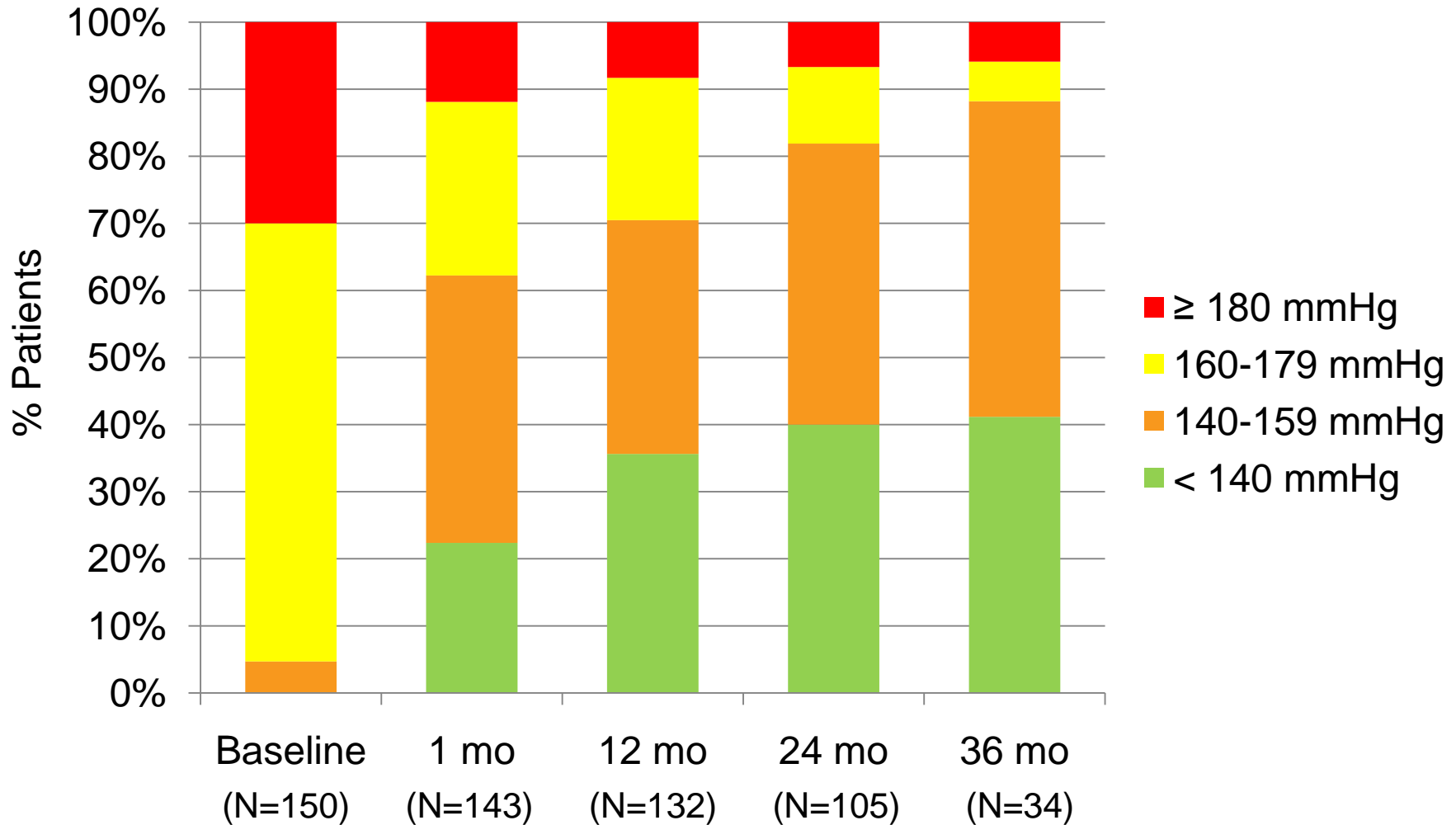
\*Analysis includes data on all patients available through 36 months



# Change in Office BP Through 36 Months

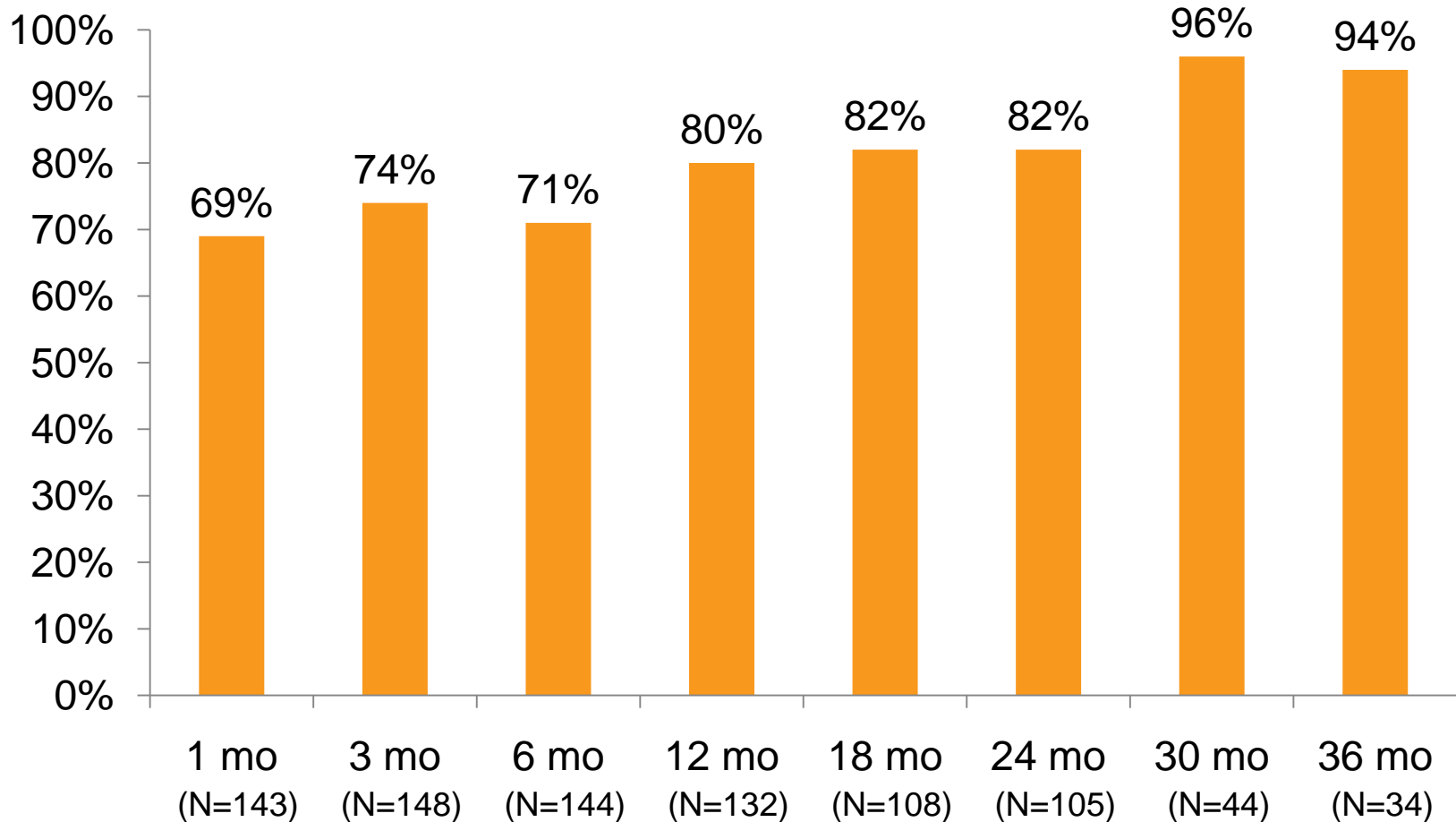


# Distribution of SBP Change at Baseline, 1, 12, 24, and 36 Months



# Percentage Responders Over Time\*

Responder was defined as an office SBP reduction  $\geq 10$  mmHg



\*Full cohort has not yet been analyzed at all time points

# Symplicity HTN-2

## THE LANCET

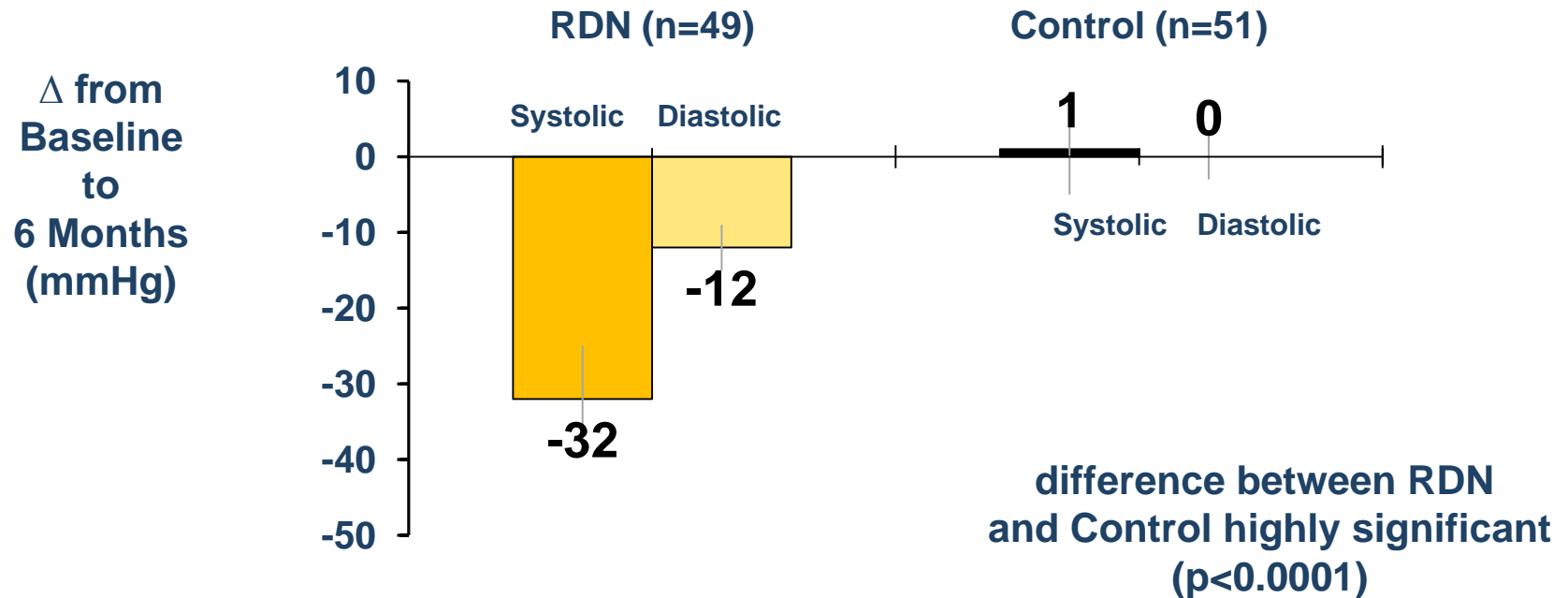
Renal sympathetic denervation in patients with treatment-resistant hypertension (The Symplicity HTN-2 Trial): a randomised controlled trial

SymplicityHTN-2 Investigators\*

*Lancet.* 2010;376:1903-1909

- **Study design:** randomized, controlled, clinical trial
- **Patients:** 106 patients randomized 1:1 to treatment with renal denervation vs. control
- **Clinical Sites:** 24 centers in Europe, Australia, & New Zealand

# Primary Endpoint: 6-Month Office BP

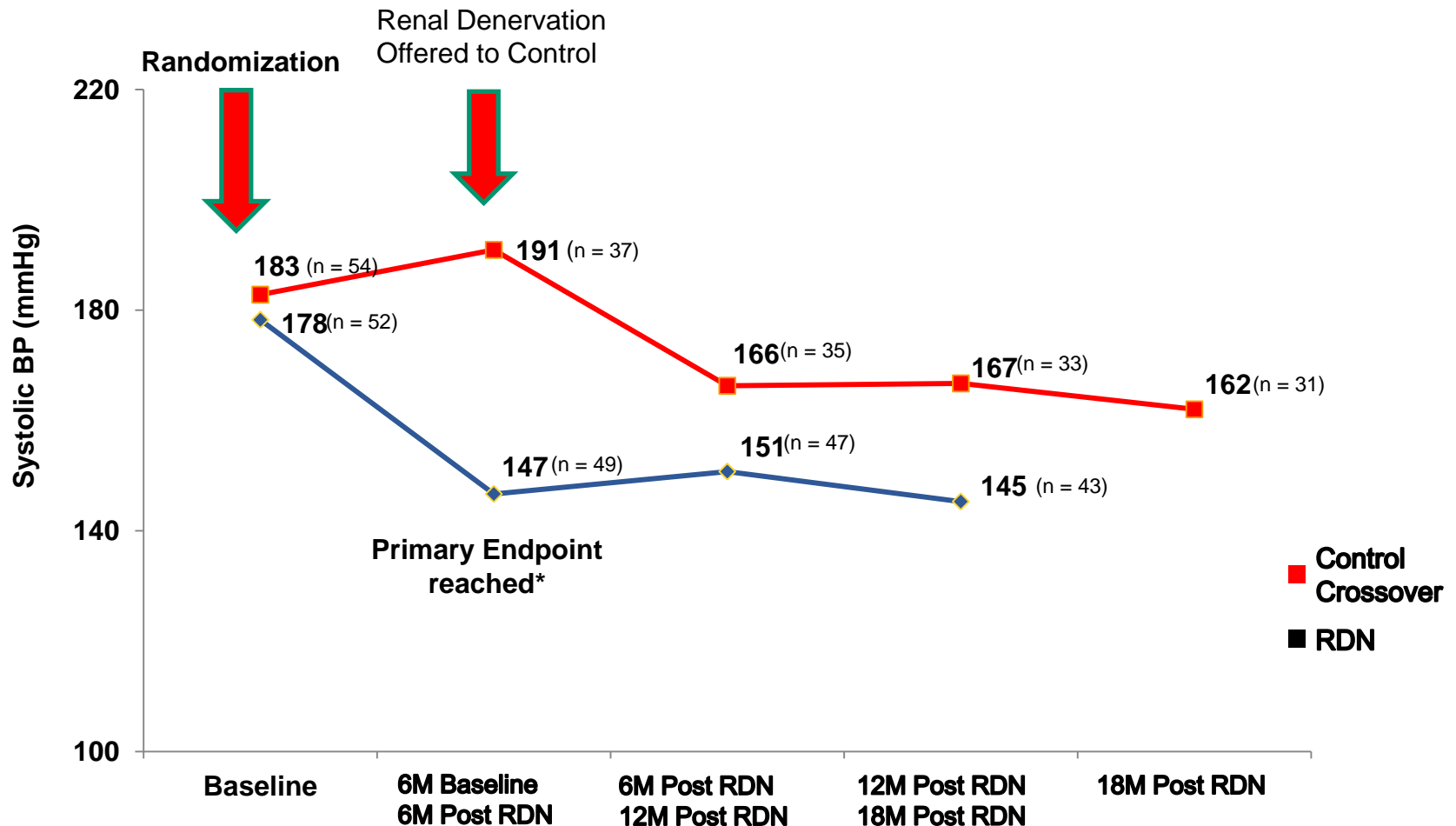


- 84% of RDN patients had  $\geq 10$  mmHg reduction in SBP
- Only 10% of RDN patients had no reduction in SBP

# Adverse events Symplicity HTN-2

- Renal artery dissection (n=1)
  - from injection of contrast into renal artery wall during dye angiography.
  - stented without further consequences
- One hospitalization prolonged due to hypotension (n=1)
  - resolved
- Minor adverse events (full cohort)
  - 1 femoral artery pseudoaneurysm treated with manual compression
  - 1 postprocedural drop in BP resulting in a reduction in medication
  - 1 urinary tract infection
  - 1 prolonged hospitalization for evaluation of paraesthesias
  - 1 back pain treated with pain medications and resolved after 1 month
- 6-month renal imaging (n=43) showed no vascular abnormalities at any RF treatment site
  - 1 MRA indicates possible progression of a pre-existing stenosis unrelated to RF treatment (no further therapy warranted)

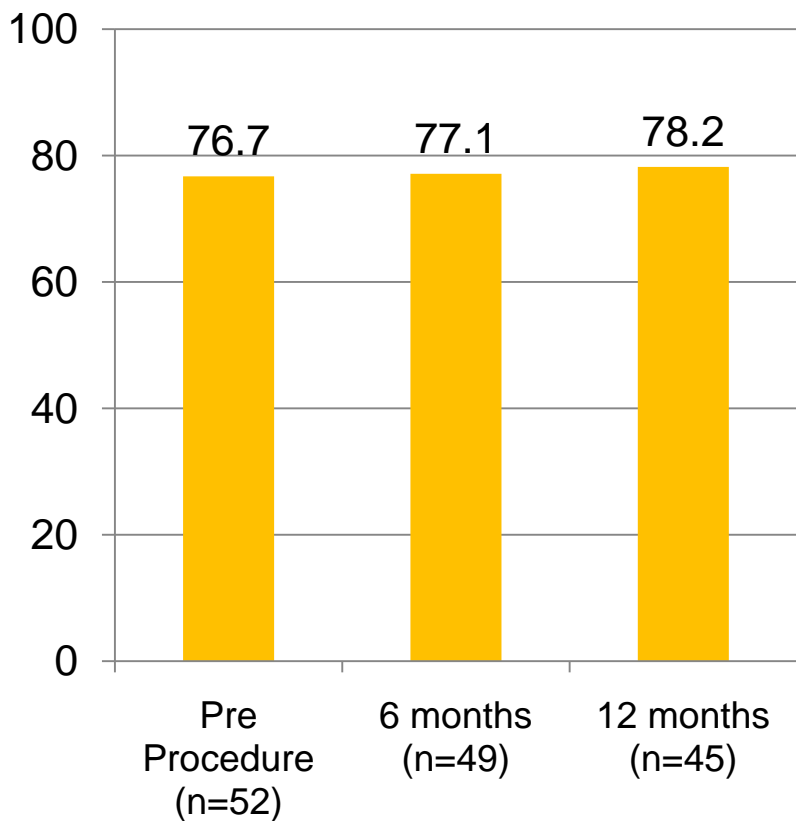
# Office BP 18 months Post Procedure



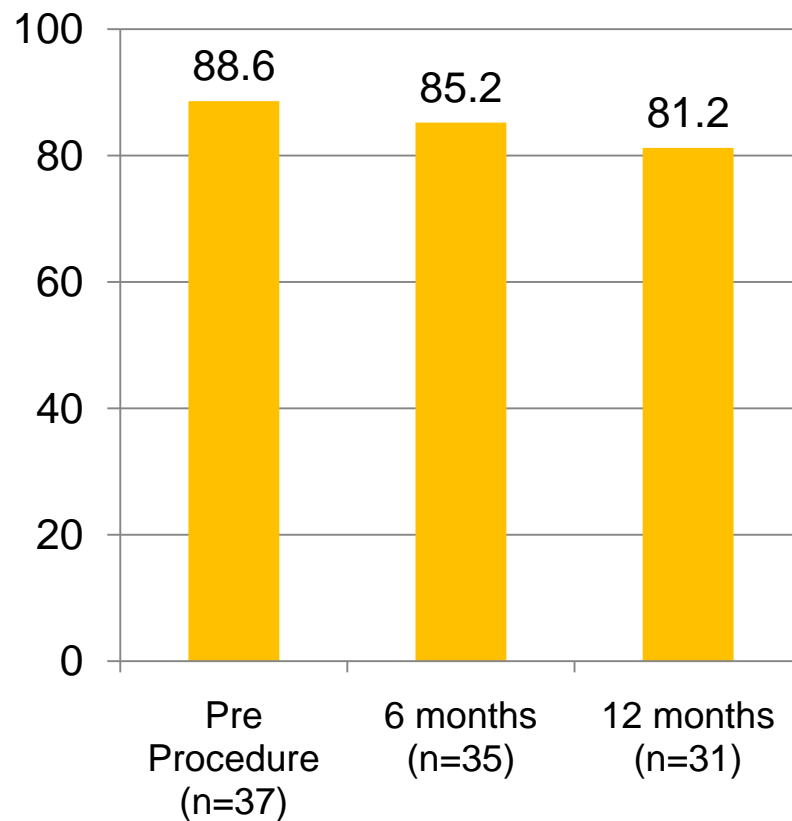
\*Patients randomized to control were offered RDN following the primary endpoint assessment. Only patients still meeting entry criteria (SBP  $\geq$  160 mmHg) were included in this analysis (n=37)

# Renal Function Over Time

## RDN eGFR\*



## Crossover eGFR\*



Renal function parameters were not obtained beyond 12 months follow up

\*eGFR mL/min/1.73m<sup>2</sup>

Esler M, Symplcity HTN-2ESC 2012



# Symlicity HTN-2: Adverse events through 18 mo post procedure

- 2 hypotensive events that required hospitalization: 1 in crossover cohort and 1 in RDN cohort
- 10 hypertensive events (in 8 patients) requiring hospitalization through 18 months post RDN in combined cohort
- 1 mild transient acute renal failure
  - resolved
- 2 unrelated deaths during follow-up

# Conclusions

- There are 5 devices available for renal denervation
- Long-term data are available for the Symplicity catheter (Medtronic)
- The magnitude of blood pressure reduction is significant and sustained through 36 months
- No late adverse events related to RDN through 36 months